		Safetab Life Science			
BATCH MANUFACTURING RECORD					
Page 1 of 78					
Product:	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200604	Mfg. Date:	06/2020	Exp. Date:	05/2025

BATCH MANUFACTURING RECORD COVER SHEET:

PRODUCT NAME	:	GLIDE M 60/850 TABLETS		
LABEL CLAIM	:	Each uncoated bilayered sustained release tablet contains: Gliclazide BP 60 mg - Metformin Hydrochloride BP 500 mg (in sustained release form) 850 Colour: Approved colours are used.		
Pack Size	:	TP: 3x10's blister pack		
Storage Condition	:	Store in a cool and dry place at a temperature not exceeding 30°C. Protect from light and moisture.		
SHELF LIFE	:	24 MONTHS		
CUSTOMER NAME	:	LUPIN Generic		
EFFECTIVE BATCH NUMBER	:	GD200604	DATE:	04/06/2020
MANUFACTURING LICENCE No.	:	PON/DRUGS/07 13 1906		
MFG. DATE:	:	06/2020	BMR. No	STBMR: 123/00
EXP. DATE:	:	05/2023	Supersedes BMR. No	Nil
BMR ISSUED BY/DATE (QA)	:	S. H. 04/06/2020		
BMR CHECKED & RECEIVED BY/DATE (PRODUCTION)	:	Ujaya 04/06/2020		
Allotted By: QA Executive Sign/Date: S. H. 04/06/2020				
DATE OF COMMENCEMENT:		04/06/2020	:	DATE OF COMPLETION: 11/06/2020
This BMR contains 78 Pages + 09 Additional Pages				
Checked by Competent Staff Sign/Date: [Signature] 11/06/2020				

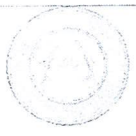
	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	S. H. 04/06/2020	Ujaya 04/06/2020	[Signature] 04/06/2020	

	Safetab Life Science				
	BATCH MANUFACTURING RECORD				Page 2 of 78
Product:	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	61D 200604	Mfg. Date:	06/2020	Exp. Date:	05/2023

1.0 LIST OF EQUIPMENTS:

S.No	Name of Equipment	Equipment ID No. to be used
1	Dispensing Booth	ST/SRDB/001
2	Balance -30 Kg Capacity	ST/SRWB/001
3	Balance -620 g Capacity	ST/SRWB/002
4	Balance -150 Kg Capacity	ST/WB/189
5	Balance -100 Kg Capacity	ST/PRWB/002
6	Balance - 220g Capacity	ST/WB/202
7	Vibro Sifter	ST/PRG/006
8	Rapid Mixer Granulator	ST/PRG/014
9	Fluid bed drier	ST/PRG/012
10	Multi mill	ST/PRG/009
11	Octagonal blender(2200L)	ST/PROB/001
12	Compression Machine	ST/PRCM/001 or ST/PRCM/003 or ST/PRC/004
13	Disintegration Tester	ST/IPDT/002
14	Friability Test Apparatus	ST/IPF/001
15	Hardness Tester	ST/IPHT/004-02
16	Vernier Caliper	ST/IPV/005
17	IR moisture Balance	ST/IPMB/001

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<i>S. C. 04/06/2020</i>	<i>Ujaya Lal Singh 04/06/2020</i>	<i>04/06/2020</i>	

	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page 3 of 78	
Product:	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	CED200604	Mfg. Date:	06/2020	Exp. Date:	05/2023

2.0 DISPENSING:

2.1 LINE CLEARANCE CHECKS:

S.No	CHECKS	Observation	
		store	IPQA
1	Ensure that all empty containers, labels, used Polybags, hand gloves of previous dispensed Product/ batch are removed from the area.	✓	✓
2	Ensure that all dispensed material of previous product / batch removed from the area.	✓	✓
3	Ensure that the previous batch BMR / documents are removed from the area.	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls, ceiling, pass box, doors and door view panels of man and material entry of dispensing area is clean.	✓	✓
5	Check the cleanliness of the working table, cupboard, washing area and waste bin.	✓	✓
6	Check the cleanliness of the drain points.	✓	✓
7	Ensure that the dispensing booth is cleaned and it's status.	✓	✓
8	Check the cleanliness of the supply and return grill.	✓	✓
9	Check the cleanliness of side wall of the dispensing booth.	✓	✓
10	Check the differential pressure of pre filter, intermediate filter and hepa filter are within the limit	✓	✓
11	Check the cleanliness of the utility line (compressed air, First RO water and purified water).	✓	✓
12	Check the cleanliness of the SS side panel and SS Stool.	✓	✓
13	Ensure that the balances are cleaned and it's calibration status.	✓	✓
14	Check the status board of the area is updated.	✓	✓
15	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓
16	Check the differential pressure of the area should be within the limit.	✓	✓
17	Ensure that dispensing tools or accessories like scoops, spoons are cleaned and labeled with "Clean" label.	✓	✓
18	Check proper gowning procedure followed as per the SOP	✓	✓
19	Ensure the concurrent entries of log book.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (store) sign/date:.....

Verified by (IPQA) sign/date:.....

Equipment	Dispensing Booth	Weighing Balance			AREA
Equipment. ID No.	ST/SRDB/001	ST/SRWB/001 (30.0 Kg)	ST/SRWB/002 (620.0g)	ST/WB/189 (150.0 Kg)	
Previous Product & Batch No.	C11AM61-XL-10/25-S200814F.				
Cleaned By	Raghu	Raghu	Raghu	Raghu	Raghu
Checked by Stores Sign/Date	Inf 04/06/20	Inf 04/06/20	Inf 04/06/20	Inf 04/06/20	Inf 04/06/20
Counter checked by IPQA/Sign/Date	Pd 04/06/20	Pd 04/06/20	Pd 04/06/20	Pd 04/06/20	Pd 04/06/20

2.2 ENVIRONMENTAL CONDITIONS:

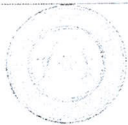
Area: Dispensing	Temperature: 23°C to 27°C	Observation	Stores Sign
	Relative Humidity 45% to 55 %	Observation	Stores Sign
		25°C	Inf
		53%	Inf

2.3 APPROVAL FOR DISPENSING BY IPQA: Sign.....

Date: 04/06/2020

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	Inf 04/06/2020	Ujjayakumar 04/06/2020	Inf 04/06/2020

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	Safetab Life Science		Page 4 of 78		
	BATCH MANUFACTURING RECORD				
Product:	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	<u>01D200604</u>	Mfg. Date:	<u>06/2020</u>	Exp. Date:	<u>05/2023</u>

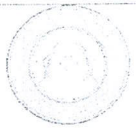
2.4 INDENT OF ACTIVE PHARMACEUTICAL INGREDIENTS (METFORMIN HYDROCHLORIDE PART)

S.No	Name of the Ingredients	Material Code	Label claim per tablet in mg	Spec	Std Qty for 5.0L					Vendor
					Total Qty (Kg)	For LOT I	For LOT II	For LOT III	For LOT IV	
1	Metformin Hydrochloride	RMAM0030	850.000	BP	425.000	106.25	106.25	106.25	106.25	Aarti Drugs

2.4.1 INDENT OF EXCIPIENTS:

S.No	Name of the Ingredients	Material Code	Unit dose per tablet in mg	Spec	Std Qty for 5.0L (Kg)					Vendor
					Total Qty (Kg)	For LOT I	For LOT II	For LOT III	For LOT IV	
2	Hydroxy Propyl Methylcellulose K 100M Premium	RMEM0035	120.000	BP	60.000	15.000	15.000	15.000	15.000	DOW
3	Microcrystalline cellulose powder	RMEM0031	60.000	BP	30.000	7.500	7.500	7.500	7.500	Sigachi
4	Povidone K90	RMEP0045	45.000	BP	22.500	5.625	5.625	5.625	5.625	Haungshan Bonsun Pharmaceuticals
5	Isopropyl Alcohol	RMEI0010	88.000	BP	44.000	11.000	11.000	11.000	11.000	Deepak fertilizers
6	Purified water	RMEP0033	132.000	BP	66.000	16.500	16.500	16.500	16.500	Inhouse
Lubrication										
7	Hydroxy Propyl Methylcellulose K 100M Premium	RMEM0035	100.000	BP	50.000	50.000				DOW
8	Magnesium stearate	RMEM0033	5.000	BP	2.500	2.500				Nitika

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>S. P. 04/06/2020</u>	<u>Ujyababhi 04/06/2020</u>	<u>04/06/2020</u>	

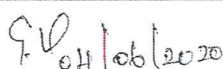
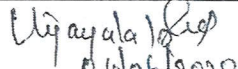
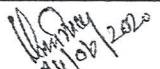
	Safetab Life Science			Page 5 of 78	
	BATCH MANUFACTURING RECORD				
Product:	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	01D200604	Mfg. Date:	06/2020	Exp. Date:	05/2023

2.5 INDENT OF ACTIVE PHARMACEUTICAL INGREDIENTS (GLICLAZIDE PART)

S.No	Name of the Ingredients	Material Code	Label claim per tablet in mg	Overages %	Spec	Std. Qty. per batch (Kg)	Vendor
1	Gliclazide	RMAG0014	60.000	nil	BP	30.000	Jiuzhou Pharmaceuticals

2.5.1 INDENT OF EXCIPIENTS:

S.No	Name of the Ingredients	Material Code	Unit dose per tablet in mg	Spec	Std. Qty. per batch (Kg)	Vendor
2	Dicalcium Phosphate @	RMED0014	50.500	BP	25.250	India Phosphate
3	Methocel K 100 Premium LVCR	RMEM0036	40.000	BP	20.000	DOW
4	Iron oxide Red	RMEI0004	1.000	IH	0.500	Neelikon
4	Povidone K30	RMEP0049	9.000	BP	4.500	Haungshan Bonsun Pharmaceuticals
5	Methylene dichloride	RMEM0029	100.000	BP	50.000	Chemplast
Blending and Lubrication						
6	Methocel K100 Premium	RMEM0035	10.000	BP	5.000	DOW
7	Colloidal silicone Dioxide	RMEC0017	2.000	BP	1.000	Wacker
8	Purified Talc	RMET0012	5.000	BP	2.500	Imerys
9	Magnesium stearate	RMEM0033	2.500	BP	1.250	Nitika

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/06/2020	 04/06/2020	 04/06/2020	

		Safetab Life Science				
		BATCH MANUFACTURING RECORD				
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014		Page No.:	6 of 78
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC No:	ST/MFC/130/R0		Batch Size	5,00,000 Tablets
Product Code:	UP200604	Batch No.:	06/2020		Supersedes MFC No:	NIL
					Batch Size:	05/2023

2.6 DISPENSING OF RAW MATERIALS AGAINST RAW MATERIAL INDENT: (METFORMIN HYDROCHLORIDE PART)

Dispensing Started at Date: 06/06/2020 Time: 7.15

S.No	Name of the Ingredients	LOT	Actual Qty. per batch (kg)	A.R No:	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)	Weighted By Stores	Checked by stores	Checked by IPQA
1	Metformin Hydrochloride	I	*	MSP/2021/06/06/00152	28.000	3.000	25.000	10th	guy.	PPH
				MSP/2021/06/06/00152	28.000	3.000	25.000	10th	guy.	PPH
				MSP/2021/06/06/00152	28.000	3.000	25.000	10th	guy.	PPH
				MSP/2021/06/06/00152	28.000	3.000	25.000	10th	guy.	PPH
				MSP/2021/06/06/00152	28.000	3.000	25.000	10th	guy.	PPH
		II	*	MSP/2021/06/06/00152	28.000	3.000	25.000	10th	guy.	PPH
				MSP/2021/06/06/00152	28.000	3.000	25.000	10th	guy.	PPH
				MSP/2021/06/06/00152	28.000	3.000	25.000	10th	guy.	PPH
				MSP/2021/06/06/00152	28.000	3.000	25.000	10th	guy.	PPH
				MSP/2021/06/06/00152	28.000	3.000	25.000	10th	guy.	PPH
		III	*	MSP/2021/06/06/00152	28.000	3.000	25.000	10th	guy.	PPH
				MSP/2021/06/06/00152	28.000	3.000	25.000	10th	guy.	PPH
				MSP/2021/06/06/00152	28.000	3.000	25.000	10th	guy.	PPH
				MSP/2021/06/06/00152	28.000	3.000	25.000	10th	guy.	PPH
				MSP/2021/06/06/00152	28.000	3.000	25.000	10th	guy.	PPH
		IV	*	MSP/2021/06/06/00152	28.000	3.000	25.000	10th	guy.	PPH
				MSP/2021/06/06/00152	28.000	3.000	25.000	10th	guy.	PPH
				MSP/2021/06/06/00152	28.000	3.000	25.000	10th	guy.	PPH
				MSP/2021/06/06/00152	28.000	3.000	25.000	10th	guy.	PPH
				MSP/2021/06/06/00152	28.000	3.000	25.000	10th	guy.	PPH

Designation	Prepared by: QA Executive / Designee G.V. 04/06/2020	Checked by: Production Head / Designee Vijayalakshmi 04/06/2020	Approved By: QA Head / Designee [Signature] 04/06/2020	
Signature with Date				

		Safetab Life Science				MASTER COPY	
		BATCH MANUFACTURING RECORD Page No.: 7 of 78					
Brand Name	GLIDE M 60/850 TABLETS		Product ID No.:	1014		Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg		MFC NO:	ST/MFC/130/RO		Supersedes MFC No:	NIL
Batch No.:	CPR200604		Mfg. Date:	06/2020		Exp. Date:	05/2023

S.No	Name of the Ingredients	LOT	Actual Qty. per batch(Kg)	A.R No:	Gross Weight (Kg)	Tare Weight(Kg)	Net Weight(Kg)	Weighted By Stores	Checked by stores	Checked by IPQA
2	Hydroxy Propyl Methylcellulose K 100M Premium	I	15.000	NFF/1920/001006/01074	15.055	0.100	14.955	NFF	NFF	PR
		II	15.000	NFF/1921/001006/00135	0.051	0.006	0.045	NFF	NFF	PR
		III	15.000	NFF/2021/001006/00135	15.100	0.100	15.000	NFF	NFF	PR
		IV	15.000	NFF/2021/001006/00135	15.100	0.100	15.000	NFF	NFF	PR
3	Microcrystalline cellulose powder	I	**	NFF/2021/001006/00008	6.759	0.060	6.699	NFF	NFF	PR
		II	**	NFF/2021/001006/00008	6.759	0.060	6.699	NFF	NFF	PR
		III	**	NFF/2021/001006/00008	6.759	0.060	6.699	NFF	NFF	PR
		IV	**	NFF/2021/001006/00008	6.759	0.060	6.699	NFF	NFF	PR

Designation	Prepared by:	Checked by:	Approved By:
	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	G. R. 04/10/2020	Ujaya Lal Sree 04/10/2020	 05/10/2020

		Safetab Life Science		MASTER COPY	
		BATCH MANUFACTURING RECORD			
Brand Name	GLIDE M 60/850 TABLETS		Product ID No.:	1014	Batch Size
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg		MFC NO:	ST/MFC/130/RO	Supersedes MFC No:
Batch No.:	C18200004		Mfg. Date:	06/2020	Exp. Date:
					05/2023
					8 of 78

S.No	Name of the Ingredients	LOT	Actual Qty. per batch (kg)	A.R. No:	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)	Weighted By Stores	Checked by stores	Checked by IPQA
4	Povidone K90	I	5.625	188/2021/06/06/00058	5.685	0.060	5.625	188	188	188
		II	5.625	188/2021/06/06/00058	5.685	0.060	5.625	188	188	188
		III	5.625	188/2021/06/06/00058	5.685	0.060	5.625	188	188	188
		IV	5.625	188/2021/06/06/00058	5.685	0.060	5.625	188	188	188
5	Isopropyl Alcohol	I	11.000	188/2021/06/06/00110	13.000	2.000	11.000	188	188	188
		II	11.000	188/2021/06/06/00110	13.000	2.000	11.000	188	188	188
		III	11.000	188/2021/06/06/00110	13.000	2.000	11.000	188	188	188
		IV	11.000	188/2021/06/06/00110	13.000	2.000	11.000	188	188	188

Designation	Prepared by:	Checked by:	Approved By:
Signature with Date	QA Executive / Designee	Production Head / Designee	QA Head / Designee
G.V. 04/06/2020	Ugaya Lakshmi 04/06/2020		05/06/2020

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		Safetab Life Science			
		BATCH MANUFACTURING RECORD			
Brand Name	GLIDE M 60/850 TABLETS		Product ID No.:	1014	Page No.: 9 of 78
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg		MFC NO:	ST/MFC/130/RO	Batch Size 5,00,000 Tablets
Batch No.:	CD2000604		Mfg. Date:	06/2020	Supersededes MFC No: NIL
			Exp. Date:	05/2023	

S.No	Name of the Ingredients	Actual Qty. per batch(Kg)	A.R No:	Gross Weight (Kg)	Tare Weight(Kg)	Net Weight(Kg)	Weighted By Stores	Checked by stores	Checked by IPQA
6	Hydroxy Propyl Methylcellulose K 100M Premium	50.000	NXP/20210606/00135	28.100	3.100	25.000	NXP	NXP	NXP
7	Magnesium stearate	2.500	NXP/20210606/00135	28.100	3.100	25.000	NXP	NXP	NXP
			NXP/19201006/00980	2.560	0.060	2.500	NXP	NXP	NXP

Dispensing Completed at Date 05/06/20 Time 8.00

[*,**refer calculation]

Designation	Prepared by:	Checked by:	Approved By:
	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	9.8 04/06/2020	NXP/20210606/00135 04/06/2020	NXP/20210606/00135 04/06/2020

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		Safetab Life Science		MASTER COPY	
		BATCH MANUFACTURING RECORD		Page No.: 10 of 78	
Brand Name	GLIDE M 60/850 TABLETS		Product ID No.:	1014	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg		MFC No:	ST/MFC/130/R0	
Batch No.:	UP200604		Mfg. Date:	06/2020	
			Supersedes MFC No:	NIL	
			Exp. Date:	05/2023	
			Batch Size	5,00,000 Tablets	

2.7 DISPENSING OF RAW MATERIALS AGAINST RAW MATERIAL INDENT: (GLICLAZIDE PART)

Dispensing Started at Date 05/06/2020 Time 8.05

S.No	Name of the Ingredients	Actual Qty. per batch (Kg)	A.R No:	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)	Weighted By Stores	Checked by stores	Checked by IQA
1	Gliclazide	*	msp/2021/06/06/00200809 msp/2021/06/06/001119 msp/2021/06/06/001220	4.674 28.085 0.522	0.100 3.100 0.016	4.574 24.985 0.506	Payhm	Payhm	PR
2	Dicalcium Phosphate	**	msp/2021/06/06/00131	16.7190	0.100	16.619	Payhm	Payhm	PR
3	Methocel K-100 Premium LVCR	20.000	msp/1920/06/06/01101 msp/1920/06/06/01073	8.666 20.100	0.100 0.100	8.566 20.000	Payhm	Payhm	PR
4	Iron oxide Red	0.500	msp/1920/06/06/00849	0.508	0.008	0.500	Payhm	Payhm	PR
5	Povidone K30	4.500	msp/1920/06/06/01050	4.560	0.060	4.500	Payhm	Payhm	PR
6	Methylene dichloride	50.000	msp/2021/06/06/00088	52.000	2.000	50.000	Payhm	Payhm	PR

Designation	Prepared by:	Checked by:	Approved By:
Signature with Date	QA Executive / Designee	Production Head / Designee	QA Head / Designee
	G. 01/06/2020	Ujayaaksh 04/06/2020	05/06/2020

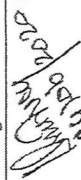
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		Safetab Life Science				MASTER COPY	
		BATCH MANUFACTURING RECORD					
Brand Name	GLIDE M 60/850 TABLETS		Product ID No.:	1014	Batch Size	5,00,000 Tablets	Page No.: 11 of 78
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg		MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	WD200604		Mfg. Date:	06/2020	Exp. Date:	05/2023	

S.No	Name of the Ingredients	Actual Qty. per batch (Kg)	A.R No:	Gross Weight (Kg)	Tare Weight (Kg)	Net Weight (Kg)	Weighted By Stores	Checked by stores	Checked by IPQA
7	Methocel K100 Premium	5.000	msp/1920/06/06/01074	5.060	0.060	5.000	Rajhu	Rajhu	PR
8	Colloidal silicone Dioxide	1.000	msp/2021/06/06/00074	1.060	0.060	1.000	Rajhu	Rajhu	PR
9	Purified Talc	2.500	msp/1920/06/06/01025	2.516	0.016	2.500	Rajhu	Rajhu	PR
10	Magnesium stearate	1.250	msp/2021/06/06/00121	1.266	0.016	1.250	Rajhu	Rajhu	PR

Dispensing Completed at Date 05/06/2020 Time 8:30

[*, **refer calculation]

Designation	Prepared by:	Checked by:	Approved By:
	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	G. V. 04/06/2020	Cejayababu 04/06/2020	 04/06/2020

CONTROLLED COPY

	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	12 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	CID 200604	Mfg. Date:	06/2020	Exp. Date:	05/2023

3.0 CALCULATION:

3.1 Potency calculation for Metformin Hydrochloride :

S.No.	Q.C AR.No. for Metformin Hydrochloride	Expiry Date	Assay of Metformin Hydrochloride On dried basis	LOD %
1	mgp/2021/0010001	Feb/25	99.7	0.450
2	—	—	—	—

The given quantity is based on 100% Assay on dried basis and without LOD.
Actual quantity to be added is calculated as:

$$\text{Actual qty. of Metformin Hcl} = \frac{850 \times 100 \times 100}{\% \text{ Assay of Metformin Hcl on dried basis} \times (100 - \% \text{ of LOD})} = \text{mg/tablet}$$

$$= \frac{8500000}{99.75 \times 1.35} = 856.412 \text{ mg/tablet}$$

**Quantity of Microcrystalline Cellulose Powder varies based on Assay content of Metformin Hcl for keeping the core tablet weight constant.

*Qty of Metformin Hcl to be added per batch	= 428.206 Kg's
Lot-I	= 107.052 Kg's
Lot-II	= 107.052 Kg's
Lot-III	= 107.052 Kg's
Lot-IV	= 107.052 Kg's

**Qty of Microcrystalline Cellulose Powder to be added per batch	= 26.794 Kg's
Lot-I	= 6.699 Kg's
Lot-II	= 6.699 Kg's
Lot-III	= 6.699 Kg's
Lot-IV	= 6.699 Kg's

Note: If the assay of Metformin Hcl is more than 100 %, calculation has to be done only for 100%

Calculation done by(store)/date: S. V. 05/06/20 checked by(production)/date: D. V. 05/06/20 Verified by(QA)/date: R. K. 10/06/20

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>S. V. 05/06/20</u>	<u>U. P. 05/06/20</u>	<u>M. K. 05/06/20</u>	CONTROLLED COPY

	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	13 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	C-1D200604	Mfg.Date:	06/2020	Exp.Date:	09/2023

3.2. Potency calculation for Gliclazide:

S.No.	Q.C AR.No. for Gliclazide	Expiry Date	Assay of Gliclazide	LOD%
1	m88/2021/AG/AR/00009	FEB/23 (Retest)	99.4	0.08
2	m88/2021/AG/AR/00119	MAY/22 (Retest)	100.1	0.13

The given quantity is based on 100% Assay on dried basis and without LOD.
Actual quantity to be added is calculated as:

Actual qty. of Gliclazide = $\frac{60 \times 100 \times 100}{\% \text{ Assay of Gliclazide on dried basis} \times (100 - \% \text{ of LOD})}$ mg/tablet

$$1) = \frac{600000}{9932.048} = 60.411 \text{ mg/iAR}, 2) = \frac{600000}{9987} = 60.078 \text{ mg/iAR}$$

$$= 4.574 \text{ Kgs.} \quad = 25.490 \text{ Kgs.} = 24.985 \text{ Kgs}$$

$$(75714 \text{ nos}) + (424286 \text{ nos}) = (415876 \text{ nos})$$

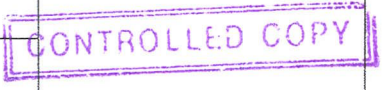
Quantity of Dicalcium Phosphate varies based on Assay and LOD of Gliclazide for keeping the core tablet weight constant.

#Qty of Gliclazide = $\frac{415876}{100}$ Kg's
##Qty of Dicalcium Phosphate = $\frac{415876}{100}$ Kg's

Note: If the assay of Gliclazide is more than 100 %, calculation has to be done only for 100%.

Calculation done by(store)/date: [Signature] 04/06/2020 checked by(production)/date: [Signature] 05/06/2020 Verified by(QA)/date: [Signature] 04/06/2020

R (REFER NEXT PAGE FOR FINAL CALCULATION)

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>[Signature]</u> 04/06/2020	<u>[Signature]</u> 04/06/2020	<u>[Signature]</u> 04/06/2020	

	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	A 13 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

3.2. Potency calculation for Gliclazide:

S.No.	Q.C AR.No. for Gliclazide	Expiry Date	Assay of Gliclazide	LOD%
3	msp/2021/a(G/a/e)/00120	may/	100.5	0.19
1	-	-	-	-

The given quantity is based on 100% Assay on dried basis and without LOD.
Actual quantity to be added is calculated as:

Actual qty. of Gliclazide = $\frac{60 \times 100 \times 100}{\% \text{ Assay of Gliclazide on dried basis} \times (100 - \% \text{ of LOD})}$ mg/tablet

$$= \frac{600000}{9981} = 60.114 \text{ mg/tablet}$$

$$= 0.506 \text{ Kgs.}$$

(8410 nos)

Quantity of Dicalcium Phosphate varies based on Assay and LOD of Gliclazide for keeping the core tablet weight constant.

#Qty of Gliclazide = 30.065 Kg's

##Qty of Dicalcium Phosphate = 25.185 Kg's

Note: If the assay of Gliclazide is more than 100 %, calculation has to be done only for 100%.

Calculation done by(store)/date:

[Signature]
04/06/2020

checked by(production)/date:

[Signature]
04/06/2020

Verified by(QA)/date

[Signature]
04/06/2020

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	CONTROLLED COPY
Signature with Date	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020	

		Safetab Life Science			
		BATCH MANUFACTURING RECORD		Page No.:	14 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	012200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

4.0 VERIFICATION OF DISPENSED MATERIALS: (METFORMIN HYDROCHLORIDE PART)

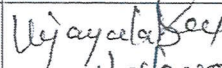
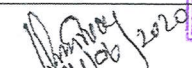
S.No	Name of the Ingredients	Lot	Gross weight in Kg	A.R.No.	Checked by Production Sign/Date	Checked by IPQA Sign/Date
1	Metformin HCL	I	28.00	msp/2021/dec/dec/00152	05/06/20	J.Roslobko
			28.00	msp/2021/dec/dec/00152	05/06/20	J.Roslobko
			28.00	msp/2021/dec/dec/00152	05/06/20	J.Roslobko
			28.00	msp/2021/dec/dec/00152	05/06/20	J.Roslobko
			7.15	msp/2021/dec/dec/00152	05/06/20	J.Roslobko
		II	28.00	msp/2021/dec/dec/00152	05/06/20	J.Roslobko
			28.00	msp/2021/dec/dec/00152	05/06/20	J.Roslobko
			28.00	msp/2021/dec/dec/00152	05/06/20	J.Roslobko
			28.00	msp/2021/dec/dec/00152	05/06/20	J.Roslobko
			7.16	msp/2021/dec/dec/00152	05/06/20	J.Roslobko
		III	28.00	msp/2021/dec/dec/00152	05/06/20	J.Roslobko
			28.00	msp/2021/dec/dec/00152	05/06/20	J.Roslobko
			28.00	msp/2021/dec/dec/00152	05/06/20	J.Roslobko
			28.00	msp/2021/dec/dec/00152	05/06/20	J.Roslobko
			7.15	msp/2021/dec/dec/00152	05/06/20	J.Roslobko
		IV	28.00	msp/2021/dec/dec/00152	05/06/20	J.Roslobko
			28.00	msp/2021/dec/dec/00152	05/06/20	J.Roslobko
			28.00	msp/2021/dec/dec/00152	05/06/20	J.Roslobko
			28.00	msp/2021/dec/dec/00152	05/06/20	J.Roslobko
			7.15	msp/2021/dec/dec/00152	05/06/20	J.Roslobko
2	Hydroxy Propyl methylcellulose K100 Premium	I	15.05	msp/1920/dec/dec/0074	05/06/20	M.Roslobko
			0.05	msp/2021/dec/dec/00136	05/06/20	J.Roslobko
		II	15.10	msp/2021/dec/dec/00135	05/06/20	M.Roslobko
			1	NA		NA
		III	15.10	msp/2021/dec/dec/00135	05/06/20	M.Roslobko
			1	NA		NA
		IV	15.10	msp/2021/dec/dec/00135	05/06/20	M.Roslobko
			1	NA		NA
3	Microcrystalline cellulose Powder	I	6.76	msp/2021/dec/dec/00008	05/06/20	M.Roslobko
			1	NA		NA
		II	6.76	msp/2021/dec/dec/00008	05/06/20	M.Roslobko
			1	NA		NA
		III	6.76	msp/2021/dec/dec/00008	05/06/20	M.Roslobko
			1	NA		NA
		IV	6.76	msp/2021/dec/dec/00008	05/06/20	M.Roslobko
			1	NA		NA

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	CONTROLLED COPY
Signature with Date	9.18 04/06/2020	M.Roslobko 04/06/2020	M.Roslobko 04/06/2020	

	Safetab Life Science				
	BATCH MANUFACTURING RECORD		Page No.:	15 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	01D200604	Mfg.Date:	06/2020	Exp.Date:	06/2023

S.No	Name of the Ingredients	Lot	Gross weight in Kg	A.R.No.	Checked by Production Sign/Date	Checked by IPQA Sign/Date
4	Povidone K90	I	5.68	msep/2021/dec/dec/00058	06/06/20	M.N.05/06/20
			1	NA		NA
		II	5.68	msep/2021/dec/dec/00058	06/06/20	M.N.05/06/20
			1	NA		NA
		III	5.68	msep/2021/dec/dec/00058	06/06/20	M.N.05/06/20
			1	NA		NA
		IV	5.68	msep/2021/dec/dec/00058	06/06/20	M.N.05/06/20
			1	NA		NA
5	Isopropyl Alcohol	I	13.00	msep/2021/dec/dec/00110	06/06/20	M.N.05/06/20
			1	NA		NA
		II	13.00	msep/2021/dec/dec/00110	06/06/20	M.N.05/06/20
			1	NA		NA
		III	13.00	msep/2021/dec/dec/00110	06/06/20	M.N.05/06/20
			1	NA		NA
		IV	12.00	msep/2021/dec/dec/00110	06/06/20	M.N.05/06/20
			1	NA		NA
6	Hydroxy Propyl methylcellulose K100 Premium		28.10	msep/2021/dec/dec/00135	06/06/20	M.N.05/06/20
			28.10	msep/2021/dec/dec/00135	06/06/20	M.N.05/06/20
			1	NA		NA
7	Magnesium stearate		2.56	msep/2021/dec/dec/00024	06/06/20	M.N.06/06/20
			1	NA		NA
8	Purified water					

Note: Check the weight of the dispensed material, if found satisfactory, then proceeds to next stage, if any discrepancy inform to QA head for further instruction

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/06/2020	 04/06/2020	 04/06/2020	

	Safetab Life Science			Page No.: 16 of 78	
	BATCH MANUFACTURING RECORD				
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GPD200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

4.1 VERIFICATION OF DISPENSED MATERIALS (GLICLAZIDE PART):

Date: 05/06/2020

S.No	Name of the Ingredients	Gross weight in Kg	A.R.No	Checked by Production Sign/Date	Checked by IPQA Sign/Date
1	Gliclazide	4.674 0.522 28.085 1	msp/2021/0111/0111 00009 msp/2021/0111/0111 000120	05/06/20	05/06/20 NA
2	Dicalcium Phosphate	16.720 8.666 1	msp/2021/0111/0111 000131 msp/2021/0111/0111 000101	05/06/20 05/06/20	05/06/20 05/06/20
3	Methocel K100 LVCR	20.100 5.000 1	msp/2021/0111/0111 000103	05/06/20	05/06/20 NA
4	Iron oxide Red	0.508 1	msp/2021/0111/0111 000143	05/06/20	05/06/20 NA
5	Povidone K30	4.560 1	msp/2021/0111/0111 000150	05/06/20	05/06/20 NA
6	Methylene Dichloride	50.100 1	msp/2021/0111/0111 000150	05/06/20	05/06/20 NA
7	Methocel K100M Premium	5.000 1	msp/2021/0111/0111 000154	05/06/20	05/06/20 NA
8	Colloidal Silicon Dioxide	1.060 1	msp/2021/0111/0111 000154	05/06/20	05/06/20 NA
9	Purified Talc	2.516 1	msp/2021/0111/0111 000155	05/06/20	05/06/20 NA
10	Magnesium Stearate	1.266 1	msp/2021/0111/0111 000154	05/06/20	05/06/20 NA

Note: Check the weight of the dispensed material, if found satisfactory, then proceeds to next stage, if any discrepancy inform to QA head for further instruction.

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	
Signature with Date	05/06/2020	05/06/2020	05/06/2020	

	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	17 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	U2200604	Mfg.Date:	06/06/20	Exp.Date:	05/2023

5.0 GRANULATION (METFORMIN HCL PART):

5.1 LINE CLEARANCE CHECKS:

S.No	Check	Observation	
		Production	IPQA
1	Ensure that all empty containers, labels, used polybags, hand gloves of previous Product/ batch are removed from the area.	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓
3	Ensure that the previous batch BMR/documents are removed from the area.	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls ceiling, tube light fixture, supply grills, riser grills, filters and electrical fixtures are clean.	✓	✓
5	Check the cleanliness of the doors, door view panel, SOP stand and compressed air filter outer surface.	✓	✓
6	Check for absence of previous batch/product from area below machine and inside the vessel.	✓	✓
7	Check whether the equipment body of Sifter, RMG, FBD and Multimill, Utensils are clean.	✓	✓
8	Ensure that the balances are cleaned and it's calibration status.	✓	✓
9	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.	✓	✓
10	Check the cleanliness of the utility line (compressed air, First RO water and purified water).	✓	✓
11	Check the cleanliness of the drain points.	✓	✓
12	Check the status board of the area is updated.	✓	✓
13	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓
14	Check the differential pressure of the area should be within the limit	✓	✓
15	Ensure the concurrent entries of log book.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (Production) sign/date: *[Signature]* 05/06/20

Verified by (IPQA) sign/date: *[Signature]* 05/06/20

Equipment	Vibro sifter	Multimill	FBD	RMG	Balance
Equipment ID No:	ST/PRG/006	ST/PRG/010	ST/PRG/012	ST/PRG/014	ST/PRWB/002
Previous Product:	GLIDE M 60/850 Tablet (M)				
Batch No.	U2200604				
Cleaned by:	<i>[Signature]</i>				
Checked by:	Production: <i>[Signature]</i>		IPQA: <i>[Signature]</i>		

5.2 ENVIRONMENTAL CONDITIONS	Date: 05/06/20 Time: 15:00	Date: 06/06/20 Time: 00:01
	Observation	Production Sign
Temperature: 23°C to 27°C	24.8°C	✓
Relative Humidity: 45% to 55 %	53.1	✓

5.3 APPROVAL FOR SIFTING:

Production Sign/Date: *[Signature]* 05/06/20 IPQA Sign/Date: *[Signature]* 05/06/20

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020	

	Safetab Life Science					
	BATCH MANUFACTURING RECORD				Page No.:	18 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	G1D200604	Mfg.Date:	06/2020	Exp.Date:	05/2023	

5.4 SIFTING INSTRUCTIONS:

Date: 05/06/20

S. NO	PROCESS INSTRUCTIONS
1	Check the cleanliness of the Vibro Sifter.
2	Use hand gloves while handling the materials.
3	Carryout the sifting operation as per current version of SOP.
4	Check the integrity of sieve before and after sifting and record in the BMR.
5	Collect sifted materials in cleaned containers in polythene bag.

5.5 SIFTING RECORD (LOT-I):

S. No	Name of Ingredient	Mesh size of sieve	Integrity checked before use	Integrity checked after use	Checked By/Date
1	Metformin Hydrochloride	12#	OK/ Not OK	OK/ Not OK	05/06/20
2	Hydroxy Propyl Methyl Cellulose (Methocel K 100 Premium)	30#	OK/ Not OK	OK/ Not OK	05/06/20
3	Microcrystalline Cellulose Powder	30#	OK/ Not OK	OK/ Not OK	05/06/20

Note: If any discrepancy found, Initiate the deviation for corrective and preventive action and proceed to next step after QA approval.

5.6 MANUFACTURING PROCESS (LOT-I):

Step No.	Process Instructions	Date : 05/06/20		Done By	Checked by/Date
		Time			
		Started	Completed		
5.6.1	Sifting; Sift Metformin Hydrochloride through 12# (If required de-lump Metformin using co-mill or RMG) and HPMC K100 premium, Microcrystalline Cellulose powder through 30#, on a vibratory sifter.	15:10	15:45	Santhosh	P 05/06/20
5.6.2	Binder preparation: Mix 11.000Kg of Isopropyl Alcohol and 16.500Kg of Purified Water.	15:20	15:35	Praveen	P 05/06/20
	Filter the solution through 100# nylon cloth.	15:38	15:42	Praveen	P 05/06/20
5.6.3	Dry mixing: Load the above sifted material of Step 5.6.1 into RMG	15:50	15:54	Sharma	P 05/06/20
	Mix for 10 minutes at slow speed of impeller.	15:55	16:05	Sharma	P 05/06/20
5.6.4	Granulation: Granulate the powder of Step 5.6.3 with binder solution of Step 5.6.2 by following steps	16:07	16:10	sharma	P 05/06/20

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	G.V. 04/06/2020	Ujaya 04/06/2020	04/06/2020	

	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	19 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	CID200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

Step No.	Process Instructions	Date : 05/06/20		Done By	Checked by/Date
		Time			
		Started	Completed		
5.6.4	Binder addition: 2 minutes mixing -impellers slow/chopper off.	16:11	16:13	Sharma	05/06/20
	Racking	16:15	16:16	Sharma	05/06/20
	Mixing time: 1 minutes at slow impeller/chopper at fast speed.	16:17	16:18	Sharma	05/06/20
	Racking	16:19	16:20	Sharma	05/06/20
	Discharge the wet granules in FBD bowl for drying.	16:22	16:25	Sharma	05/06/20

5.7 DRYING (LOT-I):

Step No	Instructions	Done by	Checked by/Date
1	Use hand gloves, nose mask while handling the materials.		
2	Check the cleanliness of the FBD.		
3	Carry out drying operation as per SOP.	Sibankhara	05/06/20

5.7.1 DRYING AND SIZING DETAILS (LOT-I):

Step	Process	Start Time	End Time	Outlet Temperature	Done by	Checked by/date
1	Air dries the wet granules for 10 minutes with intermittent racking.	16:30	16:40	—	Sibankhara	05/06/20
2	Steam Drying at 60° C±5°C with intermittent racking at every 15mins until LOD reaches the limit 1.5%to 2.5%.	16:42	17:02	38°C	Sibankhara	05/06/20
3	LOD (Limit: 1.5% to 2.5%): On IR moisture balance at 105°C (Auto mode).	Observed LOD: 1.81			Sibankhara	05/06/20
4	Pass the dried granules through mesh 20#.	17:10	17:30		Senthil	05/06/20
	Mesh integrity checks.	Before use	After use			
		OK/Not OK	OK/Not OK		Senthil	05/06/20
5	Mill the retained dried granules in 2.0 mm screen and pass through 20#.	17:32	17:50		Veerasami	05/06/20
	Mesh integrity checks.	Before use	After use			
		OK/Not OK	OK/Not OK		Veerasami	05/06/20

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	G. 04/06/2020	Vijayalakshy 04/06/2020	04/06/2020	CONTROLLED COPY

	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	20 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	51D200604	Mfg. Date:	06/2020	Exp. Date:	05/2023

5.8 DRIED GRANULES WEIGHT RECORD (LOT-I):

Container No	Gross weight (kg)	Tare weight (kg)	Net weight (kg)	Weighed By	Checked By/ Date
1	30.32	0.12	30.20	Sharma	05/06/20
2	31.32	0.12	31.20	Sharma	05/06/20
3	33.42	0.12	33.30	Sharma	05/06/20
4	39.52	0.12	39.40	Sharma	05/06/20
5					
Total weight of dried granules (kg):			134.10		

5.9 SIFTING RECORD (LOT-II):

S. No	Name of Ingredient	Mesh size of sieve	Integrity checked before use	Integrity checked after use	Checked By/Date
1	Metformin Hydrochloride	12#	OK/ Not OK	OK/ Not OK	05/06/2020
2	Hydroxy Propyl Methyl Cellulose (Methocel K 100 Premium)	30#	OK/ Not OK	OK/ Not OK	05/06/2020
3	Microcrystalline Cellulose Powder	30#	OK/ Not OK	OK/ Not OK	05/06/2020

Note: If any discrepancy found, Initiate the deviation for corrective and preventive action and proceed to next step after QA approval.

5.10 MANUFACTURING PROCESS (LOT-II):

Step No.	Process Instructions	Date : 05/06/2020		Done By	Checked by/Date
		Time			
		Started	Completed		
5.10.1	Sifting; Sift Metformin Hydrochloride through 12# (If required de-lump Metformin using co-mill or RMG) and HPMC K100 premium, Microcrystalline Cellulose powder through 30#, on a vibratory sifter.	15:50	16:30	veerami	R 05/06/20
5.10.2	Binder preparation: Mix 11.000Kg of Isopropyl Alcohol and 16.500Kg of Purified Water.	16:00	16:20	Praveen	R 05/06/20
	Filter the solution through 100# nylon cloth.	16:22	16:30	Praveen	R 05/06/20
5.10.3	Dry mixing: Load the above sifted material of Step 5.10.1 into RMG	16:30	16:35	Sharma	R 05/06/20
	Mix for 10 minutes at slow speed of impeller.	16:37	16:47	Sharma	R 05/06/20
5.10.4	Granulation: Granulate the powder of Step 5.10.3 with binder solution of Step 5.10.2 by following steps	16:50	16:52	Sharma	R 05/06/20

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	9.04/06/2020	Uyayalabey 04/06/2020	04/06/2020	

	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	21 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO.:	ST/MFC/130/R0	Supersedes MFC No.:	NIL
Batch No.:	67D200604	Mfg.Date:	06/020	Exp.Date:	05/2023

Step No.	Process Instructions	Date : 05/06/20		Done By	Checked by/Date
		Time			
		Started	Completed		
5.10.4	Binder addition: 2 minutes mixing –impellers slow/chopper off.	16:53	16:55	Sharma	05/06/20
	Racking	16:56	16:58	sharma	05/06/20
	Mixing time: 1 minutes at slow impeller/chopper at fast speed.	16:59	17:00	sharma	05/06/20
	Racking	17:01	17:03	sharma	05/06/20
	Discharge the wet granules in FBD bowl for drying.	17:05	17:10	sharma	05/06/20

5.11 DRYING (LOT-II):

Step No	Instructions	Done by	Checked by/Date
1	Use hand gloves, nose mask while handling the materials.	Sikambhar	05/06/20
2	Check the cleanliness of the FBD.		
3	Carry out drying operation as per SOP.		

5.11.1 DRYING AND SIZING DETAILS (LOT-II):

Step	Process	Start Time	End Time	Outlet Temperature	Done by	Checked by/date
1	Air dries the wet granules for 10 minutes with intermittent racking.	17:12	17:22	—	Sikambhar	05/06/20
2	Steam Drying at 60° C±5°C with intermittent racking at every 15mins until LOD reaches the limit 1.5%to 2.5%.	17:27	18:07	38°C	Sikambhar	05/06/20
3	LOD (Limit: 1.5% to 2.5%): On IR moisture balance at 105°C (Auto mode).	Observed LOD: 2.0%			Sikambhar	05/06/20
4	Pass the dried granules through mesh 20#.	18:15	18:15		Senthal	05/06/20
	Mesh integrity checks.	Before use OK/ Not OK	After use OK/ Not OK		Senthal	05/06/20
5	Mill the retained dried granules in 2.0 mm screen and pass through 20#.	18:50	19:10		Veerani	05/06/20
	Mesh integrity checks.	Before use OK/ Not OK	After use OK/ Not OK		Veerani	05/06/20

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	CONTROLLED COPY
Signature with Date	S. Y 04/06/2020	04/06/2020	04/06/2020	

	Safetab Life Science				
	BATCH MANUFACTURING RECORD				Page No.: 22 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	CD200604	Mfg. Date:	06/2020	Exp. Date:	05/2023

5.12 DRIED GRANULES WEIGHT RECORD (LOT-II):

Container No	Gross weight (kg)	Tare weight (kg)	Net weight (kg)	Weighed By	Checked By/ Date
1	28.04	0.12	28.92	Santhosh	05/06/20
2	33.32	0.12	33.20	Santhosh	05/06/20
3	30.82	0.12	30.70	Santhosh	05/06/20
4	34.32	0.12	34.20	Santhosh	05/06/20
5	6.30	0.12	6.18	Santhosh	05/06/20
Total weight of dried granules (kg):			133.50		

5.13 SIFTING RECORD (LOT-III):

S. No	Name of Ingredient	Mesh size of sieve	Integrity checked before use	Integrity checked after use	Checked By/Date
1	Metformin Hydrochloride	12#	OK/ Not OK	OK/ Not OK	05/06/20
2	Hydroxy Propyl Methyl Cellulose (Methocel K 100 Premium)	30#	OK/ Not OK	OK/ Not OK	06/06/20
3	Microcrystalline Cellulose Powder	30#	OK/ Not OK	OK/ Not OK	06/06/20

Note: If any discrepancy found, Initiate the deviation for corrective and preventive action and proceed to next step after QA approval.

5.14 MANUFACTURING PROCESS (LOT-III):

Step No.	Process Instructions	Date : 05/06/20		Done By	Checked by/Date
		Time			
		Started	Completed		
5.14.1	Sifting; Sift Metformin Hydrochloride through 12# (If required de-lump Metformin using co-mill or RMG) and HPMC K100 premium, Microcrystalline Cellulose powder through 30#, on a vibratory sifter.	19:15	19:50	veermai	05/06/20
5.14.2	Binder preparation: Mix 11.000Kg of Isopropyl Alcohol and 16.500Kg of Purified Water.	19:20	19:30	Sharma	06/06/20
	Filter the solution through 100# nylon cloth.	19:32	19:40	Sharma	05/06/20
5.14.3	Dry mixing: Load the above sifted material of Step 5.14.1 into RMG	19:55	20:00	Santhosh	05/06/20
	Mix for 10 minutes at slow speed of impeller.	20:01	20:11	Santhosh	06/06/20
5.14.4	Granulation: Granulate the powder of Step 5.14.3 with binder solution of Step 5.14.2 by following steps	20:15	20:18	Santhosh	06/06/20

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	G. U 04/06/2020	Ujaya Lakshmi 04/06/2020	Santhosh 04/06/2020	

	Safetab Life Science					
	BATCH MANUFACTURING RECORD				Page No.:	23 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	61D200604	Mfg. Date:	06/06/20	Exp. Date:	05/2023	

Step No.	Process Instructions	Date : 05/06/20		Done By	Checked by/Date
		Time			
		Started	Completed		
5.14.4	Binder addition: 2 minutes mixing –impellers slow/chopper off.	20:20	20:22	Santhosh	05/06/20
	Racking	20:23	20:24	Santhosh	05/06/20
	Mixing time: 1 minutes at slow impeller/chopper at fast speed.	20:25	20:26	Santhosh	05/06/20
	Racking	20:27	20:30	Santhosh	05/06/20
	Discharge the wet granules in FBD bowl for drying.	20:30	20:38	Santhosh	05/06/20

5.15 DRYING (LOT-III):

Step No	Instructions	Done by	Checked by/Date
1	Use hand gloves, nose mask while handling the materials.		
2	Check the cleanliness of the FBD.		
3	Carry out drying operation as per SOP.	Santhosh	05/06/20

5.15.1 DRYING AND SIZING DETAILS (LOT-III):

Step	Process	Start Time	End Time	Outlet Temperature	Done by	Checked by/date
1	Air dries the wet granules for 10 minutes with intermittent racking.	20:40	20:50	-	Sikandar	05/06/20
2	Steam Drying at 60° C±5°C with intermittent racking at every 15mins until LOD reaches the limit 1.5%to 2.5%.	20:55	21:50	38°C	Sikandar	05/06/20
3	LOD (Limit: 1.5% to 2.5%): On IR moisture balance at 105°C (Auto mode).	Observed LOD: 2.00%			Sikandar	05/06/20
4	Pass the dried granules through mesh 20#.	22:00	22:25		mohandas	05/06/20
	Mesh integrity checks.	Before use OK/ Not OK	After use OK/ Not OK		mohandas	05/06/20
5	Mill the retained dried granules in 2.0 mm screen and pass through 20#.	22:30	23:05		Sriram	05/06/20
	Mesh integrity checks.	Before use OK/ Not OK	After use OK/ Not OK		Sriram	05/06/20

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	S.L. 04/06/2020	Udayakrishnan 04/06/2020	M. Srinivas 04/06/2020	CONTROLLED COPY

	Safetab Life Science					
	BATCH MANUFACTURING RECORD				Page No.:	24 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	CMD200604	Mfg. Date:	06/2020	Exp. Date:	05/2023	

5.16 DRIED GRANULES WEIGHT RECORD (LOT-III):

Container No	Gross weight (kg)	Tare weight (kg)	Net weight (kg)	Weighed By	Checked By/ Date
1	29.72	0.12	29.60	Kaviyooran	05/06/20
2	27.92	0.12	27.80	Kaviyooran	05/06/20
3	32.02	0.12	31.90	Kaviyooran	05/06/20
4	44.02	0.12	43.90	Kaviyooran	05/06/20
5					
Total weight of dried granules (kg):			133.20		

5.17 SIFTING RECORD (LOT-IV):

S. No	Name of Ingredient	Mesh size of sieve	Integrity checked before use	Integrity checked after use	Checked By/Date
1	Metformin Hydrochloride	12#	OK/ Not OK	OK/ Not OK	05/06/20
2	Hydroxy Propyl Methyl Cellulose (Methocel K 100 Premium)	30#	OK/ Not OK	OK/ Not OK	05/06/20
3	Microcrystalline Cellulose Powder	30#	OK/ Not OK	OK/ Not OK	05/06/20

Note: If any discrepancy found, Initiate the deviation for corrective and preventive action and proceed to next step after QA approval.

5.18 MANUFACTURING PROCESS (LOT-IV):

Step No.	Process Instructions	Date : 05/06/20		Done By	Checked by/Date
		Time			
		Started	Completed		
5.18.1	Sifting; Sift Metformin Hydrochloride through 12# (If required de-lump Metformin using co-mill or RMG) and HPMC K100 premium, Microcrystalline Cellulose powder through 30#, on a vibratory sifter.	23:10	23:55	mohandas	05/06/20
5.18.2	Binder preparation: Mix 11.000Kg of Isopropyl Alcohol and 16.500Kg of Purified Water.	00:04	00:10	Sritam	06/06/20
	Filter the solution through 100# nylon cloth.	00:12	00:20	Sritam	06/06/20
5.18.3	Dry mixing: Load the above sifted material of Step 5.18.1 into RMG	00:22	00:30	mohandas	06/06/20
	Mix for 10 minutes at slow speed of impeller.	00:32	00:42	mohandas	06/06/20
5.18.4	Granulation: Granulate the powder of Step 5.18.3 with binder solution of Step 5.18.2 by following steps	00:45	00:50	Kaviraj	06/06/20

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	9.11 04/06/2020	Ujayaal Singh 04/06/2020	11/06/2020 04/06/2020	CONTROLLED COPY

	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	25 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	C1D200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

Step No.	Process Instructions	Date : 06/06/20		Done By	Checked by/Date
		Time			
		Started	Completed		
5.18.4	Binder addition: 2 minutes mixing -impellers slow/chopper off.	00:52	00:54	Harish	06/06/20
	Racking	00:55	00:57	Harish	06/06/20
	Mixing time: 1 minutes at slow impeller/chopper at fast speed.	00:58	00:59	Harish	06/06/20
	Racking	01:00	01:02	Harish	06/06/20
	Discharge the wet granules in FBD bowl for drying.	01:03	01:10	Harish	06/06/20

5.19 DRYING (LOT-IV):

Step No	Instructions	Done by	Checked by/Date
1	Use hand gloves, nose mask while handling the materials.		
2	Check the cleanliness of the FBD.		
3	Carry out drying operation as per SOP.	Harish	06/06/20

5.19.1 DRYING AND SIZING DETAILS (LOT-IV):

Step	Process	Start Time	End Time	Outlet Temperature	Done by	Checked by/date
1	Air dries the wet granules for 10 minutes with intermittent racking.	01:15	01:25	-	Harish	06/06/20
2	Steam Drying at 60° C±5°C with intermittent racking at every 15mins until LOD reaches the limit 1.5%to 2.5%.	01:30	02:25	38°C	Harish	06/06/20
3	LOD (Limit: 1.5% to 2.5%): On IR moisture balance at 105°C (Auto mode).	Observed LOD: 2.12			Harish	06/06/20
4	Pass the dried granules through mesh 20#.	02:35	03:05		Harish	06/06/20
	Mesh integrity checks.	Before use	After use			
		OK/Not OK	OK/Not OK		Harish	06/06/20
5	Mill the retained dried granules in 2.0 mm screen and pass through 20#.	03:10	03:40		Harish	06/06/20
	Mesh integrity checks.	Before use	After use			
		OK/Not OK	OK/Not OK		Harish	06/06/20

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	G. R. 04/06/2020	Harish 04/06/2020	Harish 04/06/2020	CONTROLLED COPY

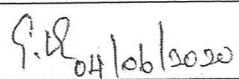
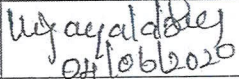
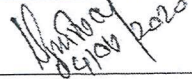
	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	26 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	G1D200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

5.20 DRIED GRANULES WEIGHT RECORD (LOT-IV):

Container No	Gross weight (kg)	Tare weight (kg)	Net weight (kg)	Weighed By	Checked By/ Date
1	38.32	0.12	38.20	Vignesh	06/06/20
2	36.82	0.12	36.70	Vignesh	06/06/20
3	34.02	0.12	33.90	Vignesh	06/06/20
4	26.78	0.12	26.66	Vignesh	06/06/20
5			N.A		
Total weight of dried granules (kg):			135.46		

5.21 YIELD OF DRIED GRANULES:

1.0	Weight of total material added in granulation.	:	537.50	Kg
2.0	Weight of dried granules.	:	535.96	Kg
3.0	Yield (NLT 99.50%) {2.0 / 1.0 x 100}	:	99.71	%

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/06/2020	 04/06/2020	 04/06/2020	

	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	27 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	CID200604	Mfg.Date:	06/06/20	Exp.Date:	05/2023

6.0 BLENDING AND LUBRICATION:

6.1 LINE CLEARANCE CHECKS:

Date: 06/06/20

S.No	Checks	Observation	
		production	IPQA
1	Ensure that all empty containers, used polybags, labels, hand gloves of previous Product/ batch are removed from the area.	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓
3	Ensure that the previous batch BMR / documents are removed from the area.	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls ceiling, tube light fixture, supply grills, riser grills, filters and electrical fixtures are clean.	✓	✓
5	Check the cleanliness of the doors, door view panel and SOP stand.	✓	✓
6	Check the cleanliness of the utility line (compressed air, First RO water and purified water).	✓	✓
7	Check the cleanliness of the drain points.	✓	✓
8	Check for absence of previous batch/product from area below machine and inside machine by opening the guards of Octagonal blender.	✓	✓
9	Check whether the machine body and control panel of octagonal blender is clean.	✓	✓
10	Ensure that the balances are cleaned and it's calibration status.	✓	✓
11	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.	✓	✓
12	Check the status board of the area is updated with cleaned label.	✓	✓
13	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓
14	Check the differential pressure of the area should be within the limit.	✓	✓
15	Ensure the concurrent entries of log book.	✓	✓
16	Check the functioning and cleaning of return riser.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (production) sign/date: 06/06/20

Verified by (IPQA) sign/date: 06/06/20

Equipment	Octagonal blender (2200L)	
Code No	ST/PROB/001	
Previous product	Clenforte	
Batch No	CID200602	
Cleaned by:	Raj	
Checked by:	Production: 06/06/20	IPQA: 06/06/20

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	S. R. 04/06/2020	Uyayalab 04/06/2020	04/06/2020	

	Safetab Life Science					
	BATCH MANUFACTURING RECORD				Page No.:	28 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	C1D200604	Mfg. Date:	06/2020	Exp. Date:	05/2023	

6.2 ENVIRONMENTAL CONDITIONS:	Date: 06/06/20	Time: 08:00	Date:	Time:
	Observation	Production Sign	Observation	Production Sign
Temperature: 23°C to 27°C	23°C			
Relative Humidity: 45% to 55 %	54%			
6.3 APPROVAL FOR BLENDING AND LUBRICATION:				
Production Sign/Date: 06/06/20		IPQA Sign/Date: 06/06/20		

6.4 BLENDING AND LUBRICATION INSTRUCTION:

Step No	Process Instructions	Date: 06/06/20		Done by	Checked by/date
		Time			
		Started	Completed		
1	Use hand gloves, nose mask while handling the materials.				
2	Operate the Octagonal Blender as per the current version of the SOP.				
3	Sift HPMC K 100 M premium through 40# Load the sifted dried granules of Lot-I, Lot-II, Lot III and Lot IV to the Octagonal blender.	08:10	08:40	Suresh	06/06/20
4	Mix for 15 minutes.	09:00	09:15	Suresh	06/06/20
5	Sift Magnesium Stearate through 60# and Distribute / sprinkle over the blended material.	09:20	09:25	Rajg	06/06/20
6	Mix for 5 minutes.	09:30	09:35	Rajg	06/06/20
7	Unload the final blend into suitable containers lined with double polythene bag with proper status label.	09:40	09:55	Rajg	06/06/20
8	Record the weight in below table.				

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	9.8 04/06/2020	Ujaya 04/06/2020	04/06/2020	

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	Safetab Life Science				
	BATCH MANUFACTURING RECORD		Page No.:	29 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	610200604	Mfg. Date:	06/06/20	Exp. Date:	05/2023

6.5 WEIGHING OF FINAL BLEND:

Date:

Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date	Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date
1	31.37	2.50	28.87	Rega	06/06/20	31					
2	41.16	2.50	38.66	Rega	06/06/20	32					
3	34.27	2.50	31.77	Rega	06/06/20	33					
4	35.70	2.50	33.20	Rega	06/06/20	34					
5	34.81	2.50	32.31	Rega	06/06/20	35					
6	31.62	2.50	29.12	Rega	06/06/20	36					
7	33.39	2.50	30.89	Rega	06/06/20	37					
8	33.55	2.50	31.05	Rega	06/06/20	38					
9	33.57	2.50	31.07	Rega	06/06/20	39					
10	35.16	2.50	32.66	Rega	06/06/20	40					
11	33.60	2.50	31.10	Rega	06/06/20	41					
12	34.59	2.50	32.09	Rega	06/06/20	42					
13	38.42	2.50	35.92	Rega	06/06/20	43					
14	33.39	2.50	30.89	Rega	06/06/20	44					
15	34.60	2.50	32.10	Rega	06/06/20	45					
16	35.68	2.50	33.18	Rega	06/06/20	46					
17	27.07	2.50	24.57	Rega	06/06/20	47					
18	20.09	2.50	17.59	Rega	06/06/20	48					
19	22.64	2.50	20.14	Rega	06/06/20	49					
20						50					
21						51					
22						52					
23						53					
24						54					
25						55					
26						56					
27						57					
28						58					
29						59					
30						60					
Total weight of Lubricated granules:							587.71		kg		
Intimate IPQA to draw the sample						Sample withdrawn by IPQA.					
Production Sign: <i>[Signature]</i> Date: 06/06/20						IPQA Sign: <i>[Signature]</i> Date: 06/06/20					
Send Test request form for testing lubricated granules to QC department.											

	Prepared by:	Checked by:	Approved By:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020

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	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	30 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	G7P200604	Mfg. Date:	06/2020	Exp. Date:	05/2023

7.0 RECONCILIATION:

1.0	Theoretical weight of blend	:	590.000 Kg
2.0	Actual weight of blend	:	587.71 Kg
3.0	Manufacturing Loss (1.0 – 6.0)	:	1.74 Kg
4.0	In-process samples	:	
	A IPQA Samples	:	
	B QC Samples	:	0.05 Kg
	C Validation Samples	:	0.50 Kg
5.0	Total samples: (A + B + C)	:	0.55 Kg
6.0	Total: (2.0+5.0)	:	588.26 Kg
7.0	$\% \text{ Yield} = \frac{6.0}{1.0} \times 100$ (Limit- NLT 99.00%)*	:	99.71 %

If yield is out of limit, raise deviation and inform to QA. After QA, investigation and approval proceed to the next stage.

*Tentative limit

Total rejects destroyed: 1.74 Kg. Done by Production sign/Date: 06/06/20 Checked by IPQA sign/Date: 06/06/20

(Rejected materials should be destroyed in the presence of QA)

Yield reconciliation done by Production sign/Date: 06/06/20 Checked by IPQA sign/Date: 06/06/20

7.1 BLENDED GRANULES RELEASED FOR COMPRESSION:

Reconciliation checked and blended granules released for compression.

Checked by Competent Staff Sign/Date: R. eeyi 09/06/2020

Verified by IPQA sign/Date: M. m 09/06/20

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	S. V 04/06/2020	Wijaya 04/06/2020	04/06/2020	CONTROLLED COPY

	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	31 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	CID200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

8.0 GRANULATION (GLICLAZIDE PART):

8.1 LINE CLEARANCE CHECKS:

S.No	Check	Observation	
		Production	IPQA
1	Ensure that all empty containers, labels, used polybags, hand gloves of previous Product/ batch are removed from the area.	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓
3	Ensure that the previous batch BMR/documents are removed from the area.	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls ceiling, tube light fixture, supply grills, riser grills, filters and electrical fixtures are clean.	✓	✓
5	Check the cleanliness of the doors, door view panel, SOP stand and compressed air filter outer surface.	✓	✓
6	Check for absence of previous batch/product from area below machine and inside the vessel.	✓	✓
7	Check whether the equipment body of Sifter, RMG, FBD and Multimill, Utensils are clean.	✓	✓
8	Ensure that the balances are cleaned and it's calibration status.	✓	✓
9	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.	✓	✓
10	Check the cleanliness of the utility line (compressed air, First RO water and purified water).	✓	✓
11	Check the cleanliness of the drain points.	✓	✓
12	Check the status board of the area is updated.	✓	✓
13	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓
14	Check the differential pressure of the area should be within the limit	✓	✓
15	Ensure the concurrent entries of log book.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (Production) sign/date: *[Signature]* 05/06/20

Verified by (IPQA) sign/date: *[Signature]* 05/06/20

Equipment	Sifter	Multi mill	RMG	FBD	Balance	AREA
Equipment ID No:	ST/PRG/006	ST/PRG/010	ST/PRG/014	ST/PRG/012	ST/PRWB/001	
Previous Product:	Granforte Tablet					
Batch No.	CID200602					
Cleaned by:	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>
Checked by	Production Sign: <i>[Signature]</i>			IPQA Sign: <i>[Signature]</i>		

8.2 ENVIRONMENTAL CONDITIONS

Area: Granulation	Temperature: 23°C to 27°C	Date: 05/06/20	Time: 09:00	Date:	Time:
	Relative Humidity: 45% to 55 %	Observation: 24.5°C	Production Sign: <i>[Signature]</i>	Observation: <i>[Signature]</i>	Production Sign: <i>[Signature]</i>

8.3 APPROVAL FOR GRANULATION:

Production Sign/Date: <i>[Signature]</i> 05/06/20	IPQA Sign/Date: <i>[Signature]</i> 05/06/20
---	---

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020	CONTROLLED COPY

	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	32 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	<u>61D200604</u>	Mfg. Date:	<u>06/2020</u>	Exp. Date:	<u>05/2023</u>

8.4 SIFTING INSTRUCTIONS:

Date: 05/06/20

S. NO	PROCESS INSTRUCTIONS
1	Check the cleanliness of the Vibro Sifter.
2	Use hand gloves while handling the materials.
3	Carryout the sifting operation as per current version of SOP.
4	Check the integrity of sieve before and after sifting and record in the BMR.
5	Collect sifted materials in cleaned containers in polythene bag.

8.5 SIFTING RECORD:

S. No	Name of Ingredient	Size of sieve	Integrity checked before use*	Integrity checked after use*	Done by	Checked By/date
1	Gliclazide	40#	OK/ Not OK	OK/ Not OK	<u>Nigam</u>	<u>05/06/20</u>
2	Dicalcium Phosphate Anhydrous Granular (A-Tab)	40#	OK/ Not OK	OK/ Not OK	<u>Nigam</u>	<u>05/06/20</u>
3	Hydroxypropyl Methylcellulose Methocel K100 Premium LVCR	40#	OK/ Not OK	OK/ Not OK	<u>Nigam</u>	<u>05/06/20</u>
4	Iron Oxide Red Lake	80#	OK/ Not OK	OK/ Not OK	<u>Nigam</u>	<u>05/06/20</u>
6	Methocel K 100M Premium Hydroxypropyl Methylcellulose	40#	OK/ Not OK	OK/ Not OK	<u>Nigam</u>	<u>05/06/20</u>
7	Colloidal silicon dioxide	40#	OK/ Not OK	OK/ Not OK	<u>Nigam</u>	<u>05/06/20</u>
8	Purified Talc	40#	OK/ Not OK	OK/ Not OK	<u>Nigam</u>	<u>05/06/20</u>
9	Magnesium stearate	60#	OK/ Not OK	OK/ Not OK	<u>Nigam</u>	<u>05/06/20</u>

Note: If any discrepancy found, Initiate the deviation for corrective and preventive action and proceed to next step after QA approval.

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>G. R. 04/06/2020</u>	<u>Nigam 04/06/2020</u>	<u>Nigam 04/06/2020</u>	

	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	33 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	<u>GPD200604</u>	Mfg. Date:	<u>06/2020</u>	Exp. Date:	<u>05/2023</u>

8.6 MANUFACTURING PROCESS:

Step No	Process Instructions	Date : <u>05/06/20</u>		Done By	Checked by/Date
		Time			
		Started	Completed		
8.6.1	Sifting Co -sift Gliclazide, Dicalcium phosphate and Methocel K 100 Premium LVCR through 40# and Iron oxide red through 80#.	<u>05/15</u>	<u>05/30</u>	<u>Nugreen</u>	<u>05/06/20</u>
8.6.2	Dry mixing: Load the above sifted material of step 8.6.1 into RMG.	<u>05/31</u>	<u>05/34</u>	<u>Nugreen</u>	<u>05/06/20</u>
	Mix for 10 minutes at fast speed impeller and chopper ON at slow/fast speed.	<u>05/35</u>	<u>05/45</u>	<u>Nugreen</u>	<u>05/06/20</u>
8.6.3	Binder preparation: Add <u>4.42</u> kg Povidone K30 in <u>800</u> kg Methylene Dichloride and mix well to get a clear solution.	<u>05/20</u>	<u>05/30</u>	<u>Nugreen</u>	<u>05/06/20</u>
8.6.4	Granulation: (Wet mixing) Granulate the blend of Step 8.6.2 with binder solution of Step 8.6.3 by following steps	-	-	-	-
	Binder addition: 1-2 minutes mixing at fast impeller speed and chopper at slow/fast speed.	<u>05/46</u>	<u>05/48</u>	<u>Day's</u>	<u>05/06/20</u>
	Racking.	<u>05/49</u>	<u>05/50</u>	<u>Day's</u>	<u>05/06/20</u>
	(If required add additional quantity of Methylene dichloride and mix for 1minutes to get the uniform granules.)	<u>05/51</u>	<u>05/53</u>	<u>Day's</u>	<u>05/06/20</u>
	Kneading:	<u>05/54</u>	<u>05/55</u>	<u>Day's</u>	<u>05/06/20</u>
	Mixing: 1-2 minutes mixing at fast speed impeller and chopper at slow/fast speed.	<u>05/56</u>	<u>05/58</u>	<u>Day's</u>	<u>05/06/20</u>
	Discharge the wet granules in FBD bowl for drying.	<u>05/59</u>	<u>10/04</u>	<u>Day's</u>	<u>05/06/20</u>

8.7 DRYING:

Step No	Instructions
1	Use hand gloves, nose mask while handling the materials.
2	Check the cleanliness of the FBD.
3	Carry out drying operation as per SOP.

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>G. V. 04/06/2020</u>	<u>Ujaya...</u> <u>04/06/2020</u>	<u>...</u> <u>04/06/2020</u>	CONTROLLED COPY

	Safetab Life Science					
	BATCH MANUFACTURING RECORD				Page No.:	34 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	CTD200604	Mfg. Date:	06/06/2020	Exp. Date:	05/2023	

8.7.1 DRYING AND SIZING DETAILS:

Step	Process	Start Time	End Time	Done by	Checked by/date
1	Load the Wet granules into FBD bowl and air drying for 10 mins & steam drying at 60° C±5°C with intermittent racking at 10-15 minutes to achieve LOD limit 0.5%-1.5%.	10:15	11:00 11:00	In process	05/06/20
3	LOD%: limit 0.5%-1.5%.	Observed LOD%: 1.26%			
4	Sift the dried granules through 30#.	11:05	11:20	Screen	05/06/20
5	Mesh integrity checks.	Before use	After use	Screen	05/06/20
		OK/ Not OK	OK/ Not OK		
6	Mill the retained granules through 1.5mm screen and pass through 30#.	11:21	11:30	Screen	05/06/20
7	Screen integrity checks.	Before use	After use	Screen	05/06/20
		OK/ Not OK	OK/ Not OK		

8.8 DRIED GRANULES WEIGHT RECORD:

Container No	Gross weight (kg)	Tare weight (kg)	Net weight (kg)	Weighed By	Checked By/ Date
1	24.84	0.16	24.70	Screen	05/06/20
2	24.76	0.16	24.60	Screen	05/06/20
3	21.46	0.16	21.30	Screen	05/06/20
4	9.60	0.16	9.40	Screen	05/06/20
5					
6					
7					
Total weight of dried granules:			80.10		

8.9 YIELD OF DRIED GRANULES:

1.0	Weight of total material added in granulation	:	80.25	Kg
2.0	Weight of dried granules	:	80.10	Kg
3.0	Yield (NLT 97.50 %) {2.0 / 1.0 x 100}	:	99.81	%

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	9.18 04/06/2020	Vijaya Lakshmi 04/06/2020	04/06/2020	CONTROLLED COPY

	Safetab Life Science					
	BATCH MANUFACTURING RECORD				Page No.:	35 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	S4D200604	Mfg.Date:	06/2020	Exp.Date:	05/2023	

9.0 BLENDING AND LUBRICATION:

9.1 LINE CLEARANCE CHECKS:

S.No	Checks	Observation	
		Production	IPQA
1	Ensure that all empty containers, used polybags, labels, hand gloves of previous Product/ batch are removed from the area.	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓
3	Ensure that the previous batch BMR / documents are removed from the area.	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls ceiling, tube light fixture, supply grills, riser grills, filters and electrical fixtures are clean.	✓	✓
5	Check the cleanliness of the doors, door view panel and SOP stand.	✓	✓
6	Check the cleanliness of the utility line (compressed air, First RO water and purified water).	✓	✓
7	Check the cleanliness of the drain points.	✓	✓
8	Check for absence of previous batch/product from area below machine and inside machine by opening the guards of Octagonal blender.	✓	✓
9	Check whether the machine body and control panel of octagonal blender is clean.	✓	✓
10	Ensure that the balances are cleaned and it's calibration status.	✓	✓
11	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.	✓	✓
12	Check the status board of the area is updated with cleaned label.	✓	✓
13	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓
14	Check the differential pressure of the area should be within the limit.	✓	✓
15	Ensure the concurrent entries of log book.	✓	✓
16	Check the functioning and cleaning of return riser.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (Production) sign/date: *[Signature]* 05/06/20

Verified by (IPQA) sign/date: *[Signature]* 05/06/20

Equipment	Octagonal blender(600L)	AREA
Code No.	SJ/PRG/015	
Previous product	Telovest. A	
Batch No	S 2083617E	

9.2 ENVIRONMENTAL CONDITIONS:

		Date: 05/06/20	Time: 11:40	Date:	Time
		Observation	Production Sign	Observation	Production Sign
Area: Blending	Temperature: 23°C to 27°C	24.7°C	✗	✗	✗
	Relative Humidity: 45% to 55 %	51 %	✗	✗	✗

9.3 APPROVAL FOR BLENDING AND LUBRICATION:

Production Sign/Date: *[Signature]* 05/06/20

IPQA Sign/Date: *[Signature]* 05/06/20

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020	

	Safetab Life Science				
	BATCH MANUFACTURING RECORD				Page No.: 36 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

9.4 BLENDING AND LUBRICATION INSTRUCTION:

Step No.	Process Instructions	Date: 05/06/20		Done by	Checked by/Date
		Time			
		Started	Completed		
1	Use hand gloves, nose mask while handling the materials.				
2	Operate the Octagonal Blender (600L) as per the current version of the SOP.				
3	Sift Methocel K100M Premium through 40# and Geometrically mix Methocel K100M Premium with half quantity of dried granules and load into octagonal blender along with remaining quantity of dried granules.	11:50	12:00	Day's	05/06/20
4	Mix for 5 minutes.	12:01	12:06	Day's	05/06/20
5	Co-sift Colloidal silicone dioxide and Purified Talc through 40#.	12:07	12:09	Day's	05/06/20
6	Load the above sifted materials into octagonal blender and mix for 10 minutes.	12:10	12:20	Day's	05/06/20
7	Sift Magnesium Stearate through 60# and distribute / sprinkle over the blended material.	12:21	12:24	Day's	05/06/20
8	Mix for 3 minutes.	12:25	12:28	Day's	05/06/20
9	Unload the final blend into suitable containers lined with double polythene bag container with proper label.	12:29	12:40	Day's	05/06/20
10	Record the weight in below mentioned table.	-	-	-	-

9.5 WEIGHING OF FINAL BLEND:

Date: 05/06/20

Container No	Gross weight (kg)	Tare weight (kg)	Net weight (kg)	Weighed by	Checked by/Date
1	27.94	2.00	25.94	Day's	05/06/20
2	33.31	2.00	31.31	Day's	05/06/20
3	34.17	2.00	32.17	Day's	05/06/20
4					
5					
6					
7					
8					
9					
10					
Total weight of blend:			89.42		

Intimate IPQA to draw the sample

Sample withdrawn by IPQA.

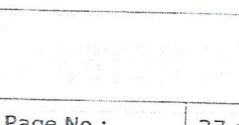
Production Sign: [Signature] Date: 05/06/20

IPQA Sign: [Signature] Date: 05/06/20

Send Test request form for testing lubricated granules to QC department.

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	[Signature] 04/06/2020	[Signature] 04/06/2020	[Signature] 04/06/2020

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		Safetab Life Science			
BATCH MANUFACTURING RECORD					
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Page No.:	37 of 78
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Batch Size	5,00,000 Tablets
Batch No.:	G1D200604	Mfg.Date:	04/02/20	Supersedes MFC No:	NIL
				Exp.Date:	05/2023

10.0 RECONCILIATION:

1.0	Theoretical weight of blend	:	90.000 Kg
2.0	Actual weight of blend	:	89.42 Kg
3.0	Manufacturing Loss (1.0 - 6.0)	:	0.43 Kg
4.0	In-process samples		
	A IPQA Samples	:	~ Kg
	B QC Samples	:	0.050 Kg
	C Validation Samples	:	0.100 Kg
5.0	Total samples: (A + B + C)	:	0.150 Kg
6.0	Total: (5.0+2.0)	:	89.57 Kg
7.0	$\% \text{ Yield} = \frac{6.0}{1.0} \times 100$ (Limit- NLT 97.00%)*	:	99.52 %

If yield is out of limit, raise deviation and inform to QA. After QA, investigation and approval proceed to the next stage.

*Tentative limit.

Total rejects destroyed: 0.43 Kg. Done by Production sign/Date: * 05/06/20 Checked by IPQA sign/Date: 05/06/20

(Rejected materials should be destroyed in the presence of QA)

Yield reconciliation done by Production sign/Date: * 05/06/20 Checked by IPQA sign/Date: 05/06/20

10.1 BLENDED GRANULES RELEASED FOR COMPRESSION:

Reconciliation checked and blended granules are released for compression.

Checked by Competent Staff Sign/Date: R. Roy 09/06/20

IPQA sign/Date: 09/06/20

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>G. R. 04/06/2020</u>	<u>04/06/2020</u>	<u>04/06/2020</u>	

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	Safetab Life Science				
	BATCH MANUFACTURING RECORD		Page No.:	38 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC No.:	ST/MFC/130/R0	Supersedes MFC No.:	NIL
Batch No.:	C1D200604	Mfg. Date:	06/06/2020	Exp. Date:	05/06/23

11.0 COMPRESSION:

11.1 LINE CLEARANCE CHECKS:

S.No	Checks	Observation	
		production	IPQA
1	Ensure that all empty containers, used polybags, labels, hand gloves of previous Product/ batch are removed from the area.	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓
3	Ensure that the previous batch BMR / documents are removed from the area.	✓	✓
4	Check the housekeeping general cleanliness of the floor, walls, ceiling, tube light fixture, supply grills, riser grills, filters and electrical fixtures are clean.	✓	✓
5	Check the cleanliness of the doors, door view panel and compressed air filter outer surface.	✓	✓
6	Check whether the machine body and machine parts like hoppers, feed frame, discharge chute and ejection chute and control panel are clean.	✓	✓
7	Check whether the dust collector main body and hosepipe of the dust collector is clean.	✓	✓
8	Ensure that the balances are cleaned and it's calibration status.	✓	✓
9	Check whether the Equipments/ Instruments to be used are within calibration/preventive maintenance due date.	✓	✓
10	Check the status board of the area is updated with cleaned label.	✓	✓
11	Check the temperature & relative humidity of the area meet as per BMR requirement and ensure that the records are updated.	✓	✓
12	Check the differential pressure of the area should be within the limit.	✓	✓
13	Ensure the concurrent entries of log book.	✓	✓
14	Check the Release Status of product Lubricated blend.	✓	✓
15	Check the calibration status of related IPQA Equipment like hardness tester, Vernier Caliper, DT apparatus, Friability etc.	✓	✓
16	Check the functioning and cleaning of return riser.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (production) sign/date: R. Pooj 09/06/20

Verified by (IPQA) sign/date: M. Pooj 09/06/20

Equipment	Double Rotary/Single Rotary Compression Machine	Balance	Area
Equipment ID No.:	ST/PRCM/001 or ST/PRCM/003 or ST/PRC/004	ST/WB/202	
Previous product:	Voglow Gm2		
Batch No.	S2082607E		

11.2 ENVIRONMENTAL CONDITIONS:	Date: 09/06/20		Date: 10/06/2020	
	Observation	Production Sign	Observation	Production sign
Temperature: 23°C to 27°C	25°C	R. Pooj	23°C	✓
Relative Humidity: 45% to 55 %	50%	R. Pooj	52%	✓

11.3 APPROVAL FOR COMPRESSION:

Production sign/Date: R. Pooj 09/06/20 IPQA sign/Date: M. Pooj 09/06/20

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	
Signature with Date	G. Mah 10/06/2020	Udaya 09/06/2020	M. Pooj 09/06/2020	

	Safetab Life Science					
	BATCH MANUFACTURING RECORD				Page No.:	39 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	69D200604	Mfg.Date:	06/0020	Exp.Date:	05/2023	

11.4 PROCESS INSTRUCTIONS:

S. No	Process Instructions	Start Time	End Time	Done By	Checked by/date
1	Check the cleanliness of area and equipment.				
2	Ensure that the correct punch sets are issued as per the Punch issue record and ensure the cleanliness and verification of the punch and dies. Checked by/date(production): R. Beary 09/06/20 Verified by/date(IPQA): M. V. 09/06/20				
3	Set the 27- station Double Rotary Compression Machine with Upper Punch : 22.00 x 9.50 mm Caplet shape with breakline. Lower punch : 22.00 x 9.50 mm Caplet shape biconcave and plain. Dies : 22.00 x 9.50 mm Caplet shape.	14:10	14:35	Suyash	R. Beary 09/06/20
4	Transfer the blend to compression cubicle. Load the granules of Metformin Hcl in one hopper and Gliclazide in other hopper of the compression machine.	14:40	14:50	Suyash	R. Beary 09/06/20
5	Operate the Double Rotary Compression machine as per the current version of the SOP and reject tablets of the first three round which shall be destroyed as per SOP.	14:55	15:10	Suyash	R. Beary 09/06/20
6	Check the initial tablet for all the parameters as described below and set the machine accordingly.	15:15	15:50	Suyash	R. Beary 09/06/20
7	Collect the compressed tablets in polythene bag lined and labeled cleaned containers.	16:15	16:30	Suyash	R. Beary 09/06/20
8	Check and record the weight of the compressed tablets.				

11.5 COMPRESSION SPECIFICATION/PARAMETERS:

S. No	Parameter	Limits	No. of tablets to be checked	Frequency	
				Production	IPQA
1	Appearance	Red / white colored, Caplet shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides.	20	Every 30 min	Every 1 hrs
2	Average weight	1360 mg $\pm$ 5% (1292.00mg - 1428.000mg)	20	Every 30 min	Every 1 hrs
3	Weight of 20 tablets	27.200g $\pm$ 3 % (26.384g to 28.016g)	20	Every 30 min	Every 1 hrs
4	Uniformity of weight	$\pm$ 5% of actual average weight	20	Every 1 hrs	Every 2 hrs
5	Uniformity weight checks for individual layer	Metformin - 1180mg $\pm$ 3% (Limit: 1144.600mg - 1215.400mg) Gliclazide- 180mg $\pm$ 3% (Limit: 174.600mg - 185.400mg)	20	Every 2 hrs	Every 2 hrs
6	Hardness	(250N-350N) (To be monitored)	5	Every 30 min	Every 1 hrs
7	Thickness	7.10 $\pm$ 0.30mm (6.80mm - 7.40mm) (To be monitored)	5	Every 30 min	Every 1 hrs
8	Friability	NMT 1.0 %w/w	20	Every 1 hrs	Every 2 hrs
9	Machine rpm	12 - 18 rpm	NA	Every 1 hrs	Every 2 hrs

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	G. R. 04/06/2020	U. Jayashree 04/06/2020	M. V. 04/06/2020	CONTROLLED COPY

		Safetab Life Science			
		BATCH MANUFACTURING RECORD		Page No.:	40 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GTD200604	Mfg. Date:	06/2020	Exp. Date:	05/2023

11.5.1 MACHINE SETTING FOR COMPRESSION: (UNIFORMITY OF WEIGHT AND THICKNESS)

Sr. No.	Weight			Thickness	Sr. No.	Weight			Thickness
	Tablet wt.	Metformin Hcl part	Gliclazide Part			Tablet wt.	Metformin Hcl part	Gliclazide Part	
1	1857	1176	181	6.99	16	1365	1183	182	6.97
2	1362	1179	183	7.00	17	1362	1178	184	7.02
3	1355	1175	180	6.99	18	1368	1184	184	7.01
4	1360	1181	179	6.99	19	1362	1185	177	6.96
5	1361	1179	182	7.03	20	1371	1186	185	7.02
6	1361	1183	178	6.96	21	1371	1185	184	7.02
7	1369	1185	184	6.99	22	1365	1180	185	6.99
8	1364	1182	182	6.99	23	1363	1179	184	6.98
9	1371	1187	184	6.98	24	1369	1184	185	7.01
10	1368	1181	184	7.03	25	1366	1183	183	6.96
11	1359	1178	181	6.95	26	1359	1178	181	7.02
12	1365	1182	183	6.98	27	1365	1180	185	6.98
13	1371	1187	184	7.03					
14	1367	1183	184	6.94					
15	1362	1179	183	7.02					

Parameters	Instrument used	Observations		Limits
		Min	Max	
Uniformity of weight	Balance	1355	1371	±5% of actual average weight
Group weight of 20 tablets	Balance	27.200		27.200g ± 3 % (26.384g to 28.016g)
Average weight	Balance	1360		1360.000 mg ± 5% (1292.000mg - 1428.000mg)
Uniformity weight checks for individual layer	Balance	1176	1187	Metformin - 1180mg ± 3% (Limit: 1144.600mg - 1215.400mg)
		177	185	Gliclazide - 180.000mg ± 3% (Limit: 174.600mg - 185.400mg)
Hardness	Hardness tester	251		(250N-350N) (To be monitored)
Thickness	Vernier	7.01		7.10 ± 0.30mm (6.80 - 7.40) (To be monitored)
Friability	Friabilator	0.13%		NMT 1.0 %
Appearance	visual	complies		Red / white colored, Capsule shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides.

Initial M/C set up checked by (Production): R. Raju Date: 09/06/20 Verified by (IPQA): M. Ravi Date: 09/06/20

Initial Setting tablets Destroyed by: Sign: R. Raju Date: 09/06/20

Initial setting tablets destruction checked by IPQA: Sign: M. Ravi Date: 09/06/20

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>G. Ravi</u> 04/06/2020	<u>Udaya Lakshmi</u> 04/06/2020	<u>M. Ravi</u> 04/06/2020	CONTROLLED COPY

	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	41 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	C9D2 00604	Mfg.Date:	06/2020	Exp.Date:	05/2023

11.6 IN-PROCESS CHECKS: (EVERY 30 MINUTES) BY PRODUCTION:

DATE	TIME	Group Wt: 27.200g $\pm$ 3 % (26.384g to 28.016g) Avg. Wt: 1360.000 mg $\pm$ 5% (1292.000mg - 1428.000mg)		HARDNESS (250N-350N) (To be monitored)	THICKNESS 7.10 $\pm$ 0.30mm (6.80mm - 7.40mm) (To be monitored)	APPEARANCE Red / white colored, Capsule shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides.	Done by Production
		Weight of 20 Tab (g)	Avg. Weight (mg)				
09/06/20	16:30	27.307	1365	264	7.02	complies	R. Esw
09/06/20	17:00	27.325	1366	256	6.98	complies	R. Esw
09/06/20	17:30	27.342	1367	269	7.00	complies	R. Esw
09/06/20	18:00	27.128	1356	267	7.00	complies	R. Esw
09/06/20	18:30	27.321	1366	268	7.00	complies	R. Esw
09/06/20	19:00	27.307	1365	262	7.01	complies	R. Esw
M/C Stopped at 19:30 to 20:00 due to dinner break							
09/06/20	20:10	27.243	1362	265	7.03	complies	R. Esw
09/06/20	20:40	27.203	1360	267	6.99	complies	R. Esw
09/06/20	21:10	27.185	1359	269	6.99	complies	R. Esw
09/06/20	21:45	27.285	1364	258	7.02	complies	R. Esw
09/06/20	22:20	27.204	1360	251	7.10	complies	R. Esw
09/06/20	22:55	27.245	1362	260	7.10	complies	R. Esw
09/06/20	23:20	27.168	1358	262	7.08	complies	R. Esw
M/C stopped at 00:00 to 00:10 due to tea Break							
10/06/20	00:30	27.282	1364	268	7.02	complies	R. Esw
10/06/20	01:00	27.225	1361	255	7.08	complies	R. Esw
10/06/20	01:35	27.305	1365	261	6.98	complies	R. Esw
10/06/20	02:05	27.165	1358	260	7.01	complies	R. Esw
10/06/20	02:35	27.225	1361	268	7.08	complies	R. Esw
10/06/20	03:05	27.205	1360	257	6.98	complies	R. Esw
10/06/20	03:35	27.285	1364	264	6.95	complies	R. Esw
M/C stopped at 04:00 to 04:10 due to tea Break							
10/06/20	04:30	27.205	1360	268	6.98	complies	R. Esw
10/06/20	05:05	27.203	1360	285	7.05	complies	R. Esw
M/C stopped at 05:25 due to shift closed							

*If appearance are satisfactory document as complies.

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	G. V. 04/06/2020	Vijayalaxmi 04/06/2020	[Signature] 04/06/2020	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	42 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	C10200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

11.6-A IN-PROCESS CHECKS: (EVERY 30 MINUTES) BY PRODUCTION:

DATE	TIME	Group Wt: 27.200g $\pm$ 3 % (26.384g to 28.016g) Avg. Wt: 1360.000 mg $\pm$ 5% (1292.000mg - 1428.000mg)		HARDNESS (250N-350N) (To be monitored)	THICKNESS 7.10 $\pm$ 0.30mm (6.80mm - 7.40mm) (To be monitored)	APPEARANCE Red / white colored, Capsule shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides.	Done by Production
		Weight of 20 Tab (g)	Avg. Weight (mg)				
10/06/20	06:25	27.244	1362	274	7.18	Complies	S.Pi
10/06/20	06:55	27.204	1360	282	7.10	Complies	S.Pi
10/06/20	07:25	27.164	1358	264	7.14	Complies	S.Pi
10/06/20	07:55	27.282	1364	270	7.24	Complies	S.Pi
10/06/20	08:25	27.124	1356	272	7.12	Complies	S.Pi
M/C Stopped at 08:45 to 09:00 due to Break fast							
10/06/20	09:15	27.244	1362	280	7.18	Complies	S.Pi
10/06/20	09:45	27.281	1364	271	7.06	Complies	Pimp
10/06/20	10:15	27.186	1359	276	7.09	Complies	Pimp
10/06/20	10:45	27.261	1363	268	7.01	Complies	Pimp
M/C Stopped at 11:00 to 11:10 due to tea break							
10/06/20	11:20	27.209	1360	266	7.04	Complies	Pimp
10/06/20	11:50	27.206	1362	271	7.06	Complies	Pimp
10/06/20	12:30	27.261	1363	269	7.00	Complies	Pimp
10/06/20	13:00	27.228	1361	270	7.01	Complies	Pimp
10/06/20	13:30	27.206	1360	266	6.96	Complies	Pimp
10/06/20	14:05	27.261	1363	275	6.94	Complies	Pimp
10/06/20	14:35	27.209	1360	278	6.98	Complies	Pimp
10/06/20	15:05	27.246	1362	263	6.91	Complies	Pimp
10/06/20	15:35	27.266	1363	271	6.96	Complies	Pimp
M/C Stopped at 16:00 to 16:10 due to tea break							
10/06/20	16:20	27.209	1360	268	6.95	Complies	Pimp
10/06/20	16:50	27.227	1361	270	6.93	Complies	Pimp
10/06/20	M/C Stopped at 17:00 to 18:30 due to validation sample taken						
10/06/20	18:45	27.265	1363	263	7.02	Complies	R.Ey
10/06/20	19:25	27.184	1359	269	6.99	Complies	R.Ey

*If appearance are satisfactory document as complies.

	Prepared by:	Checked by:	Approved By:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	G. 04/06/2020	Vijayalaxmi 04/06/2020	M. 04/06/2020

CONTROLLED COPY

	Safetab Life Science			100% GMP CERTIFIED ISO 9001:2015	
	BATCH MANUFACTURING RECORD			Page No.:	43 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	UD200604	Mfg. Date:	06/02/20	Exp. Date:	05/02/23

11.6-B IN-PROCESS CHECKS: (EVERY 30 MINUTES) BY PRODUCTION:

DATE	TIME	Group Wt: 27.200g ± 3 % (26.384g to 28.016g)		HARDNESS	THICKNESS	APPEARANCE	Done by Production
		Avg. Wt: 1360.000 mg ± 5% (1292.000mg - 1428.000mg)		(250N-350N) (To be monitored)	7.10 ± 0.30mm (6.80mm - 7.40mm) (To be monitored)	Red / white colored, Capsule shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides.	
		Weight of 20 Tab (g)	Avg. Weight (mg)				
———— m/c stopped at 19:30 to 20:00 due to dinner break ————							
10/06/20	20:10	27.283	1364	267	7.01	Complies	R. Bay
10/06/20	20:40	27.247	1362	273	7.04	Complies	R. Bay
10/06/20	21:10	27.205	1360	265	6.98	Complies	R. Bay
10/06/20	21:50	27.284	1364	260	7.05	Complies	R. Bay
10/06/20	22:20	27.187	1359	268	7.01	Complies	R. Bay
10/06/20	22:50	27.205	1360	258	7.03	Complies	R. Bay
10/06/20	23:30	27.225	1361	264	7.05	Complies	R. Bay
———— m/c stopped at 00:00 to 00:10 due to the Break ————							
10/06/20	00:20	27.285	1364	260	7.01	Complies	R. Bay
10/06/20	00:50	27.164	1358	257	7.08	Complies	R. Bay
10/06/20	01:30	27.225	1361	265	6.96	Complies	R. Bay
10/06/20	02:05	27.205	1360	261	6.98	Complies	R. Bay
———— Batch completed at 02:30 ————							

*If appearance are satisfactory document as complies.

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/06/2020	 04/06/2020	 04/06/2020	

		Safetab Life Science			
		BATCH MANUFACTURING RECORD		Page No.:	45 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	41D200604	Mfg. Date:	06/2020	Exp. Date:	05/2023

11.7 IN-PROCESS CHECKS: (EVERY 1 HOUR) BY IPQA:

DATE	TIME	Group Wt: 27.200g $\pm$ 3 % (26.384g to 28.016g) Avg. Wt: 1360.000 mg $\pm$ 5% (1292.000mg - 1428.000mg)		HARDNESS (250N-350N) (To be monitored)	THICKNESS 7.10 $\pm$ 0.30mm (6.80mm - 7.40mm) (To be monitored)	APPEARANCE Red / white colored, Capsule shaped biconvex uncoated bilayered tablets with break line on one side and plain on other sides.	Done by IPQA
		Weight of 20 Tab (g)	Avg. Weight (mg)				
09/06/20	17:00	27.285	1364	278	7.01	Complies	M.M
09/06/20	18:05	27.212	1360	265	6.98	Complies	M.M
09/06/20	19:10	27.145	1357	262	7.03	Complies	M.M
M/c stopped at 19:30 to 20:00 due to dinner							
09/06/20	20:15	27.248	1362	269	6.99	Complies	M.M
09/06/20	21:20	27.203	1360	275	7.03	Complies	M.M
09/06/20	22:30	27.246	1362	281	7.04	Complies	Ch
09/06/20	23:35	27.228	1361	277	7.01	Complies	Ch
M/c stopped at 00:00 to 00:10 for tea break							
10/06/20	00:55	27.205	1360	275	7.05	Complies	Ch
10/06/20	01:40	27.191	1359	281	7.09	Complies	Ch
10/06/20	02:40	27.244	1362	277	7.11	Complies	Ch
10/06/20	03:40	27.231	1361	279	7.09	Complies	Ch
M/c stopped at 04:00 to 04:10 for tea break							
10/06/20	04:45	27.218	1360	269	7.06	Complies	Ch
M/c stopped at 05:50 due to shift closed							
10/06/20	06:40	27.287	1364	253	6.95	Complies	Rd
10/06/20	07:40	27.282	1361	260	7.01	Complies	Rd
10/06/20	08:40	27.244	1362	254	7.00	Complies	Rd
M/c stopped at 08:45 to 09:00 due to break fast							
10/06/20	09:40	27.264	1363	284	6.98	Complies	Rd
10/06/20	10:40	27.211	1360	273	6.96	Complies	Rd
M/c stopped at 11:00 to 11:10 due tea break							
10/06/20	11:45	27.228	1361	285	7.04	Complies	Rd
10/06/20	12:45	27.247	1362	253	7.01	Complies	Rd
10/06/20	13:50	27.209	1360	251	7.04	Complies	Rd

*If appearance are satisfactory document as complies.

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/06/2020	 04/06/2020	 04/06/2020	

	Safetab Life Science					
	BATCH MANUFACTURING RECORD				Page No.:	47 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	9D200604	Mfg. Date:	06/2020	Exp. Date:	05/2023	

11.8 IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date: 09/06/20		Time: 16:40	
Weight of 20 tablets: 27.228			
1	1.362	8	1.359
2	1.365	9	1.362
3	1.356	10	1.365
4	1.362	11	1.367
5	1.360	12	1.360
6	1.355	13	1.359
7	1.359	14	1.355
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M/C Speed: 12 RPM	
Min. weight: 1.355 g	99.55 %	Max. weight: 1.367 g	100.44 %
Average weight of 20 Tablets: 1.361 g			
Friability: 0.14 %		NMT 1.0 %	
Done by: R. Ex (Production)			
Date: 09/06/20		Time: 17:40	
Weight of 20 tablets: 27.235			
1	1.365	8	1.356
2	1.359	9	1.360
3	1.360	10	1.362
4	1.358	11	1.365
5	1.360	12	1.367
6	1.362	13	1.365
7	1.365	14	1.358
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M/C Speed: 12 RPM	
Min. weight: 1.356 g	99.62 %	Max. weight: 1.367 g	100.44 %
Average weight of 20 Tablets: 1.361 g			
Friability: 0.14 %		NMT 1.0 %	
Done by: R. Ex (Production)			
Date: 09/06/20		Time: 18:40	
Weight of 20 tablets: 27.232			
1	1.362	8	1.365
2	1.359	9	1.360
3	1.362	10	1.359
4	1.360	11	1.362
5	1.358	12	1.365
6	1.361	13	1.367
7	1.364	14	1.362
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M/C Speed: 12 RPM	
Min. weight: 1.355 g	99.55 %	Max. weight: 1.368 g	100.51 %
Average weight of 20 Tablets: 1.361 g			
Friability: 0.14 %		NMT 1.0 %	
Done by: R. Ex (Production)			

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G. R 04/06/2020	Uyayalab 04/06/2020	12/04/2020

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	Safetab Life Science					
	BATCH MANUFACTURING RECORD				Page No.:	48 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	UP200604	Mfg. Date:	06/2020	Exp. Date:	05/2023	

11.8-A IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION:

Date: 09/06/20		Time: 20:35	
Weight of 20 tablets: 27.248			
1	1.357	8	1.367
2	1.362	9	1.365
3	1.365	10	1.368
4	1.361	11	1.359
5	1.362	12	1.361
6	1.359	13	1.365
7	1.367	14	1.362
15	1.364	16	1.365
17	1.361	18	1.359
19	1.363	20	1.365
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg) M/C Speed: 12 RPM			
Min. weight: 1.356 g		99.12 %	
Average weight of 20 Tablets: 1.362 g		Max. weight: 1.368 g	
Friability: 0.14 %		NMT 1.0 %	
Done by: R. Ruy (Production)			
Date: 09/06/20		Time: 21:50	
Weight of 20 tablets: 27.204 gm			
1	1.364	8	1.362
2	1.360	9	1.360
3	1.364	10	1.362
4	1.362	11	1.365
5	1.365	12	1.361
6	1.361	13	1.364
7	1.364	14	1.362
15	1.362	16	1.360
17	1.361	18	1.365
19	1.365	20	1.365
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg) M/C Speed: 12 RPM			
Min. weight: 1.360 g		99.63 %	
Average weight of 20 Tablets: 1.365 g		Max. weight: 1.370 g	
Friability: 0.18 %		NMT 1.0 %	
Done by: (Production)			
Date: 09/06/20		Time: 22:28	
Weight of 20 tablets: 27.235 gm			
1	1.355	8	1.364
2	1.362	9	1.362
3	1.360	10	1.367
4	1.364	11	1.360
5	1.361	12	1.358
6	1.362	13	1.361
7	1.368	14	1.360
15	1.362	16	1.362
17	1.358	18	1.360
19	1.365	20	1.362
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg) M/C Speed: 12 RPM			
Min. weight: 1.358 g		99.58 %	
Average weight of 20 Tablets: 1.361 g		Max. weight: 1.368 g	
Friability: 0.11 %		NMT 1.0 %	
Done by: (Production)			

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G. R 04/06/2020	U. Ruy 04/06/2020	M. Ruy 04/06/2020

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	Safetab Life Science				
	BATCH MANUFACTURING RECORD		Page No.:	49 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	97D800604	Mfg.Date:	06/2020	Exp.Date:	05/2023

11.8-B IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION

Date: 10/06/20		Time: 00:15	
Weight of 20 tablets: 27.2428g			
1	1.368	8	1.356
2	1.356	9	1.316
3	1.361	10	1.358
4	1.362	11	1.358
5	1.365	12	1.360
6	1.360	13	1.361
7	1.362	14	1.358
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M /C Speed: 12 RPM	
Min. weight: 1.356g	99.58%	Max. weight: 1.368g	100.44%
Average weight of 20 Tablets: 1.362g			
Friability: 0.11%		NMT 1.0 %	
Done by: (Production)			
Date: 10/06/20		Time: 01:20	
Weight of 20 tablets: 27.2348g			
1	1.364	8	1.362
2	1.361	9	1.360
3	1.362	10	1.362
4	1.361	11	1.362
5	1.365	12	1.365
6	1.362	13	1.362
7	1.361	14	1.362
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M /C Speed: 12 RPM	
Min. weight: 1.358g	99.58%	Max. weight: 1.368g	100.51%
Average weight of 20 Tablets: 1.361g			
Friability: 0.15%		NMT 1.0 %	
Done by: (Production)			
Date: 10/06/20		Time: 02:25	
Weight of 20 tablets: 27.2388g			
1	1.358	8	1.360
2	1.362	9	1.362
3	1.360	10	1.358
4	1.364	11	1.358
5	1.360	12	1.358
6	1.356	13	1.362
7	1.362	14	1.360
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M /C Speed: 12 RPM	
Min. weight: 1.358g	99.58%	Max. weight: 1.365g	100.29%
Average weight of 20 Tablets: 1.361g			
Friability: 0.08%		NMT 1.0 %	
Done by: (Production)			

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	9.18 04/06/2020	04/06/2020	04/06/2020

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	Safetab Life Science				
	BATCH MANUFACTURING RECORD		Page No.:	50 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	C7D2006024	Mfg. Date:	06/2020	Exp. Date:	05/2023

11.8-C IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION

Date: 10/06/20		Time: 03:30	
Weight of 20 tablets: 27.205 gm			
1	1.364	8	1.362
2	1.358	9	1.360
3	1.362	10	1.358
4	1.365	11	1.355
5	1.362	12	1.360
6	1.365	13	1.362
7	1.360	14	1.365
Limit: 5% of actual average weight, (1292.000 - 1428.000 mg)		M /C Speed: 12 RPM	
Min. weight: 1.355 g		Max. weight: 1.365 g	
Average weight of 20 Tablets: 1.360 g		100.36 %	
Friability: 0.13 %		NMT 1.0 %	
Done by: (Production)			
Date: 10/06/20		Time: 04:35	
Weight of 20 tablets: 27.204 gm			
1	1.361	8	1.362
2	1.354	9	1.364
3	1.358	10	1.364
4	1.362	11	1.362
5	1.361	12	1.368
6	1.365	13	1.360
7	1.360	14	1.362
Limit: 5% of actual average weight, (1292.000 - 1428.000 mg)		M /C Speed: 12 RPM	
Min. weight: 1.352 g		Max. weight: 1.368 g	
Average weight of 20 Tablets: 1.360 g		100.58 %	
Friability: 0.17 %		NMT 1.0 %	
Done by: (Production)			
Date: 10/06/2020		Time: 06:35	
Weight of 20 tablets: 27.208 gm			
1	1.360	8	1.367
2	1.362	9	1.365
3	1.354	10	1.362
4	1.357	11	1.360
5	1.359	12	1.357
6	1.360	13	1.354
7	1.362	14	1.357
Limit: 5% of actual average weight, (1292.000 - 1428.000 mg)		M /C Speed: 12 RPM	
Min. weight: 1.354 g		Max. weight: 1.367 g	
Average weight of 20 Tablets: 1.360 g		100.51 %	
Friability: 0.15 %		NMT 1.0 %	
Done by: S. Pi (Production)			

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G. L. 04/06/2020	W. Jayalaxmi 04/06/2020	04/06/2020

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	Safetab Life Science					
	BATCH MANUFACTURING RECORD				Page No.:	51 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	C7D200604	Mfg. Date:	06/2020	Exp. Date:	05/2023	

11.8-D IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION

Date: 10/06/2020		Time: 07:45	
Weight of 20 tablets: 27.224 gm			
1	1.359	8	1.368
2	1.362	9	1.362
3	1.368	10	1.365
4	1.356	11	1.360
5	1.359	12	1.368
6	1.355	13	1.360
7	1.362	14	1.364
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M/C Speed: 12 RPM	
Min. weight: 1.355 g	99.04 %	Max. weight: 1.368 g	100.51 %
Average weight of 20 Tablets: 1.361 g			
Friability: 0.15% NMT 1.0 %			
Done by: S. Pi (Production)			
Date: 10/06/20		Time: 09:20	
Weight of 20 tablets: 27.208 gm			
1	1.362	8	1.366
2	1.365	9	1.362
3	1.360	10	1.361
4	1.362	11	1.349
5	1.370	12	1.363
6	1.371	13	1.362
7	1.360	14	1.365
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M/C Speed: 12 RPM	
Min. weight: 1.349 g	99.19 %	Max. weight: 1.371 g	100.80 %
Average weight of 20 Tablets: 1.360 g			
Friability: 0.18% NMT 1.0 %			
Done by: Pmp (Production)			
Date: 10/06/20		Time: 10:25	
Weight of 20 tablets: 27.176 gm			
1	1.361	8	1.356
2	1.364	9	1.358
3	1.360	10	1.361
4	1.358	11	1.365
5	1.364	12	1.350
6	1.362	13	1.362
7	1.359	14	1.360
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M/C Speed: 12 RPM	
Min. weight: 1.350 g	99.41 %	Max. weight: 1.367 g	100.66 %
Average weight of 20 Tablets: 1.358 g			
Friability: 0.16% NMT 1.0 %			
Done by: Pmp (Production)			

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	Gil 04/06/2020	Udayalakshy 04/06/2020	Murthy 04/06/2020

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	Safetab Life Science					
	BATCH MANUFACTURING RECORD				Page No.:	52 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	CMPD00604	Mfg.Date:	06/2020	Exp.Date:	05/2023	

11.8-E IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION

Date: 10/06/20		Time: 11:30	
Weight of 20 tablets: 27.216 gm			
1	1.360	8	1.355
2	1.357	9	1.361
3	1.362	10	1.360
4	1.360	11	1.352
5	1.363	12	1.362
6	1.365	13	1.360
7	1.358	14	1.365
Limit: 5% of actual average weight, (1292.000 - 1428.000 mg)			
Min. weight: 1.352 g		M/C Speed: 12 RPM	
Average weight of 20 Tablets: 1.360 g		Max. weight: 1.369 g	
Friability: 0.16%		NMT 1.0 %	
Done by: Pmp (Production)			
Date: 10/06/20		Time: 12:35	
Weight of 20 tablets: 27.219 gm			
1	1.355	8	1.364
2	1.360	9	1.360
3	1.363	10	1.360
4	1.362	11	1.350
5	1.358	12	1.361
6	1.371	13	1.364
7	1.359	14	1.368
Limit: 5% of actual average weight, (1292.000 - 1428.000 mg)			
Min. weight: 1.350 g		M/C Speed: 12 RPM	
Average weight of 20 Tablets: 1.360 g		Max. weight: 1.371 g	
Friability: 0.18%		NMT 1.0 %	
Done by: Pmp (Production)			
Date: 10/06/20		Time: 13:40	
Weight of 20 tablets: 27.236 gm			
1	1.360	8	1.358
2	1.358	9	1.360
3	1.362	10	1.367
4	1.360	11	1.354
5	1.361	12	1.362
6	1.369	13	1.360
7	1.356	14	1.357
Limit: 5% of actual average weight, (1292.000 - 1428.000 mg)			
Min. weight: 1.354 g		M/C Speed: 12 RPM	
Average weight of 20 Tablets: 1.361 g		Max. weight: 1.369 g	
Friability: 0.16%		NMT 1.0 %	
Done by: Pmp (Production)			

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G.O 04/06/2020	Udaya Lal 04/06/2020	M. Narayana 04/06/2020

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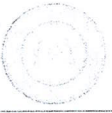
	Safetab Life Science				
	BATCH MANUFACTURING RECORD		Page No.:	53 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Glizalide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	CTD200604	Mfg. Date:	06/2020	Exp. Date:	05/2028

11.8-F IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION

Date: 10/06/20		Time: 14:45	
Weight of 20 tablets: 27.216 gm			
1	1.361	8	1.357
2	1.360	9	1.359
3	1.357	10	1.362
4	1.359	11	1.360
5	1.365	12	1.353
6	1.360	13	1.361
7	1.364	14	1.365
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M/C Speed: 12 RPM	
Min. weight: 1.353 g	99.48 %	Max. weight: 1.368 g	100.58 %
Average weight of 20 Tablets: 1.360 g			
Friability: 0.18 %		NMT 1.0 %	
Done by: Pmp (Production)			
Date: 10/06/20		Time: 15:50	
Weight of 20 tablets: 27.228 gm			
1	1.355	8	1.368
2	1.360	9	1.360
3	1.371	10	1.364
4	1.362	11	1.361
5	1.360	12	1.351
6	1.357	13	1.359
7	1.362	14	1.365
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M/C Speed: 12 RPM	
Min. weight: 1.351 g	99.26 %	Max. weight: 1.371 g	100.73 %
Average weight of 20 Tablets: 1.361 g			
Friability: 0.18 %		NMT 1.0 %	
Done by: Pmp (Production)			
Date: 10/06/20		Time: 16:55	
Weight of 20 tablets: 27.229 gm			
1	1.361	8	1.364
2	1.360	9	1.362
3	1.364	10	1.365
4	1.358	11	1.361
5	1.362	12	1.355
6	1.367	13	1.360
7	1.360	14	1.358
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M/C Speed: 12 RPM	
Min. weight: 1.355 g	99.55 %	Max. weight: 1.367 g	100.44 %
Average weight of 20 Tablets: 1.361 g			
Friability: 0.16 %		NMT 1.0 %	
Done by: Pmp (Production)			

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G. R. 04/06/2020	Ujaya Lal Singh 04/06/2020	04/06/2020

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	Safetab Life Science			A	
	BATCH MANUFACTURING RECORD			Page No.:	53 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	G-1D 200 604	Mfg. Date:	06/2020	Exp. Date:	05/2023

11.8-F IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION

Date: 10/06/20		Time: 17:55	
Weight of 20 tablets: 27.225			
1	1.362	8	1.359
2	1.365	9	1.365
3	1.356	10	1.367
4	1.362	11	1.359
5	1.357	12	1.366
6	1.366	13	1.368
7	1.359	14	1.359
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M/C Speed: 12 RPM	
Min. weight: 1.35454g	99.48%	Max. weight: 1.368g	100.51%
Average weight of 20 Tablets: 1.361g			
Friability: 0.14%		NMT 1.0%	
Done by: P. Parv (Production)			
Date: 10/06/20		Time: 18:55	
Weight of 20 tablets: 27.238			
1	1.362	8	1.358
2	1.357	9	1.362
3	1.368	10	1.368
4	1.368	11	1.360
5	1.359	12	1.358
6	1.360	13	1.363
7	1.361	14	1.367
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M/C Speed: 12 RPM	
Min. weight: 1.35555g	99.55%	Max. weight: 1.368g	100.51%
Average weight of 20 Tablets: 1.361g			
Friability: 0.15%		NMT 1.0%	
Done by: P. Parv (Production)			
Date: 10/06/20		Time: 20:25	
Weight of 20 tablets: 27.223			
1	1.362	8	1.355
2	1.359	9	1.360
3	1.367	10	1.367
4	1.359	11	1.359
5	1.360	12	1.361
6	1.365	13	1.359
7	1.362	14	1.355
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M/C Speed: 12 RPM	
Min. weight: 1.355g	98.12%	Max. weight: 1.367g	100.44%
Average weight of 20 Tablets: 1.361g			
Friability: 0.15%		NMT 1.0%	
Done by: P. Parv (Production)			

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G. B. 04/06/2020	Ujaya Lal Singh 04/06/2020	10/06/2020

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	Safetab Life Science		B		
	BATCH MANUFACTURING RECORD		Page No.:	53 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GID200604	Mfg. Date:	06/2020	Exp. Date:	05/2023

11.8-F IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION

Date: 10/06/20		Time: 21:50	
Weight of 20 tablets: 27.234			
1	1.364	8	1.361
2	1.358	9	1.365
3	1.362	10	1.365
4	1.360	11	1.362
5	1.363	12	1.360
6	1.365	13	1.365
7	1.360	14	1.358
Limit: 5% of actual average weight, (1292.000 - 1428.000 mg)		M / C Speed: 12 RPM	
Min. weight: 1.356 g		99.63%	
Average weight of 20 Tablets: 1.361 g		Max. weight: 1.367 g	
Friability: 0.187		NMT 1.0 %	
Done by: (Production)			
Date: 10/06/20		Time: 22:58	
Weight of 20 tablets: 27.201			
1	1.364	8	1.361
2	1.362	9	1.360
3	1.360	10	1.358
4	1.362	11	1.362
5	1.360	12	1.358
6	1.355	13	1.350
7	1.358	14	1.360
Limit: 5% of actual average weight, (1292.000 - 1428.000 mg)		M / C Speed: 12 RPM	
Min. weight: 1.355 g		99.63%	
Average weight of 20 Tablets: 1.360 g		Max. weight: 1.367 g	
Friability: 0.117		NMT 1.0 %	
Done by: (Production)			
Date: 10/06/20		Time: 00:120	
Weight of 20 tablets: 27.178			
1	1.358	8	1.368
2	1.364	9	1.360
3	1.360	10	1.358
4	1.362	11	1.360
5	1.361	12	1.362
6	1.363	13	1.358
7	1.362	14	1.350
Limit: 5% of actual average weight, (1292.000 - 1428.000 mg)		M / C Speed: 12 RPM	
Min. weight: 1.352 g		99.55%	
Average weight of 20 Tablets: 1.358 g		Max. weight: 1.368 g	
Friability: 0.125		NMT 1.0 %	
Done by: (Production)			

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G. 04/06/2020	Udaya Lakshmi 04/06/2020	10/06/2020

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	Safetab Life Science		Page No.: 53 of 78		
	BATCH MANUFACTURING RECORD		C		
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

11.8-F IN- PROCESS CHECK FREQUENCY: EVERY 1 HOUR BY PRODUCTION

Date: 06/20		Time: 01:25	
Weight of 20 tablets: 27.251			
1	1.367	8	1.362
2	1.360	9	1.358
3	1.365	10	1.362
4	1.368	11	1.360
5	1.358	12	1.361
6	1.361	13	1.365
7	1.358	14	1.366
Limit: 5% of actual average weight, (1292.000 - 1428.000 mg)		M /C Speed: 12 RPM	
Min. weight: 1.355 g		99.48 %	
Average weight of 20 Tablets: 1.362 g		Max. weight: 1.368 g	
Friability: 0.177 %		NMT 1.0 %	
Done by: (Production)			
Date: 06/20		Time: 02:20	
Weight of 20 tablets: 27.225			
1	1.360	8	1.362
2	1.356	9	1.365
3	1.361	10	1.360
4	1.362	11	1.369
5	1.360	12	1.361
6	1.365	13	1.367
7	1.360	14	1.360
Limit: 5% of actual average weight, (1292.000 - 1428.000 mg)		M /C Speed: 12 RPM	
Min. weight: 1.354 g		99.48 %	
Average weight of 20 Tablets: 1.361 g		Max. weight: 1.367 g	
Friability: 0.187 %		NMT 1.0 %	
Done by: (Production)			
Date:		Time:	
Weight of 20 tablets:			
1		8	
2		9	
3		10	
4		11	
5		12	
6		13	
7		14	
Limit: 5% of actual average weight, (1292.000 - 1428.000 mg)		M /C Speed: RPM	
Min. weight: g		Max. weight: g	
Average weight of 20 Tablets: g		Friability: %	
Friability: %		NMT 1.0 %	
Done by: (Production)			

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G. 04/06/2020	Ujaya Lakshmi 04/06/2020	04/06/2020

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		Safetab Life Science		Page No.:		54 of 78
				BATCH MANUFACTURING RECORD		
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	050200604	Mfg.Date:	06/2020	Exp.Date:	05/2023	

11.9 IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BY IPQA

Date: 05/06/20		Time: 14:10	
Weight of 20 tablets: 27.279 g			
1	1.367	8	1.367
2	1.360	9	1.366
3	1.351	10	1.362
4	1.359	11	1.358
5	1.373	12	1.369
6	1.371	13	1.373
7	1.358	14	1.356
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M / C Speed: 12 RPM	
Min. weight: 1.354 g	99.33 %	Max. weight: 1.373 g	100.73 %
Average weight of 20 Tablets: 1.363 g			
Friability: 0.161		NMT 1.0 %	
Done by: M.P. (IPQA)			
Date: 05/06/20		Time: 15:15	
Weight of 20 tablets: 27.211 g			
1	1.358	8	1.364
2	1.365	9	1.356
3	1.352	10	1.352
4	1.359	11	1.358
5	1.363	12	1.367
6	1.363	13	1.362
7	1.365	14	1.360
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M / C Speed: 12 RPM	
Min. weight: 1.352 g	99.41 %	Max. weight: 1.368 g	100.58 %
Average weight of 20 Tablets: 1.360 g			
Friability: 0.131		NMT 1.0 %	
Done by: M.P. (IPQA)			
Date: 05/06/20		Time: 21:20	
Weight of 20 tablets: 27.287 g			
1	1.368	8	1.371
2	1.362	9	1.370
3	1.360	10	1.356
4	1.356	11	1.359
5	1.353	12	1.365
6	1.365	13	1.362
7	1.356	14	1.356
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M / C Speed: 12 RPM	
Min. weight: 1.356 g	99.70 %	Max. weight: 1.371 g	100.51 %
Average weight of 20 Tablets: 1.364 g			
Friability: 0.141		NMT 1.0 %	
Done by: M.P. (IPQA)			

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G.P. 04/06/2020	Udayalakshy 04/06/2020	M. P. 04/06/2020

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	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	55 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	LD200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

11.9-A IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BY IPQA

Date:	09/06/20	Time:	23:30
Weight of 20 tablets: 27.248 gms			
1	1.358	8	1.368
2	1.351	9	1.364
3	1.364	10	1.367
4	1.372	11	1.360
5	1.369	12	1.358
6	1.359	13	1.351
7	1.370	14	1.369
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)			
M /C Speed: 12 RPM			
Min. weight:	1.351 g	99.19 %	Max. weight: 1.372 g
Average weight of 20 Tablets:	1.362 g		100.21 %
Friability:	0.12 %	NMT 1.0 %	
Done by: CM (IPQA)			
Date:	10/06/20	Time:	01:30
Weight of 20 tablets: 27.248			
1	1.362	8	1.362
2	1.367	9	1.359
3	1.358	10	1.354
4	1.354	11	1.367
5	1.361	12	1.365
6	1.369	13	1.354
7	1.357	14	1.369
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)			
M /C Speed: 12 RPM			
Min. weight:	1.354 g	98.62 %	Max. weight: 1.369 g
Average weight of 20 Tablets:	1.361 g		100.32 %
Friability:	0.13 %	NMT 1.0 %	
Done by: CM (IPQA)			
Date:	10/06/20	Time:	03:35
Weight of 20 tablets: 27.201			
1	1.358	8	1.364
2	1.353	9	1.360
3	1.364	10	1.362
4	1.367	11	1.353
5	1.358	12	1.358
6	1.353	13	1.361
7	1.360	14	1.359
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)			
M /C Speed: 12 RPM			
Min. weight:	1.353 g	98.60 %	Max. weight: 1.367 g
Average weight of 20 Tablets:	1.360 g		100.47 %
Friability:	0.13 %	NMT 1.0 %	
Done by: CM (IPQA)			

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	9.4 10/06/2020	10/06/2020	10/06/2020

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	Safetab Life Science					
	BATCH MANUFACTURING RECORD				Page No.:	56 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	CID200604	Mfg.Date:	06/2020	Exp.Date:	05/2023	

11.9-B IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BY IPQA

Date: 10/06/2020		Time: 07:15	
Weight of 20 tablets: 27.2489			
1	1.361	8	1.368
2	1.365	9	1.366
3	1.364	10	1.365
4	1.365	11	1.370
5	1.354	12	1.363
6	1.355	13	1.360
7	1.357	14	1.363
Limit: 5% of actual average weight, (1292.000 - 1428.000 mg)		M/C Speed: 12 RPM	
Min. weight: 1.354 g	99.41 %	Max. weight: 1.370 g	100.59 %
Average weight of 20 Tablets: 1.362 g			
Friability: 0.11 %		NMT 1.0 %	
Done by: PA (IPQA)			
Date: 10/06/2020		Time: 09:20	
Weight of 20 tablets:			
1	1.361	8	1.361
2	1.360	9	1.363
3	1.367	10	1.364
4	1.368	11	1.365
5	1.358	12	1.367
6	1.364	13	1.366
7	1.365	14	1.366
Limit: 5% of actual average weight, (1292.000 - 1428.000 mg)		M/C Speed: 12 RPM	
Min. weight: 1.358 g	99.63 %	Max. weight: 1.368 g	100.36 %
Average weight of 20 Tablets: 1.363 g			
Friability: 0.10 %		NMT 1.0 %	
Done by: PA (IPQA)			
Date: 10/06/2020		Time: 11:30	
Weight of 20 tablets: 27.2459			
1	1.366	8	1.360
2	1.366	9	1.359
3	1.358	10	1.356
4	1.366	11	1.364
5	1.365	12	1.370
6	1.360	13	1.368
7	1.362	14	1.359
Limit: 5% of actual average weight, (1292.000 - 1428.000 mg)		M/C Speed: 12 RPM	
Min. weight: 1.356 g	99.55 %	Max. weight: 1.370 g	100.58 %
Average weight of 20 Tablets: 1.362 g			
Friability: 0.12 %		NMT 1.0 %	
Done by: PA (IPQA)			

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G. V. 04/06/2020	Ujaya 04/06/2020	04/06/2020

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	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	57 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	UJ0200604	Mfg. Date:	06/2020	Exp. Date:	05/2023

11.9-C IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BY IPQA

Date: 10/06/2020		Time: 13:30	
Weight of 20 tablets: 27.284 gm			
1	1.361	8	1.370
2	1.365	9	1.369
3	1.360	10	1.368
4	1.358	11	1.367
5	1.359	12	1.370
6	1.360	13	1.371
7	1.361	14	1.365
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M/C Speed: 12 RPM	
Min. weight: 1.357 g	99.48 %	Max. weight: 1.371 g	100.51 %
Average weight of 20 Tablets: 1.362 g			
Friability: 0.11 %		NMT 1.0 %	
Done by: P. (IPQA)			
Date: 10/06/2020		Time: 15:35	
Weight of 20 tablets: 27.089 gm			
1	1.359	8	1.360
2	1.360	9	1.352
3	1.360	10	1.360
4	1.359	11	1.352
5	1.352	12	1.357
6	1.366	13	1.360
7	1.360	14	1.358
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M/C Speed: 14 RPM	
Min. weight: 1.352 g	99.22 %	Max. weight: 1.366 g	100.64 %
Average weight of 20 Tablets: 1.359 g			
Friability: 0.18 %		NMT 1.0 %	
Done by: M. (IPQA)			
Date: 10/06/2020		Time: 19:05	
Weight of 20 tablets: 27.244 g			
1	1.359	8	1.356
2	1.362	9	1.359
3	1.356	10	1.363
4	1.357	11	1.361
5	1.362	12	1.360
6	1.365	13	1.356
7	1.360	14	1.358
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M/C Speed: 15 RPM	
Min. weight: 1.356 g	98.32 %	Max. weight: 1.363 g	100.47 %
Average weight of 20 Tablets: 1.362 g			
Friability: 0.12 %		NMT 1.0 %	
Done by: M. (IPQA)			

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	S. 04/06/2020	Ujwalak 04/06/2020	04/06/2020	

	Safetab Life Science					
	BATCH MANUFACTURING RECORD				Page No.:	58 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	GD200604	Mfg.Date:	06/2020	Exp.Date:	05/2023	

11.9-D IN- PROCESS CHECK FREQUENCY: EVERY 2 HOUR BY IPQA

Date: 10/06/20		Time: 21:15	
Weight of 20 tablets: 21.211 g			
1	1.361	8	1.359
2	1.365	9	1.362
3	1.360	10	1.366
4	1.354	11	1.354
5	1.358	12	1.358
6	1.362	13	1.361
7	1.354	14	1.365
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M / C Speed: 12 RPM	
Min. weight: 1.354 g		98.69 %	
Average weight of 20 Tablets: 1.360 g		Max. weight: 1.366 g	
Friability: 0.91%		NMT 1.0 %	
Done by: (Signature) (IPQA)			
Date: 10/06/20		Time: 23:30	
Weight of 20 tablets: 27.209 g			
1	1.359	8	1.365
2	1.366	9	1.359
3	1.361	10	1.355
4	1.364	11	1.361
5	1.356	12	1.365
6	1.359	13	1.361
7	1.363	14	1.365
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M / C Speed: 12 RPM	
Min. weight: 1.352 g		99.11 %	
Average weight of 20 Tablets: 1.360 g		Max. weight: 1.368 g	
Friability: 0.12%		NMT 1.0 %	
Done by: (Signature) (IPQA)			
Date: 11/06/20		Time: 01:35	
Weight of 20 tablets: 27.249 g			
1	1.359	8	1.359
2	1.366	9	1.356
3	1.364	10	1.366
4	1.366	11	1.361
5	1.361	12	1.370
6	1.359	13	1.363
7	1.365	14	1.356
Limit: 5% of actual average weight, (1292.000 – 1428.000 mg)		M / C Speed: 12 RPM	
Min. weight: 1.352 g		99.55 %	
Average weight of 20 Tablets: 1.362 g		Max. weight: 1.370 g	
Friability: 0.12%		NMT 1.0 %	
Done by: (Signature) (IPQA)			

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	(Signature) 04/06/2020	(Signature) 04/06/2020	(Signature) 04/06/2020

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	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	59 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	UHD2006024	Mfg. Date:	06/2020	Exp. Date:	05/2023

11.10 IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY PRODUCTION:

Date: 09/06/20 Time: 16:50					Done by: R. Ex (Production)						
WHITE PART [METFORMIN HCL] 23.612 Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.592 Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.179	8	1.183	15	1.186	1	0.179	8	0.181	15	0.181
2	1.183	9	1.175	16	1.175	2	0.181	9	0.179	16	0.179
3	1.178	10	1.183	17	1.179	3	0.179	10	0.183	17	0.181
4	1.182	11	1.179	18	1.181	4	0.175	11	0.178	18	0.181
5	1.185	12	1.186	19	1.183	5	0.181	12	0.181	19	0.179
6	1.183	13	1.179	20	1.186	6	0.184	13	0.175	20	0.175
7	1.179	14	1.183			7	0.181	14	0.181		
Min. weight: 1.175 g 99.57% Max. weight: 1.186 g 100.50% Average weight of 20 Tablets: 1.180 g					Min. weight: 0.175 g 97.78% Max. weight: 0.184 g 102.79% Average weight of 20 Tablets: 0.179 g						
Date: 09/06/20 Time: 18:50					Done by: R. Ex (Production)						
WHITE PART [METFORMIN HCL] 23.601 Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.602 Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.185	8	1.183	15	1.186	1	0.178	8	0.183	15	0.181
2	1.179	9	1.179	16	1.185	2	0.181	9	0.180	16	0.179
3	1.181	10	1.174	17	1.179	3	0.183	10	0.179	17	0.178
4	1.175	11	1.183	18	1.174	4	0.179	11	0.181	18	0.181
5	1.180	12	1.181	19	1.181	5	0.183	12	0.178	19	0.183
6	1.183	13	1.181	20	1.183	6	0.178	13	0.176	20	0.184
7	1.181	14	1.181			7	0.181	14	0.180		
Min. weight: 1.174 g 99.49% Max. weight: 1.186 g 100.50% Average weight of 20 Tablets: 1.180 g					Min. weight: 0.176 g 97.77% Max. weight: 0.184 g 102.77% Average weight of 20 Tablets: 0.180 g						
Date: 09/06/20 Time: 20:55					Done by: R. Ex (Production)						
WHITE PART [METFORMIN HCL] 23.627 Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.593 Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.178	8	1.181	15	1.178	1	0.179	8	0.175	15	0.179
2	1.175	9	1.183	16	1.176	2	0.181	9	0.181	16	0.181
3	1.183	10	1.176	17	1.183	3	0.180	10	0.183	17	0.183
4	1.181	11	1.179	18	1.185	4	0.178	11	0.179	18	0.185
5	1.183	12	1.181	19	1.180	5	0.175	12	0.183	19	0.178
6	1.187	13	1.183	20	1.179	6	0.181	13	0.181	20	0.183
7	1.185	14	1.187			7	0.184	14	0.184		
Min. weight: 1.175 g 99.49% Max. weight: 1.187 g 100.50% Average weight of 20 Tablets: 1.181 g					Min. weight: 0.175 g 97.77% Max. weight: 0.184 g 102.77% Average weight of 20 Tablets: 0.179 g						

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	
Signature with Date	G. V. 09/06/2020	Udaya Lakshmi 04/06/2020	10/06/2020	

	Safetab Life Science				Page No.:		60 of 78
	BATCH MANUFACTURING RECORD				Batch Size		5,00,000 Tablets
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size			5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:			NIL
Batch No.:	U10200604	Mfg. Date:	06/2020	Exp. Date:			05/2023

11.10- A IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY PRODUCTION:

Date: 09/06/20 Time: 22:00										Done by: (Production)									
WHITE PART [METFORMIN HCL] 23.598m Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]										COLOUR PART [GLICLAZIDE] 3.6348m Limit: 180.000 ± 3% [174.600mg - 185.400mg]									
1	1.182	8	1.185	15	1.182	1	0.181	8	0.182	15	0.186								
2	1.175	9	1.180	16	1.180	2	0.184	9	0.185	16	0.180								
3	1.180	10	1.176	17	1.184	3	0.176	10	0.180	17	0.178								
4	1.182	11	1.178	18	1.185	4	0.180	11	0.176	18	0.187								
5	1.184	12	1.176	19	1.176	5	0.178	12	0.181	19	0.180								
6	1.180	13	1.182	20	1.180	6	0.181	13	0.180	20	0.185								
7	1.182	14	1.180			7	0.180	14	0.184										
Min. weight: 1.175 g 99.66 %					Min. weight: 0.176 g 97.23 %					Max. weight: 1.184 g 100.52 %					Max. weight: 0.185 g 102.31 %				
Average weight of 20 Tablets: 1.178 g					Average weight of 20 Tablets: 0.181 g														
Date: 10/06/20 Time: 01:05										Done by: (Production)									
WHITE PART [METFORMIN HCL] 23.6018m Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]										COLOUR PART [GLICLAZIDE] 3.6058m Limit: 180.000 ± 3% [174.600mg - 185.400mg]									
1	1.181	8	1.175	15	1.178	1	0.182	8	0.181	15	0.181								
2	1.176	9	1.178	16	1.183	2	0.175	9	0.176	16	0.184								
3	1.184	10	1.176	17	1.175	3	0.180	10	0.178	17	0.181								
4	1.180	11	1.178	18	1.181	4	0.180	11	0.175	18	0.184								
5	1.182	12	1.184	19	1.183	5	0.181	12	0.178	19	0.175								
6	1.185	13	1.180	20	1.180	6	0.181	13	0.181	20	0.180								
7	1.180	14	1.176			7	0.186	14	0.180										
Min. weight: 1.175 g 99.57 %					Min. weight: 0.175 g 97.23 %					Max. weight: 1.185 g 102.33 %					Max. weight: 0.185 g 102.33 %				
Average weight of 20 Tablets: 1.180 g					Average weight of 20 Tablets: 0.180 g														
Date: 10/06/20 Time: 03:10										Done by: (Production)									
WHITE PART [METFORMIN HCL] 23.5958m Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]										COLOUR PART [GLICLAZIDE] 3.5958m Limit: 180.000 ± 3% [174.600mg - 185.400mg]									
1	1.174	8	1.180	15	1.180	1	0.182	8	0.183	15	0.178								
2	1.180	9	1.181	16	1.182	2	0.175	9	0.180	16	0.181								
3	1.176	10	1.185	17	1.180	3	0.177	10	0.175	17	0.181								
4	1.178	11	1.180	18	1.176	4	0.175	11	0.178	18	0.180								
5	1.178	12	1.176	19	1.178	5	0.180	12	0.175	19	0.178								
6	1.181	13	1.178	20	1.180	6	0.181	13	0.181	20	0.180								
7	1.184	14	1.181			7	0.182	14	0.180										
Min. weight: 1.174 g 99.57 %					Min. weight: 0.175 g 97.26 %					Max. weight: 1.184 g 102.36 %					Max. weight: 0.182 g 102.36 %				
Average weight of 20 Tablets: 1.179 g					Average weight of 20 Tablets: 0.180 g														

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G. V. 04/06/2020	Udaya 04/06/2020	04/06/2020

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		Safetab Life Science		BATCH MANUFACTURING RECORD		Page No.:	61 of 78
				Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg		MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	G1D200604		Mfg.Date:	06/2020	Exp.Date:	05/2023	

11.10-B IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY PRODUCTION:

Date: 10/06/20 Time: 05:10 WHITE PART [METFORMIN HCL] 23.6188gm Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					Done by: (Production) COLOUR PART [GLICLAZIDE] 3.5989gm Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.183	8	1.185	15	1.185	1	0.184	8	0.185	15	0.186
2	1.176	9	1.180	16	1.182	2	0.178	9	0.178	16	0.180
3	1.128	10	1.182	17	1.180	3	0.180	10	0.177	17	0.176
4	1.180	11	1.176	18	1.182	4	0.181	11	0.180	18	0.180
5	1.182	12	1.128	19	1.178	5	0.182	12	0.181	19	0.185
6	1.181	13	1.181	20	1.176	6	0.180	13	0.180	20	0.180
7	1.182	14	1.185			7	0.181	14	0.185		
Min. weight: 1.176 g 99.48% Max. weight: 1.185 g 100.52% Average weight of 20 Tablets: 1.180 g					Min. weight: 0.175 g 97.76% Max. weight: 0.184 g 102.22% Average weight of 20 Tablets: 0.179 g						
Date: 10/06/20 Time: 06:45 WHITE PART [METFORMIN HCL] Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					Done by: S.P. (Production) COLOUR PART [GLICLAZIDE] Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.175	8	1.180	15	1.184	1	0.177	8	0.180	15	0.180
2	1.180	9	1.182	16	1.182	2	0.179	9	0.182	16	0.175
3	1.182	10	1.184	17	1.180	3	0.182	10	0.183	17	0.177
4	1.184	11	1.180	18	1.176	4	0.183	11	0.177	18	0.178
5	1.175	12	1.175	19	1.178	5	0.180	12	0.179	19	0.180
6	1.182	13	1.174	20	1.176	6	0.181	13	0.181	20	0.175
7	1.184	14	1.172			7	0.182	14	0.180		
Min. weight: 1.172 g 95.49% Max. weight: 1.184 g 100.52% Average weight of 20 Tablets: 1.178 g					Min. weight: 0.175 g 97.76% Max. weight: 0.183 g 102.22% Average weight of 20 Tablets: 0.179 g						
Date: 10/06/20 Time: 09:10 WHITE PART [METFORMIN HCL] 23.6078gm Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					Done by: (Production) COLOUR PART [GLICLAZIDE] 3.6078gm Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.186	8	1.183	15	1.178	1	0.177	8	0.181	15	0.179
2	1.182	9	1.180	16	1.192	2	0.179	9	0.177	16	0.182
3	1.180	10	1.178	17	1.174	3	0.181	10	0.180	17	0.180
4	1.178	11	1.186	18	1.175	4	0.180	11	0.176	18	0.177
5	1.174	12	1.170	19	1.178	5	0.178	12	0.178	19	0.181
6	1.177	13	1.177	20	1.176	6	0.184	13	0.177	20	0.184
7	1.181	14	1.181			7	0.182	14	0.183		
Min. weight: 1.170 g 99.06% Max. weight: 1.192 g 100.93% Average weight of 20 Tablets: 1.181 g					Min. weight: 0.176 g 97.77% Max. weight: 0.187 g 102.22% Average weight of 20 Tablets: 0.180 g						

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	
Signature with Date	G. 18/06/2020	Udaya 04/06/2020	M. 04/06/2020	

	Safetab Life Science					
	BATCH MANUFACTURING RECORD				Page No.:	62 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	4D200604	Mfg.Date:	06/2020	Exp.Date:	05/2023	

11.10-C IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY PRODUCTION:

Date: 10/06/20 Time: 11:20					Done by: <u>Pmp</u> (Production)						
WHITE PART [METFORMIN HCL] 23.6178m Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.6192m Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.182	8	1.177	15	1.182	1	0.181	8	0.178	15	0.183
2	1.177	9	1.176	16	1.187	2	0.177	9	0.181	16	0.185
3	1.175	10	1.178	17	1.180	3	0.179	10	0.183	17	0.181
4	1.180	11	1.174	18	1.182	4	0.182	11	0.180	18	0.180
5	1.182	12	1.175	19	1.176	5	0.179	12	0.176	19	0.177
6	1.180	13	1.176	20	1.178	6	0.181	13	0.178	20	0.179
7	1.183	14	1.180			7	0.180	14	0.180		
Min. weight: 1.174 g 98.43% Max. weight: 1.187 g 100.53% Average weight of 20 Tablets: 1.180 g					Min. weight: 0.176 g 97.77% Max. weight: 0.185 g 102.77% Average weight of 20 Tablets: 0.180 g						
Date: 10/06/20 Time: 13:25					Done by: <u>Pmp</u> (Production)						
WHITE PART [METFORMIN HCL] 23.6068m Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.6078m Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.180	8	1.182	15	1.181	1	0.180	8	0.180	15	0.181
2	1.174	9	1.185	16	1.180	2	0.181	9	0.177	16	0.180
3	1.176	10	1.180	17	1.188	3	0.177	10	0.179	17	0.183
4	1.179	11	1.176	18	1.185	4	0.179	11	0.177	18	0.180
5	1.181	12	1.172	19	1.180	5	0.178	12	0.181	19	0.177
6	1.180	13	1.178	20	1.183	6	0.183	13	0.180	20	0.181
7	1.181	14	1.176			7	0.182	14	0.181		
Min. weight: 1.172 g 99.32% Max. weight: 1.188 g 100.67% Average weight of 20 Tablets: 1.180 g					Min. weight: 0.177 g 98.33% Max. weight: 0.183 g 100.66% Average weight of 20 Tablets: 0.180 g						
Date: 10/06/20 Time: 15:35					Done by: <u>Pmp</u> (Production)						
WHITE PART [METFORMIN HCL] 23.6018m Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.6068m Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.181	8	1.177	15	1.183	1	0.183	8	0.184	15	0.179
2	1.180	9	1.179	16	1.181	2	0.180	9	0.180	16	0.185
3	1.176	10	1.182	17	1.185	3	0.177	10	0.176	17	0.181
4	1.178	11	1.180	18	1.180	4	0.179	11	0.178	18	0.183
5	1.181	12	1.175	19	1.177	5	0.182	12	0.175	19	0.180
6	1.183	13	1.183	20	1.179	6	0.180	13	0.182	20	0.182
7	1.180	14	1.180			7	0.181	14	0.180		
Min. weight: 1.175 g 99.57% Max. weight: 1.185 g 100.43% Average weight of 20 Tablets: 1.180 g					Min. weight: 0.175 g 97.22% Max. weight: 0.185 g 102.77% Average weight of 20 Tablets: 0.180 g						

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	<u>G. R. 04/06/2020</u>	<u>Wipraya 04/06/2020</u>	<u>04/06/2020</u>

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	Safetab Life Science			A	
	BATCH MANUFACTURING RECORD			Page No.:	62 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

11.10-C IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY PRODUCTION:

Date: 10/06/20 Time: 17:135					Done by: P. E. (Production)						
WHITE PART [METFORMIN HCL] 23.593 Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.605 Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.183	8	1.173	15	1.175	1	0.182	8	0.181	15	0.175
2	1.178	9	1.173	16	1.179	2	0.181	9	0.179	16	0.177
3	1.175	10	1.175	17	1.180	3	0.179	10	0.173	17	0.184
4	1.183	11	1.182	18	1.181	4	0.175	11	0.185	18	0.180
5	1.185	12	1.186	19	1.172	5	0.181	12	0.181	19	0.182
6	1.186	13	1.185	20	1.183	6	0.183	13	0.183	20	0.181
7	1.175	14	1.182			7	0.185	14	0.181		
Min. weight: 1.173 g 99.49 % Max. weight: 1.186 g 100.59 % Average weight of 20 Tablets: 1.179 g					Min. weight: 0.175 g 97.22 % Max. weight: 0.185 g 102.77 % Average weight of 20 Tablets: 0.180 g						
Date: 10/06/20 Time: 20:20					Done by: P. B. (Production)						
WHITE PART [METFORMIN HCL] 23.607 Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.607 Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.185	8	1.185	15	1.181	1	0.180	8	0.175	15	0.183
2	1.178	9	1.180	16	1.179	2	0.179	9	0.181	16	0.185
3	1.179	10	1.175	17	1.182	3	0.181	10	0.183	17	0.175
4	1.182	11	1.179	18	1.183	4	0.185	11	0.179	18	0.179
5	1.185	12	1.178	19	1.179	5	0.182	12	0.185	19	0.182
6	1.180	13	1.182	20	1.180	6	0.179	13	0.180	20	0.180
7	1.182	14	1.186			7	0.180	14	0.182		
Min. weight: 1.175 g 99.57 % Max. weight: 1.186 g 100.50 % Average weight of 20 Tablets: 1.180 g					Min. weight: 0.175 g 97.22 % Max. weight: 0.185 g 102.77 % Average weight of 20 Tablets: 0.180 g						
Date: 10/06/20 Time: 22:35					Done by: (Production)						
WHITE PART [METFORMIN HCL] 23.624 gm Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.607 gm Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.182	8	1.178	15	1.182	1	0.180	8	0.178	15	0.180
2	1.178	9	1.178	16	1.180	2	0.175	9	0.178	16	0.176
3	1.178	10	1.175	17	1.182	3	0.178	10	0.177	17	0.180
4	1.181	11	1.180	18	1.175	4	0.181	11	0.182	18	0.178
5	1.185	12	1.182	19	1.178	5	0.180	12	0.183	19	0.180
6	1.180	13	1.181	20	1.181	6	0.181	13	0.185	20	0.178
7	1.178	14	1.184			7	0.180	14	0.180		
Min. weight: 1.175 g 99.48 % Max. weight: 1.185 g 100.50 % Average weight of 20 Tablets: 1.181 g					Min. weight: 0.175 g 97.22 % Max. weight: 0.185 g 102.77 % Average weight of 20 Tablets: 0.180 g						

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G. P. 04/06/2020	W. P. 04/06/2020	04/06/2020

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	Safetab Life Science		B		
	BATCH MANUFACTURING RECORD		Page No.:	62 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	CED200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

11.10-C IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY PRODUCTION:

Date: 11/06/20 Time: 00:45					Done by:  (Production)						
WHITE PART [METFORMIN HCL] Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.181	8	1.180	15	1.181	1	0.182	8	0.182	15	0.181
2	1.176	9	1.182	16	1.182	2	0.176	9	0.185	16	0.180
3	1.175	10	1.180	17	1.184	3	0.180	10	0.180	17	0.178
4	1.178	11	1.182	18	1.180	4	0.178	11	0.178	18	0.176
5	1.175	12	1.181	19	1.176	5	0.178	12	0.181	19	0.180
6	1.181	13	1.184	20	1.185	6	0.184	13	0.178	20	0.181
7	1.182	14	1.178			7	0.180	14	0.181		
Min. weight: 1.175 g Max. weight: 1.185 g Average weight of 20 Tablets: 1.181 g					Min. weight: 0.176 g Max. weight: 0.185 g Average weight of 20 Tablets: 0.180 g						
Date: Time:					Done by: (Production)						
WHITE PART [METFORMIN HCL] Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1		8		15		1		8		15	
2		9		16		2		9		16	
3		10		17		3		10		17	
4		11		18		4		11		18	
5		12		19		5		12		19	
6		13		20		6		13		20	
7		14				7		14			
Min. weight: g Max. weight: g Average weight of 20 Tablets: g					Min. weight: g Max. weight: g Average weight of 20 Tablets: g						
Date: Time:					Done by: (Production)						
WHITE PART [METFORMIN HCL] Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1		8		15		1		8		15	
2		9		16		2		9		16	
3		10		17		3		10		17	
4		11		18		4		11		18	
5		12		19		5		12		19	
6		13		20		6		13		20	
7		14				7		14			
Min. weight: g Max. weight: g Average weight of 20 Tablets: g					Min. weight: g Max. weight: g Average weight of 20 Tablets: g						

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	9.8 04/06/2020	Wijaya 04/06/2020	11/06/2020

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	Safetab Life Science					
	BATCH MANUFACTURING RECORD				Page No.:	63 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	61D200604	Mfg. Date:	06/2020	Exp. Date:	08/2023	

11.11 IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY IPQA:

Date: 09/06/20 Time: 14:20						Done by: M.W. (IPQA)					
WHITE PART [METFORMIN HCL] 23.612g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] 2.582g Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.146	8	1.183	15	1.185	1	0.144	8	0.185	15	0.146
2	1.142	9	1.172	16	1.181	2	0.145	9	0.178	16	0.147
3	1.185	10	1.178	17	1.186	3	0.184	10	0.182	17	0.182
4	1.180	11	1.183	18	1.178	4	0.146	11	0.180	18	0.180
5	1.142	12	1.180	19	1.172	5	0.145	12	0.176	19	0.185
6	1.148	13	1.176	20	1.186	6	0.145	13	0.174	20	0.182
7	1.188	14	1.188			7	0.182	14	0.185		
Min. weight: 1.142 g 89.32% Max. weight: 1.188 g 100.67% Average weight of 20 Tablets: 1.180 g						Min. weight: 0.144 g 97.20% Max. weight: 0.185 g 102.22% Average weight of 20 Tablets: 0.179 g					
Date: 09/06/20 Time: 19:25						Done by: M.W. (IPQA)					
WHITE PART [METFORMIN HCL] 23.626g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] 3.628g Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.183	8	1.186	15	1.187	1	0.148	8	0.181	15	0.185
2	1.188	9	1.181	16	1.185	2	0.146	9	0.146	16	0.182
3	1.186	10	1.146	17	1.176	3	0.183	10	0.178	17	0.146
4	1.175	11	1.185	18	1.188	4	0.180	11	0.183	18	0.178
5	1.178	12	1.188	19	1.146	5	0.146	12	0.185	19	0.185
6	1.179	13	1.182	20	1.185	6	0.148	13	0.146	20	0.182
7	1.182	14	1.176			7	0.185	14	0.178		
Min. weight: 1.175 g 89.40% Max. weight: 1.188 g 100.50% Average weight of 20 Tablets: 1.183 g						Min. weight: 0.146 g 97.23% Max. weight: 0.185 g 102.22% Average weight of 20 Tablets: 0.179 g					
Date: 09/06/20 Time: 21:20						Done by: M.W. (IPQA)					
WHITE PART [METFORMIN HCL] 23.669g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] 3.612g Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.182	8	1.149	15	1.185	1	0.182	8	0.146	15	0.184
2	1.186	9	1.185	16	1.181	2	0.181	9	0.178	16	0.182
3	1.180	10	1.180	17	1.186	3	0.180	10	0.183	17	0.180
4	1.146	11	1.182	18	1.183	4	0.146	11	0.181	18	0.176
5	1.189	12	1.189	19	1.146	5	0.178	12	0.180	19	0.178
6	1.176	13	1.176	20	1.186	6	0.184	13	0.146	20	0.184
7	1.179	14	1.148			7	0.181	14	0.178		
Min. weight: 1.146 g 89.40% Max. weight: 1.189 g 100.50% Average weight of 20 Tablets: 1.183 g						Min. weight: 0.176 g 97.77% Max. weight: 0.184 g 102.22% Average weight of 20 Tablets: 0.180 g					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	
Signature with Date	G. 04/06/2020	Ujwal Bhatnagar 04/06/2020	M. W. 04/06/2020	

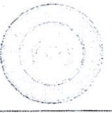
	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	64 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Glliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	67D200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

11.11-A IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY IPQA:

Date: 05/06/20 Time: 23:10					Done by: Chy (IPQA)						
WHITE PART [METFORMIN HCL] 23.609					COLOUR PART [GLICLAZIDE] 3.609						
Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.181	8	1.172	15	1.180	1	0.176	8	0.183	15	0.176
2	1.177	9	1.181	16	1.182	2	0.181	9	0.182	16	0.175
3	1.186	10	1.183	17	1.177	3	0.180	10	0.175	17	0.179
4	1.181	11	1.180	18	1.188	4	0.177	11	0.178	18	0.180
5	1.180	12	1.172	19	1.174	5	0.175	12	0.185	19	0.185
6	1.176	13	1.176	20	1.181	6	0.182	13	0.181	20	0.181
7	1.177	14	1.188			7	0.176	14	0.180		
Min. weight: 1.172 g 99.32%					Min. weight: 0.175 g 97.22%						
Max. weight: 1.188 g 100.68%					Max. weight: 0.185 g 102.78%						
Average weight of 20 Tablets: 1.180 g					Average weight of 20 Tablets: 0.180 g						
Date: 10/06/20 Time: 01:10					Done by: Chy (IPQA)						
WHITE PART [METFORMIN HCL] 23.626					COLOUR PART [GLICLAZIDE] 3.651						
Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.176	8	1.185	15	1.176	1	0.179	8	0.185	15	0.181
2	1.181	9	1.180	16	1.173	2	0.182	9	0.180	16	0.183
3	1.180	10	1.173	17	1.181	3	0.180	10	0.179	17	0.180
4	1.183	11	1.181	18	1.180	4	0.178	11	0.178	18	0.185
5	1.174	12	1.184	19	1.189	5	0.183	12	0.182	19	0.179
6	1.179	13	1.181	20	1.180	6	0.180	13	0.183	20	0.177
7	1.180	14	1.186			7	0.182	14	0.176		
Min. weight: 1.175 g 99.32%					Min. weight: 0.176 g 97.25%						
Max. weight: 1.189 g 100.68%					Max. weight: 0.185 g 102.77%						
Average weight of 20 Tablets: 1.181 g					Average weight of 20 Tablets: 0.181 g						
Date: 10/06/20 Time: 05:45					Done by: Chy (IPQA)						
WHITE PART [METFORMIN HCL] 23.617					COLOUR PART [GLICLAZIDE] 3.626						
Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.179	8	1.178	15	1.174	1	0.179	8	0.179	15	0.179
2	1.182	9	1.183	16	1.183	2	0.182	9	0.180	16	0.180
3	1.183	10	1.181	17	1.185	3	0.180	10	0.178	17	0.182
4	1.185	11	1.183	18	1.180	4	0.178	11	0.178	18	0.180
5	1.178	12	1.179	19	1.186	5	0.181	12	0.185	19	0.183
6	1.181	13	1.180	20	1.180	6	0.180	13	0.179	20	0.178
7	1.180	14	1.179			7	0.185	14	0.183		
Min. weight: 1.174 g 99.49%					Min. weight: 0.176 g 97.25%						
Max. weight: 1.186 g 100.51%					Max. weight: 0.185 g 102.77%						
Average weight of 20 Tablets: 1.180 g					Average weight of 20 Tablets: 0.181 g						

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G. V. 04/06/2020	Wijayabharathi 04/06/2020	M. S. 04/06/2020

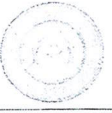
CONTROLLED COPY

	Safetab Life Science					
	BATCH MANUFACTURING RECORD				Page No.:	65 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	44200604	Mfg. Date:	06/2020	Exp. Date:	05/2023	

11.11-B IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY IPQA:

Date: 10/06/20 Time: 07:35						Done by: RA (IPQA)					
WHITE PART [METFORMIN HCL] 23.545mg Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] 3.584mg Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.174	8	1.178	15	1.179	1	0.178	8	0.176	15	0.176
2	1.173	9	1.179	16	1.181	2	0.177	9	0.175	16	0.177
3	1.171	10	1.175	17	1.183	3	0.176	10	0.181	17	0.176
4	1.182	11	1.176	18	1.182	4	0.175	11	0.182	18	0.179
5	1.180	12	1.174	19	1.181	5	0.178	12	0.178	19	0.177
6	1.181	13	1.171	20	1.180	6	0.182	13	0.179	20	0.183
7	1.183	14	1.172			7	0.177	14	0.177		
Min. weight: 1.171 g 99.49% Max. weight: 1.183 g 100.57% Average weight of 20 Tablets: 1.177 g						Min. weight: 0.175 g 97.76% Max. weight: 0.183 g 102.23% Average weight of 20 Tablets: 0.179 g					
Date: 10/06/20 Time: 09:45						Done by: RA (IPQA)					
WHITE PART [METFORMIN HCL] 23.616g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] 3.627g Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.183	8	1.178	15	1.180	1	0.180	8	0.181	15	0.177
2	1.181	9	1.177	16	1.178	2	0.182	9	0.180	16	0.182
3	1.182	10	1.180	17	1.174	3	0.177	10	0.178	17	0.185
4	1.187	11	1.181	18	1.178	4	0.179	11	0.181	18	0.180
5	1.180	12	1.187	19	1.182	5	0.180	12	0.180	19	0.179
6	1.179	13	1.174	20	1.185	6	0.177	13	0.180	20	0.180
7	1.181	14	1.181			7	0.180	14	0.180		
Min. weight: 1.174 g 99.49% Max. weight: 1.187 g 100.57% Average weight of 20 Tablets: 1.180 g						Min. weight: 0.177 g 97.79% Max. weight: 0.185 g 102.20% Average weight of 20 Tablets: 0.181 g					
Date: 10/06/20 Time: 11:40						Done by: RA (IPQA)					
WHITE PART [METFORMIN HCL] 23.648g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] 3.617g Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.183	8	1.179	15	1.182	1	0.181	8	0.184	15	0.180
2	1.180	9	1.183	16	1.178	2	0.178	9	0.180	16	0.176
3	1.179	10	1.190	17	1.190	3	0.176	10	0.179	17	0.180
4	1.175	11	1.175	18	1.178	4	0.184	11	0.180	18	0.181
5	1.178	12	1.178	19	1.184	5	0.180	12	0.181	19	0.176
6	1.182	13	1.187	20	1.180	6	0.181	13	0.179	20	0.180
7	1.180	14	1.190			7	0.180	14	0.181		
Min. weight: 1.175 g 99.40% Max. weight: 1.190 g 100.67% Average weight of 20 Tablets: 1.182 g						Min. weight: 0.176 g 97.77% Max. weight: 0.184 g 102.22% Average weight of 20 Tablets: 0.180 g					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	
Signature with Date	S. R. 04/06/2020	U. S. 04/06/2020	M. S. 04/06/2020	

	Safetab Life Science		A		
	BATCH MANUFACTURING RECORD		Page No.:	65 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	CTD200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

11.11-B IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY IPQA:

Date: 10/06/2020 Time: 13:40						Done by: Pd (IPQA)					
WHITE PART [METFORMIN HCL] 23.614 gm Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] 3.563 gm Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.176	8	1.187	15	1.179	1	0.179	8	0.177	15	0.182
2	1.177	9	1.180	16	1.178	2	0.178	9	0.175	16	0.181
3	1.178	10	1.183	17	1.177	3	0.180	10	0.179	17	0.180
4	1.180	11	1.185	18	1.174	4	0.181	11	0.174	18	0.177
5	1.181	12	1.184	19	1.175	5	0.181	12	0.177	19	0.178
6	1.183	13	1.183	20	1.180	6	0.175	13	0.176	20	0.180
7	1.184	14	1.180			7	0.176	14	0.180		
Min. weight: 1.174 g 99.49% Max. weight: 1.185 g 100.60% Average weight of 20 Tablets: 1.180 g						Min. weight: 0.174 g 97.75% Max. weight: 0.182 g 102.24% Average weight of 20 Tablets: 0.178 g					
Date: 10/06/20 Time: 15:45						Done by: M.W (IPQA)					
WHITE PART [METFORMIN HCL] 23.567 gm Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] 3.627 gm Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.179	8	1.185	15	1.180	1	0.179	8	0.179	15	0.178
2	1.182	9	1.178	16	1.176	2	0.181	9	0.180	16	0.176
3	1.185	10	1.173	17	1.175	3	0.184	10	0.179	17	0.180
4	1.180	11	1.180	18	1.185	4	0.185	11	0.175	18	0.179
5	1.178	12	1.175	19	1.180	5	0.180	12	0.180	19	0.180
6	1.180	13	1.178	20	1.178	6	0.178	13	0.182	20	0.182
7	1.182	14	1.180			7	0.181	14	0.185		
Min. weight: 1.173 g 99.57% Max. weight: 1.185 g 100.57% Average weight of 20 Tablets: 1.178 g						Min. weight: 0.175 g 96.68% Max. weight: 0.186 g 102.26% Average weight of 20 Tablets: 0.181 g					
Date: 12/06/20 Time: 19:15						Done by: M.W (IPQA)					
WHITE PART [METFORMIN HCL] 23.609 gm Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]						COLOUR PART [GLICLAZIDE] 3.612 gm Limit: 180.000 ± 3% [174.600mg - 185.400mg]					
1	1.182	8	1.185	15	1.182	1	0.181	8	0.185	15	0.176
2	1.176	9	1.181	16	1.188	2	0.182	9	0.181	16	0.178
3	1.172	10	1.176	17	1.182	3	0.180	10	0.176	17	0.185
4	1.179	11	1.182	18	1.176	4	0.176	11	0.178	18	0.182
5	1.183	12	1.180	19	1.185	5	0.177	12	0.182	19	0.180
6	1.180	13	1.176	20	1.181	6	0.181	13	0.185	20	0.185
7	1.188	14	1.179			7	0.180	14	0.181		
Min. weight: 1.172 g 98.49% Max. weight: 1.188 g 101.47% Average weight of 20 Tablets: 1.180 g						Min. weight: 0.176 g 98.61% Max. weight: 0.185 g 100.49% Average weight of 20 Tablets: 0.180 g					

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	S. R. 04/06/2020	U. S. 04/06/2020	M. W. 04/06/2020	

	Safetab Life Science		B		
	BATCH MANUFACTURING RECORD		Page No.:	65 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GPD200604	Mfg.Date:	06/02/20	Exp.Date:	05/2023

11.11-B IN PROCESS CHECK FREQUENCY FOR INDIVIDUAL LAYER: EVERY 2 HOUR BY IPQA:

Date: 10/06/20 Time: 21:20					Done by: M.W. (IPQA)						
WHITE PART [METFORMIN HCL] 23.605g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.591g Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.177	8	1.183	15	1.176	1	0.179	8	0.184	15	0.184
2	1.180	9	1.182	16	1.179	2	0.181	9	0.182	16	0.180
3	1.183	10	1.180	17	1.181	3	0.180	10	0.180	17	0.183
4	1.185	11	1.176	18	1.183	4	0.182	11	0.176	18	0.180
5	1.180	12	1.182	19	1.188	5	0.181	12	0.179	19	0.176
6	1.179	13	1.185	20	1.172	6	0.176	13	0.175	20	0.179
7	1.175	14	1.180			7	0.179	14	0.181		
Min. weight: 1.172 g 99.29 % Max. weight: 1.188 g 101.21 % Average weight of 20 Tablets: 1.180 g					Min. weight: 0.175 g 98.47 % Max. weight: 0.184 g 100.67 % Average weight of 20 Tablets: 0.179 g						
Date: 10/06/20 Time: 23:35					Done by: Ch. (IPQA)						
WHITE PART [METFORMIN HCL] 23.629g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.629g Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.176	8	1.186	15	1.178	1	0.181	8	0.176	15	0.185
2	1.181	9	1.179	16	1.173	2	0.179	9	0.181	16	0.182
3	1.180	10	1.179	17	1.180	3	0.183	10	0.179	17	0.179
4	1.184	11	1.180	18	1.189	4	0.180	11	0.185	18	0.180
5	1.181	12	1.189	19	1.181	5	0.178	12	0.179	19	0.185
6	1.186	13	1.180	20	1.182	6	0.181	13	0.176	20	0.183
7	1.180	14	1.174			7	0.176	14	0.182		
Min. weight: 1.173 g 97.32 % Max. weight: 1.189 g 100.68 % Average weight of 20 Tablets: 1.181 g					Min. weight: 0.176 g 97.23 % Max. weight: 0.185 g 102.77 % Average weight of 20 Tablets: 0.181 g						
Date: 11/06/20 Time: 01:40					Done by: Ch. (IPQA)						
WHITE PART [METFORMIN HCL] 23.608g Limit: 1180.000 ± 3% [1144.600mg - 1215.400mg]					COLOUR PART [GLICLAZIDE] 3.619g Limit: 180.000 ± 3% [174.600mg - 185.400mg]						
1	1.181	8	1.186	15	1.176	1	0.179	8	0.185	15	0.185
2	1.179	9	1.180	16	1.188	2	0.181	9	0.180	16	0.181
3	1.181	10	1.172	17	1.182	3	0.180	10	0.178	17	0.179
4	1.183	11	1.173	18	1.180	4	0.176	11	0.180	18	0.181
5	1.180	12	1.183	19	1.179	5	0.182	12	0.175	19	0.184
6	1.179	13	1.186	20	1.180	6	0.178	13	0.180	20	0.179
7	1.178	14	1.184			7	0.183	14	0.182		
Min. weight: 1.172 g 99.52 % Max. weight: 1.188 g 100.68 % Average weight of 20 Tablets: 1.180 g					Min. weight: 0.175 g 97.22 % Max. weight: 0.185 g 102.78 % Average weight of 20 Tablets: 0.180 g						

Prepared by:	Checked by:	Approved By:	
QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date: 9.804/06/2020	Signature with Date: 04/06/2020	Signature with Date: 04/06/2020	

	Safetab Life Science				
	BATCH MANUFACTURING RECORD		Page No.:	66 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	C7D200604	Mfg. Date:	06/2020	Exp. Date:	05/2023

11.12 WEIGHING RECORD OF COMPRESSED TABLETS:-

Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date	Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date
1	18.62	1.80	16.82	Suyana	R. B. 10/06/20	31	17.84	1.80	16.04	Suyana	R. B. 10/06/20
2	18.31	1.80	16.51	Suyana	R. B. 10/06/20	32	17.41	1.80	15.61	Suyana	R. B. 10/06/20
3	17.00	1.80	15.20	Suyana	R. B. 10/06/20	33	18.15	1.80	16.35	Suyana	R. B. 10/06/20
4	18.06	1.80	16.26	Suyana	R. B. 10/06/20	34	18.90	2.60	16.30	Suyana	R. B. 10/06/20
5	17.80	1.80	16.00	Suyana	R. B. 10/06/20	35	25.36	2.60	22.76	Suyana	R. B. 10/06/20
6	18.10	1.80	16.30	Suyana	R. B. 10/06/20	36	24.48	2.60	21.88	Suyana	R. B. 10/06/20
7	17.80	1.80	16.00	Suyana	R. B. 10/06/20	37	26.00	2.60	23.40	Suyana	R. B. 10/06/20
8	18.13	1.80	16.33	Suyana	R. B. 10/06/20	38	23.96	2.60	21.36	Suyana	R. B. 10/06/20
9	17.80	1.80	16.00	Suyana	R. B. 10/06/20	39	23.70	2.60	21.10	Suyana	R. B. 10/06/20
10	16.67	1.80	14.87	Suyana	R. B. 10/06/20	40					
11	17.80	1.80	16.00	Suyana	R. B. 10/06/20	41					
12	17.80	1.80	16.00	Suyana	R. B. 10/06/20	42					
13	16.80	1.80	15.00	Suyana	R. B. 10/06/20	43					
14	16.80	1.80	15.00	Suyana	R. B. 10/06/20	44					
15	17.30	1.80	15.50	Suyana	R. B. 10/06/20	45					
16	16.65	1.80	14.85	Suyana	R. B. 10/06/20	46					
17	17.80	1.80	16.00	Suyana	R. B. 10/06/20	47					
18	17.46	1.80	15.66	Baker	R. B. 10/06/20	48					
19	18.11	1.80	16.31	Vijayan	R. B. 10/06/20	49					
20	18.12	1.80	16.32	Vijayan	R. B. 10/06/20	50					
21	16.49	1.80	14.69	Vijayan	R. B. 10/06/20	51					
22	16.29	1.80	14.49	Vijayan	R. B. 10/06/20	52					
23	16.16	1.80	14.36	Vijayan	R. B. 10/06/20	53					
24	16.76	1.80	14.96	Vijayan	R. B. 10/06/20	54					
25	16.61	1.80	14.81	Vijayan	R. B. 10/06/20	55					
26	17.64	1.80	15.84	Vijayan	R. B. 10/06/20	56					
27	18.36	1.80	16.56	Suyana	R. B. 10/06/20	57					
28	16.90	1.80	15.10	Suyana	R. B. 10/06/20	58					
29	18.70	1.80	16.90	Suyana	R. B. 10/06/20	59					
30	17.10	1.80	15.30	Suyana	R. B. 10/06/20	60					
Total weight of compressed tablets:							645.03		kg		

Intimate IPQA to draw the sample.	Sample withdrawn by IPQA.
Production Sign:  Date: 11/06/20	IPQA Sign:  Date: 11/06/20
Send Test Request Form for analysis of compressed tablets to QC department.	

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G. R. 04/06/2020	Vijayan 04/06/2020	 04/06/2020

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	Safetab Life Science					
	BATCH MANUFACTURING RECORD				Page No.:	67 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	CIDR006021	Mfg. Date:	06/2020	Exp. Date:	05/2023	

12.0 RECONCILIATION:

1.0	Theoretical weight of Compressed tablets	:	680.00 Kg	500000 No's
2.0	Actual weight of Compressed tablets	:	645.03 Kg	4174286
3.0	Manufacturing Loss (1.0 - 6.0)	:	31.544 Kg	23194
4.0	In-process samples			
	A IPQA Samples	:	1.800. Kg	1300
	B QC Samples	:	0.130 Kg	100
	C Validation Samples	:	1.496 Kg	1100
5.0	Total samples: (A + B + C)	:	3.426 Kg	2500
6.0	Total: (5.0 + 2.0)	:	648.456 Kg	4176808
7.0	% Yield = $\frac{6.0}{1.0} \times 100$ Limit: NLT 95.00%*	:	95.36	%
If yield is out of limit raise deviation and inform to QA. After QA investigation and approval proceed to the next stage.				

*Tentative limit

Total rejects destroyed: 31.544 Kg. by Production sign/Date: 04/06/2020 Checked By IPQA sign/Date: 04/11/2020

(Rejected materials should be destroyed in the presence of IPQA.)

Yield reconciliation done by Production sign/Date: 04/06/2020 Checked By IPQA sign/Date: 04/11/2020

12.1 COMPRESSED TABLETS RELEASED FOR INSPECTION:

Checked by Production Sign/Date: 04/06/2020

IPQA sign/Date: 04/06/2020

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	S. R. 04/06/2020	Ujaya B. 04/06/2020	R. R. 04/06/2020	

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	Safetab Life Science					
	BATCH MANUFACTURING RECORD				Page No.:	68 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	67D 200604	Mfg. Date:	06/2020	Exp. Date:	05/2023	

13.0 TABLET INSPECTION:

13.1 LINE CLEARANCE CHECKS:

S.No	Checks	Observation	
		Production	IPQA
1	Check whether empty containers, polythene bags and documents of previous batch/product are removed from the area.	✓	✓
2	Check whether the scrap from waste bin is removed and new polythene bag is put into it.	✓	✓
3	Check the absence of tablets of previous batch/product in the container and surrounding area.	✓	✓
4	Check whether the area (floor, wall, ceiling, door, windows) are clean.	✓	✓
5	Check whether the tubelight fixture, supply grills, riser grills, filters and electrical fixtures are clean.	✓	✓
6	Check whether the daily records are updated and signed.	✓	✓
7	Check the environmental condition and record in BMR	✓	✓
8	Check whether area and equipment status board is updated.	✓	✓

Note: Tick mark (✓) if Complies and (X) if Does not comply

Checked by (Production) sign/date: *[Signature]* 09/06/2020

Verified by (IPQA) sign/date: *[Signature]* 09/06/2020

13.2 ENVIRONMENTAL CONDITIONS		Date: 09/06/2020		Date: 10/06/2020	
		Observation	Production Sign	Observation	Production Sign
Refer Current version of SOP	Temperature: 23°C to 27°C	24.2	✓	24.2	✓
	Relative Humidity: 45% to 55 %	53%	✓	53%	✓

13.3 APPROVAL FOR INSPECTION:

Production Sign/Date: *[Signature]* 09/06/2020

Line clearance IPQA Sign./Date.: *[Signature]* 09/06/2020

S. No	Process Instructions
1	Carry out visual inspection of tablets on tablet manual inspection area.
2	Collect inspected tablets in containers lined with polythene bags. Weigh the containers and record the weight.
3	Intimate In-process Quality Assurance.

13.4 TABLETS VISUAL INSPECTION RECORD:

Types of rejection: broken tablets, damage edges, capping, sticking, foreign particle and for other rejections.							
Date	Container No		Time		Total Quantity Rejected	Tablets Inspection Done by/Date	Checked by/Date
	From	To	Started	Completed			
09/06/2020	01	04	20:45	21:55	0.09 kg	Kannigamall	✓
						Mayavathi	09/06/2020
10/06/2020	05	25	06:30	21:50	0.15 kg	manjula, male kg	✓ 10/06/2020
11/06/2020	26	39	06:30	12:00	0.15 kg	manjula, male kg	✓ 11/06/2020

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020

CONTROLLED COPY

	Safetab Life Science				
	BATCH MANUFACTURING RECORD		Page No.:	69 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	C10200604	Mfg. Date:	06/2020	Exp. Date:	05/2023

13.5 WEIGHING RECORD OF INSPECTED TABLETS:

Date: 09/06/2020

Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date	Container No	Gross weight in Kg	Tare weight in Kg	Net weight in Kg	Weighed by	Checked by/date
1	18.60	1.80	16.80	Gopi	06/06/2020	31	17.83	1.80	16.03	Gopi	06/06/2020
2	18.30	1.80	16.50	Gopi	06/06/2020	32	17.40	1.80	15.60	Gopi	06/06/2020
3	17.00	1.80	15.20	Gopi	06/06/2020	33	18.15	1.80	16.35	Gopi	06/06/2020
4	18.05	1.80	16.25	Gopi	06/06/2020	34	18.90	2.60	16.30	Gopi	06/06/2020
5	17.80	1.80	16.00	Gopi	06/06/2020	35	25.35	2.60	22.75	Gopi	06/06/2020
6	18.10	1.80	16.30	Gopi	06/06/2020	36	24.45	2.60	21.85	Gopi	06/06/2020
7	17.80	1.80	16.00	Gopi	06/06/2020	37	26.00	2.60	23.40	Gopi	06/06/2020
8	18.10	1.80	16.30	Gopi	06/06/2020	38	23.95	2.60	21.35	Gopi	06/06/2020
9	17.80	1.80	16.00	Gopi	06/06/2020	39	23.60	2.60	21.00	Gopi	06/06/2020
10	16.65	1.80	14.85	Gopi	06/06/2020	40					
11	17.90	1.80	16.10	Gopi	06/06/2020	41					
12	17.80	1.80	16.00	Gopi	06/06/2020	42					
13	16.90	1.80	15.10	Gopi	06/06/2020	43					
14	16.80	1.80	15.00	Gopi	06/06/2020	44					
15	17.30	1.80	15.50	Gopi	06/06/2020	45					
16	16.65	1.80	14.85	Gopi	06/06/2020	46					
17	17.90	1.80	16.10	Gopi	06/06/2020	47					
18	17.45	1.80	15.65	Gopi	06/06/2020	48					
19	18.10	1.80	16.30	Gopi	06/06/2020	49					
20	16.45	1.80	14.65	Gopi	06/06/2020	50					
21	16.28	1.80	14.48	Gopi	06/06/2020	51					
22	18.10	1.80	16.30	Gopi	06/06/2020	52					
23	16.15	1.80	14.35	Gopi	06/06/2020	53					
24	16.75	1.80	14.95	Gopi	06/06/2020	54					
25	16.60	1.80	14.80	Gopi	06/06/2020	55					
26	17.63	1.80	15.83	Gopi	06/06/2020	56					
27	18.35	1.80	16.55	Gopi	06/06/2020	57					
28	16.90	1.80	15.10	Gopi	06/06/2020	58					
29	18.70	1.80	16.90	Gopi	06/06/2020	59					
30	17.10	1.80	15.30	Gopi	06/06/2020	60					
Total weight of inspected tablets:							644.64		kg		

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	G. V. 04/06/2020	04/06/2020	04/06/2020	CONTROLLED COPY

	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	70 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	UD200604	Mfg. Date:	06/2020	Exp. Date:	05/2023

14.0 RECONCILIATION: (INSPECTION OF TABLETS)

1.0	Theoretical weight of tablets	:	680.00 kg	500000 No's
2.0	Tablets transferred for Inspection	:	645.03 kg	474286 No's
3.0	Rejected tablets	:	0.39 kg	287 No's
4.0	Total weight of good tablets	:	644.64 kg	474000 No's
5.0	% Yield = $\frac{4.0}{1.0} \times 100$ (Limit- NLT 94.0%)*	:	94.80	%

If yield is out of limit, raise deviation and inform to QA. After QA, investigation and approval proceed to the next stage.

*Tentative limit

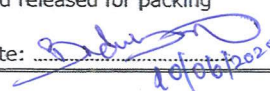
Total rejects destroyed: 0.39 Kg by Production/Date: 11/06/2020 Checked by IPQA/Date: 11/06/2020

(Rejected materials should be destroyed in the presence of QA)

Yield reconciliation done by Production/Date: 11/06/2020 Checked by IPQA/Date: 11/06/2020

14.1 RELEASE FOR PACKING

Compressed tablet report checked and released for packing

Checked by Competent Staff Sign/Date:  10/06/2020 IPQA Sign/Date: JKR 10/06/2020

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	S. L. 04/06/2020	Ujaya 04/06/2020	10/06/2020	CONTROLLED COPY

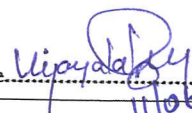
	Safetab Life Science				
	BATCH MANUFACTURING RECORD		Page No.:	71 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	U1D200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

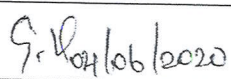
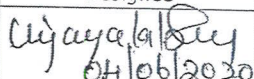
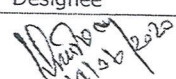
15.0 PROCESS HISTORY

Refer deviation no:- ST/DR/20/070

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	G. D. 04/06/2020	Ujaya Lal 04/06/2020	04/06/2020	

	Safetab Life Science					
	BATCH MANUFACTURING RECORD				Page No.:	72 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	MD200604	Mfg.Date:	06/2020	Exp.Date:	05/2023	

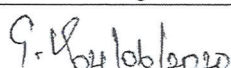
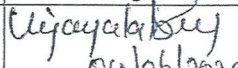
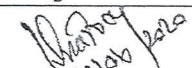
16.0 Following the BMR records in additional attached.		Checked by Production Head	Reviewed by QA Head
1	Raw Materials dispensed labels	✓	✓
2	Granulation stage analytical report	✓	✓
3	Compression stage analytical report	✓	✓
Note: Tick mark (✓) if Complies and (X) if Does not comply. This Batch Manufacturing reviewed on date.....11/06/2020 Production Head sign/date..... 11/06/2020 This Batch Manufacturing Record received, reviewed and batch is released for packing on date.....11/06/20 Reviewed by QA Head..... 11/06/20			

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 04/06/2020	 04/06/2020	 04/06/2020	

	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	73 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	WID200604	Mfg.Date:	06/02/2020	Exp.Date:	05/02/2023

17.0 ABBREVIATIONS

S.No.	Short Form	Abbreviation	S.No.	Short Form	Abbreviation
1	BP	British Pharmacopeia	19	A.R.No.	Analytical Report Number
2	API	Active Pharmaceutical Ingredients	20	IPQA	In Process Quality Assurance
3	BMR	Batch Manufacturing Record	21	L	Lakhs
4	MFG	Manufacturing	22	TRF	Test Request Form
5	EXP	Expiry	23	RMG	Rapid Mixer Granulator
6	QA	Quality Assurance	24	FBD	Fluid Bed Drier
7	Kg	Kilogram	25	SOP	Standard Operating Procedure
8	g	Gram	26	mm	Millimeter
9	lts	Liters	27	NLT	Not Less Than
10	Min	Minutes	28	NMT	Not More Than
11	Hrs	Hours	29	Tab	Tablet
12	M/C	Machine	30	RHS	Right Hand Side
13	Prod	Production	31	LHS	Left Hand Side
14	B.No	Batch number	32	Std	Standard
15	mg	Milligram	33	Avg	Average
16	Qty	Quantity	34	rpm	Rotation Per Minute
17	QC	Quality Control	35	No's	Numbers
18	LOD	Loss On Drying	36	Sign	Signature

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	 04/06/2020	 04/06/2020	 04/06/2020	

	Safetab Life Science					
	BATCH MANUFACTURING RECORD				Page No.:	74 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets	
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL	
Batch No.:	27D200604	Mfg.Date:	06/2020	Exp.Date:	05/2023	

BMR COPY/QUALITY CONTROL COPY

18.0 TEST REQUEST FORM FOR LUBRICATED GRANULES [METFORMIN HYDROCHLORIDE.PART]

From: Manufacturing Department	To: Q.A. Department
To be filled by production	To be filled by IPQA
Date of Mfg.: 06/2020 Date of exp.: 05/2023	Quantity Sampled : 50gm
Test Request for : Content	Sampled by : RSH on date: 06/06/20
TRF raised by : [Signature] on date: 06/06/20	No. of containers : 5
To be filled by QC	Sample received by : [Signature] on date: 06/06/20
TRF received on : 06/06/2020	
Sample tested on : 06/06/2020	
Test Results	Limits
Each 1180mg lubricated granule contains Assay:- Metformin Hydrochloride 821.29mg (96.6%)	(95.0% to 110.0%)
Analytical Reference no.: CF/00349/2020	Space for QC Approval (Stamping and Signing)
Analysed By : [Signature] on : 06/06/2020	APPROVED [Signature] Date: 08/06/20

	Prepared by:	Checked by:	Approved By:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	[Signature] 04/06/2020	[Signature] 04/06/2020	[Signature] 04/06/2020

CONTROLLED COPY

	Safetab Life Science				
	BATCH MANUFACTURING RECORD		Page No.:	75 of 78	
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO.:	ST/MFC/130/R0	Supersedes MFC No.:	NIL
Batch No.:	L2200604	Mfg.Date:	06/06/20	Exp.Date:	05/06/23

BMR COPY/QUALITY CONTROL COPY

19.0 TEST REQUEST FORM FOR LUBRICATED GRANULES [GLICLAZIDE PART]

From: Manufacturing Department	To: Q.A. Department
To be filled by production	To be filled by IPQA
Date of Mfg. : 06/2020 Date of exp : 05/2023	Quantity Sampled : 50gm
Test Request for : Content	Sampled by : Rky on date: 05/06/20
TRF raised by : [Signature] on date: 05/06/2020	No. of containers : 3
	Sample received by : [Signature] on date: 05/06/20
To be filled by QC	
TRF received on : 05/06/2020	
Sample tested on : 06/06/2020	
Test Results	Limits
Each 180mg lubricated granule containing Assay: Gliclazide 58.21mg (97.0%)	(95.0% to 110.0%)
Analytical Reference no.: GF/00344/2020	Space for QC Approval (Stamping and Signing)
Analysed By : [Signature] on : 08/06/2020	[Signature] Date: 08/06/20

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	S.V. 04/06/2020	Vijayalakshmi 04/06/2020	[Signature] 04/06/2020	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	76 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	<u>6200604</u>	Mfg.Date:	<u>06/2020</u>	Exp.Date:	<u>05/2023</u>

BMR COPY/QUALITY CONTROL COPY

20.0 TEST REQUEST FORM FOR COMPRESSED TABLETS

From: Manufacturing Department		To: Q.A. Department																																					
To be filled by production		To be filled by IPQA																																					
Date of Mfg.: <u>06/2020</u> Date of exp: <u>05/2023</u>		Quantity Sampled: <u>100 tab/lot</u>																																					
Test Request for: <u>Content</u>		Sampled by: <u>M.H</u> on date: <u>09/06/20</u>																																					
TRF raised by: <u>R. Ray</u> on date: <u>09/06/20</u>		No. of containers: <u>45</u>																																					
To be filled by QC		Sample received by: <u>[Signature]</u> on date: <u>09/06/20</u>																																					
TRF received on: <u>09/06/2020</u>																																							
Sample tested on: <u>10/06/2020</u>																																							
Test Results		Limits																																					
Each uncoated bilayered sustained release tablet contains Assay: metformin HCl 836.84mg (98.5%) gliclazide 58.02mg (96.7%) Dissolution:- <table border="1"> <thead> <tr> <th></th> <th>Min</th> <th>Max</th> <th>Av</th> </tr> </thead> <tbody> <tr> <td>Gliclazide</td> <td></td> <td></td> <td></td> </tr> <tr> <td> 1st hr</td> <td>18.1%</td> <td>23.3%</td> <td>20.7%</td> </tr> <tr> <td> 5th hr</td> <td>43.6%</td> <td>51.8%</td> <td>48.1%</td> </tr> <tr> <td> 12th hr</td> <td>80.4%</td> <td>89.2%</td> <td>86.3%</td> </tr> <tr> <td>Metformin HCl</td> <td></td> <td></td> <td></td> </tr> <tr> <td> 1st hr</td> <td>25.1%</td> <td>26.1%</td> <td>25.7%</td> </tr> <tr> <td> 3rd hr</td> <td>48.7%</td> <td>49.9%</td> <td>49.6%</td> </tr> <tr> <td> 10th hr</td> <td>98.4%</td> <td>100.1%</td> <td>100.1%</td> </tr> </tbody> </table>					Min	Max	Av	Gliclazide				1st hr	18.1%	23.3%	20.7%	5th hr	43.6%	51.8%	48.1%	12th hr	80.4%	89.2%	86.3%	Metformin HCl				1st hr	25.1%	26.1%	25.7%	3rd hr	48.7%	49.9%	49.6%	10th hr	98.4%	100.1%	100.1%
	Min	Max	Av																																				
Gliclazide																																							
1st hr	18.1%	23.3%	20.7%																																				
5th hr	43.6%	51.8%	48.1%																																				
12th hr	80.4%	89.2%	86.3%																																				
Metformin HCl																																							
1st hr	25.1%	26.1%	25.7%																																				
3rd hr	48.7%	49.9%	49.6%																																				
10th hr	98.4%	100.1%	100.1%																																				
Analytical Reference no.: <u>SER/F100518/2020</u>		Space for QC Approval (Stamping and Signing)																																					
Reprinted by: <u>[Signature]</u> on: <u>10/06/2020</u>		<u>[Signature]</u> PROVED <u>10/06/20</u>																																					

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<u>[Signature]</u> <u>10/06/2020</u>	<u>[Signature]</u> <u>04/06/2020</u>	<u>[Signature]</u> <u>09/06/2020</u>	

	Safetab Life Science				
	BATCH MANUFACTURING RECORD			Page No.:	77 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	CD200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

21.0 BATCH MANUFACTURING RECORD REVIEW CHECK LIST		
S.No. No.	CHECK POINTS	Status
1	The entire Page no: <u>01</u> to <u>78</u> are available, verified and found correct.	Yes / No
2	Batch numbers available in all pages verified and are correct.	Yes / No
3	Manufacturing and expiry is correctly allotted verified.	Yes / No
4	Dispensing carried out on calibrated balance verified.	Yes / No
5	Dispensing Cards attached.	Yes / No
6	Line clearance is taken prior to all dispensing and manufacturing activities.	Yes / No
7	Dispensing is carried out as per indent of raw materials are correct.	Yes / No
8	Environmental conditions comply during all the manufacturing steps.	Yes / No
9	All wrong entries if any have been strike out and signed and verified.	Yes / No
10	Actual equipment used is as specified and verified.	Yes / No
11	Dry mixing, compression and coating reconciliation is filled and variance is within acceptance limit.	Yes / No
12	If any deviation and change control raised related to this batch attached with Batch record.	Yes / No / NA
Note:	If any abnormalities noticed during batch manufacturing record review it should be brought to the notice of QA Head.	

Batch Manufacturing Record reviewed by IPQA Sign/Date:

G. R.
11/06/2020

QA Head Sign/Date:

R.
11/06/20

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	<i>G. R.</i> 04/06/2020	<i>W. Jayalaxmi</i> 04/06/2020	<i>R. Ravi</i> 04/06/2020	

	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page No.:	78 of 78
Brand Name	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic Name:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	GD 200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

22.0 REVISION HISTORY:

Revision No.	Date of Revision	Changes Made	Effective Date
00	--	1.0 New product introduced, refer, change control no. ST/CC/20/21.	04/06/20

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	S. R. 04/06/2020	Ujjayalaxmi 04/06/2020	M. Ravi 04/06/2020	