

	Safetab Life Science				Page 1 of 41	
	BATCH PACKING 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.:	GD200604	Mfg.Date:	06/2020	Exp.Date:	05/2023	

BATCH PACKING RECORD COVER SHEET:

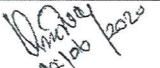
PRODUCT NAME	:	GLIDE M 60/850 TABLETS		
LABEL CLAIM	:	Each uncoated bilayered sustained release tablet contains:		
		Gliclazide	BP	60 mg
	-	Metformin Hydrochloride (in sustained release form)	BP	850 mg
	:	Colour: Approved colours are used.		
Pack Size	:	TP: 3x10's blister pack		
Storage Condition	:	Store in a cool and dry place at a temperature not exceeding 30°C. Protect from light and moisture.		
SHELF LIFE	:	36 MONTHS		
CUSTOMER NAME	:	GENERIC HEALTHCARE PVT LTD		
EFFECTIVE BATCH NUMBER	:	GD200604	DATE:	04/06/2020
MANUFACTURING LICENCE No.	:	PON/DRUGS/07 13 1906		
MFG. DATE:	:	06/2020	BPR. No	STBPR: 123/00
EXP. DATE:	:	05/2023	Supersedes BPR. No	Nil
BMR ISSUED BY/DATE (QA)	:	G-11 04/06/2020		
BPR CHECKED & RECEIVED BY/DATE (PRODUCTION)	:	16/06/2020		
Allotted By: QA Executive Sign/Date: G-11 04/06/2020				
DATE OF COMMENCEMENT:		04/06/2020	DATE OF COMPLETION: 16/06/2020	
This BPR contains 41 Pages + Additional Pages				
Checked by Competent Staff Sign/Date: 16/06/2020				

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	G-11 04/06/2020	16/06/2020	04/06/2020	

	Safetab Life Science				
	BATCH PACKING RECORD			Page 2 of 41	
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:	05/2023

1.0 LIST OF EQUIPMENTS:

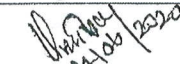
S.No.	Name of Equipments	Equipment ID No. to be used
1	Balance – 600 g Capacity	ST/WB/192
2	Balance – 300 g Capacity	ST/WB/191
3	Balance – 31 kg Capacity	ST/WB/196
4	Leak test apparatus	ST/IPL/003-02
5	Blister packing machine	ST/PPB/001 or ST/PPB2/001

	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			MASTER COPY	
	BATCH PACKING RECORD			Page No.:	3 of 41
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.:	C.D200604	Mfg.Date:	06/02/2020	Exp.Date:	05/2022

2.0 RECORD FOR PACKING MATERIALS: SALES										
S.No	Material Name	Standard Qty.	Unit	Material code	Excess material issued qty	A.R No:	Issued qty	Checked by stores	Checked by production	verified by IPQA
1	Printed Aluminium foil:186mm	30.000	Kg	PMG00077		MSP/2021/04/04/00365	37.460	OK	✓	Ⓟ
2	PVC clear back foil: 190mm	132.000	Kg	PVPV0021		MSP/2021/04/04/00363	129.300	OK	✓	Ⓟ
3	Printed cartons 3 X 10's	16667	No's	PMG00075		MSP/2021/04/04/00370	16665	OK	✓	Ⓟ

11/06/2020
11/06/2020
11/06/2020

	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	 04/06/2020	 04/06/2020	

	Safetab Life Science			DUPLICATE COPY	
	BATCH PACKING RECORD			Page No.:	4 of 41
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.:	<i>C2D200604</i>	Mfg.Date:	<i>06/2020</i>	Exp.Date:	<i>05/2023</i>

S.No	Material Name	Standard Qty.	Unit	Material code	Excess material issued qty	A.R No:	Issued qty	Checked by stores	Checked by production	verified by IPQA
5	Shippers 240X3X10's (345X390X395)	70	No's	PMS00031	-	<i>MSP/2021/aw/oup/00265</i>	<i>70</i>	<i>OK</i>	<i>L</i>	<i>Q</i>
								<i>na</i>		
6	Glide M60/850 Leaflet	16667	No's	PML00086	-	<i>mSP/2021/aw/oup/00369</i>	<i>16665</i>	<i>OK</i>	<i>L</i>	<i>Q</i>
7	Transparent GHPL printed Bopp Tape 2"	7	No's	PMG00071	-	<i>mSP/2021/aw/oup/00002</i>	<i>7</i>	<i>OK</i>	<i>L</i>	<i>Q</i>
8	Labels	70	No's	--	-	<i>na</i>	<i>70</i>	<i>na</i>	<i>L</i>	<i>Q</i>

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

	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	5 of 41
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.:	G200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

3.0 CARTON OVER PRINTING RECORD:

3.1 CARTON OVER PRINTING DETAILS					
PRODUCT NAME :		Glide m60/850			
BATCH NO :		GD 200604			
MFG DT :		06/2020			
EXP DT :		05/2023			
PREVIOUS BATCH:		Telmiprime CH	B.NO	S2089502E	
REQ.QTY OF CARTON PER BATCH :		16667			
3.1.1 CARTON OVER PRINTING LINE CLEARANCE:					
1	Check the cleanliness of the printing area.				
2	Ensure the Left over carton of previous batch/product if any is removed from area.				
3	Check the waste bin for the absence of previous product cartons.				
4	Check the machine log book are updated and signed.				
5	Ensure free from previous product /batch details in inject printing machine.				
6	Attached specimen copy of over printed carton with batch record.				
3.1.2 INITIAL CHECKS					
DATE :	09/06/2020				
PRODUCT NAME :	Glide m60/850				
BATCH NO :	GD 200604				
MFG.DT :	06/2020				
EXP.DT :	05/2023				
CHECKED BY PRODUCTION:	09/06/2020				
CHECKED BY IPQA :	Q				
REMARKS :	-NA-				
Note: If any deviation observed inform to QA head and production head for further course of action.					

	Prepared by:	Checked by:	Approved By:	CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	Q 09/06/2020	09/06/2020	09/06/2020	

	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	6 of 41
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.:	C2200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

3.1.3 CARTON PRINTING INPROCESS CHECKS PRODUCTION AND IPQA: EVERY ONE HOUR

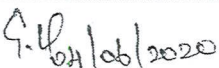
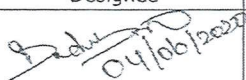
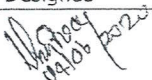
DATE :	09/06/2020	09/06/2020	09/06/2020	09/06/2020
TIME :	20.45	20.50	21.40	21.45
PRODUCT NAME :	Glide m60/850	Glide M60/850	Glide m60/850	Glide M60/850
BATCH NO :	G2200604	G2200604	G2200604	G2200604
MFG.DT :	06/2020	06/2020	06/2020	06/2020
EXP.DT :	05/2023	05/2023	05/2023	05/2023
PRINTING CLARITY :	ok	ok	ok	ok
CARTON PRINTED BY	Gayathri	Gayathri	Gayathri	Gayathri
PRINTING CHECKED BY	Vinitha	Vinitha	Vinitha	Vinitha
CHECKED BY PRODUCTION/IPQA				
SIGN/DATE :	09/06/2020	09/06/2020	09/06/2020	09/06/2020
REMARKS :	-NA-	-	-NA-	-
DATE :	09/06/2020	09/06/2020	09/06/2020	09/06/2020
TIME :	22.30	22.20	23.25	23.20
PRODUCT NAME :	Glide m60/850	Glide M60/850	Glide m60/850	Glide M60/850
BATCH NO :	G2200604	G2200604	G2200604	G2200604
MFG.DT :	06/2020	06/2020	06/2020	06/2020
EXP.DT :	05/2023	05/2023	05/2023	05/2023
PRINTING CLARITY :	ok	ok	ok	ok
CARTON PRINTED BY	Lakshman	Lakshman	Lakshman	Lakshman
PRINTING CHECKED BY	Sampath	Sampath	Sampath	Sampath
CHECKED BY PRODUCTION/IPQA				
SIGN/DATE :	09/06/2020	09/06/2020	09/06/2020	09/06/2020
REMARKS :	-NA-	-	-NA-	-
DATE :	10/06/2020	10/06/2020	10/06/2020	10/06/2020
TIME :	00.40	00:50	01.45	01:50
PRODUCT NAME :	Glide m60/850	Glide M60/850	Glide m60/850	Glide M60/850
BATCH NO :	G2200604	G2200604	G2200604	G2200604
MFG.DT :	06/2020	06/2020	06/2020	06/2020
EXP.DT :	05/2023	05/2023	05/2023	05/2023
PRINTING CLARITY :	ok	ok	ok	ok
CARTON PRINTED BY	Sampath	Sampath	Sampath	Sampath
PRINTING CHECKED BY	Lakshman	Lakshman	Lakshman	Lakshman
CHECKED BY PRODUCTION/IPQA				
SIGN/DATE :	10/06/2020	10/06/2020	10/06/2020	10/06/2020
REMARKS :	-NA-	-	-NA-	-

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

	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	7 of 41
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.:	G02200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

3.1.4 CARTON PRINTING IN PROCESS CHECKS PRODUCTION AND IPQA: EVERY ONE HOUR

DATE :	10/06/2020	10/06/2020	10/06/2020	10/06/2020
TIME :	02:40	02:45	03:45	03:50
PRODUCT NAME :	Glide M 60/850	Glide M 60/850	Glide M 60/850	Glide M 60/850
BATCH NO :	G02200604	G02200604	G02200604	G02200604
MFG.DT :	06/2020	06/2020	06/2020	06/2020
EXP.DT :	05/2023	05/2023	05/2023	05/2023
PRINTING CLARITY :	OK	OK	OK	OK
CARTON PRINTED BY	Sam Pathy	Sam Pathy	Sam Pathy	Sam Pathy
PRINTING CHECKED BY	Lakshman	Lakshman	Lakshman	Lakshman
CHECKED BY PRODUCTION/IPQA SIGN/DATE :	10/06/2020	10/06/2020	10/06/2020	10/06/2020
REMARKS :	-NA-	-NA-	-NA-	-NA-
DATE :	10/06/2020	10/06/2020		
TIME :	07:00	07:10		
PRODUCT NAME :	Glide M 60/850	Glide M 60/850		
BATCH NO :	G02200604	G02200604		
MFG.DT :	06/2020	06/2020		
EXP.DT :	05/2023	05/2023		
PRINTING CLARITY :	OK	OK		
CARTON PRINTED BY	Kousalya	Kousalya		
PRINTING CHECKED BY	Kanmani	Kanmani		
CHECKED BY PRODUCTION/IPQA SIGN/DATE :	10/06/2020	10/06/2020		
REMARKS :	-NA-	-NA-		
DATE :				
TIME :				
PRODUCT NAME :				
BATCH NO :				
MFG.DT :				
EXP.DT :				
PRINTING CLARITY :				
CARTON PRINTED BY				
PRINTING CHECKED BY				
CHECKED BY PRODUCTION/IPQA SIGN/DATE :				
REMARKS :				

	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			Page No.: 8 of 41	
	BATCH PACKING RECORD			Batch Size: 5,00,000 Tablets	
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.:	65200604	Mfg.Date:	06/06/2020	Exp.Date:	05/06/23

4.0 PACKING PROCESS INSTRUCTIONS:

S.NO	INSTRUTION
1	Wear hand gloves during operation.
2	Transfer approved bulk product and packing material to packing area after verification, record the verification details.
3	Set and operate the machine as per current version of SOP.
4	Check the initial machine setting parameters and record the observations.
5	Check and attach specimen of printed foil, carton and overprinted shipper label before starting the packing activity.
6	Check and attach specimen of overprinted /embossed foil, carton and overprinted shipper label before starting the packing activity.
7	Check the initially run blister for all the parameters recorded in the process checks. It should be counter checked by IPQA.
8	Carry out in-process checks and record observations in respective tables as per frequency.
9	If any of the parameters does not comply, stop the machine, rectify and recheck the parameters for compliance. Fill process interruption sheet.
10	Record the shipper weight for individual shipper.
11	After completing the batch packing, fill Finished Goods Transfer Note and transfer the batch to Finished goods store.

5.0 LINE CLEARANCE CHECKS - PRIMARY PACKING SALES

Date: 10/06/2020

S. No	Checks	Observation	
		Prod.	IPQA
1	Check whether area status board is updated for "CLEANED" status.	✓	✓
2	Left over Printed Aluminum blister foil and Base foil/PVC film rolls of previous batch/product if any is removed from machine and cubicle.	✓	✓
3	Scrap (empty packs, trims) from rejection box below machine is removed.	✓	✓
4	Scrap of defoiled packs is removed from the defoiling machine.	✓	✓
5	Check whether empty containers of previous product/ batch are removed from the cubicle.	✓	✓
6	Check for the absence of Capsules/tablets of previous batch/ product from hopper, below vibrator and feeding box/channel.	✓	✓
7	Check for the absence of Capsules/tablets of previous batch/ product at punching tool and area below machine and machine conveyor belt.	✓	✓
8	Check for the absence of Capsules/tablets of previous batch/ product from collection box of defoiling machine.	✓	✓
9	Check for the absence of Capsules/tablets of previous batch/product from rejected tablets box.	✓	✓
10	Check for cleaning of hopper, feeding channel, vibrator plate	✓	✓
11	Check for cleaning of area below machine, backside of machine by opening the machine guards.	✓	✓
12	Check for removal of previous product stereos from the roller.	✓	✓
13	Check for cleaning of defoiling machine and its collection box.	✓	✓
14	Check the working desk for absence of container label, dispensing labels, other labels and document of previous batch/product.	✓	✓
15	Check whether the cubicle (floor, wall, ceiling, door, windows) is clean.	✓	✓
16	Check whether the daily records are updated and signed.	✓	✓

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

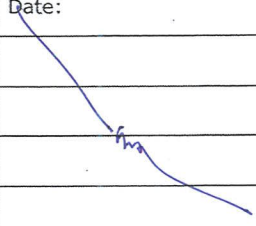
Checked by (production) sign/date: 8/10/06/2020

Verified by (IPQA) sign/date: 10/06/2020

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	8/10/06/2020	11/06/2020	

	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	9 of 41
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:	05/2028

Equipment	Blister pack Machine	AREA
Equipment ID. No.	ST/PPB/001 or ST/PPB2/001	
Previous Product	Gliclazide 60.5 forte	
Batch No.	S2086705E	
Cleaned by	Gopi	crupi
Checked by (Production):	10/06/2020	
Verified by (IPQA):	JPR	

5.1 ENVIRONMENTAL CONDITIONS:	Observation		
	Date: 10/06/2020	Date: 11/06/2020	Date:
Temperature: 23°C to 27°C	24°C	24°C	
Relative Humidity: 45% to 55 %	53 %	53 %	
Production Sign	2	by	
IPQA Sign	JPR	JPR	
Primary Packing started at: 06:40		Completed at: 14:00	
5.2 APPROVAL FOR PRIMARY PACKING:		IPQA Sign/Date: JPR 10/06/2020	
Packing Sign/Date: 10/06/2020			

5.3 RECEIPT OF PRODUCT AND MATERIALS:

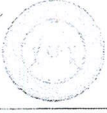
Check the following before start of packing activity and record the observation

Check Points	Date: 10/06/2020		
	Observation	Checked by (Packing)	Verified By (IPQA)
Bulk product containers are of the required product /final analytical request in present.	ok	2	JPR
Status label of machine / line is for same product.	ok	2	JPR
All secondary packing materials are of the required product.	ok	2	JPR

5.4 VERIFICATION OF PRODUCT:

	Observations	Checked By (Packing)	Observations	Verified By (IPQA)
1. Average Weight	1360 mg	10/06/2020	1360 mg	Q
2. Quantity	644.64 kg	11/06/2020	644.64 kg	Q
3. Number of containers	39 nos	10/06/2020	39 Nos	Q
If any Remarks:				

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

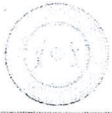
		Safetab Life Science			
		BATCH PACKING RECORD		Page No.:	10 of 41
Product:	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/RO	Supersedes MFC No:	NIL
Batch No.:	C22000004	Mfg.Date:	06/2020	Exp.Date:	05/2023

5.5 RECEIPT WEIGHING RECORD OF BULK PRODUCT:

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	11/06/2020	31	17.83	1.80	16.03	Gopi	11/06/2020
2	18.30	1.80	16.50	Gopi	11/06/2020	32	17.40	1.80	15.60	Gopi	11/06/2020
3	17.00	1.80	15.20	Gopi	11/06/2020	33	18.15	1.80	16.35	Gopi	11/06/2020
4	18.05	1.80	16.25	Gopi	11/06/2020	34	18.90	2.60	16.30	Gopi	11/06/2020
5	17.80	1.80	16.00	Gopi	11/06/2020	35	25.35	2.60	22.75	Gopi	11/06/2020
6	18.10	1.80	16.30	Gopi	11/06/2020	36	24.45	2.60	21.85	Gopi	11/06/2020
7	17.80	1.80	16.00	Gopi	11/06/2020	37	26.00	2.60	23.40	Gopi	11/06/2020
8	18.10	1.80	16.30	Gopi	11/06/2020	38	23.95	2.60	21.35	Gopi	11/06/2020
9	17.80	1.80	16.00	Gopi	11/06/2020	39	23.60	2.60	21.00	Gopi	11/06/2020
10	16.65	1.80	14.85	Gopi	11/06/2020	40					
11	17.90	1.80	16.10	Gopi	11/06/2020	41					
12	17.80	1.80	16.00	Gopi	11/06/2020	42					
13	16.90	1.80	15.10	Gopi	11/06/2020	43					
14	16.80	1.80	15.00	Gopi	11/06/2020	44					
15	17.30	1.80	15.50	Gopi	11/06/2020	45					
16	16.65	1.80	14.85	Gopi	11/06/2020	46					
17	17.90	1.80	16.10	Gopi	11/06/2020	47					
18	17.45	1.80	15.65	Gopi	11/06/2020	48					
19	18.10	1.80	16.30	Gopi	11/06/2020	49					
20	16.45	1.80	14.65	Gopi	11/06/2020	50					
21	16.28	1.80	14.48	Gopi	11/06/2020	51					
22	18.10	1.80	16.30	Gopi	11/06/2020	52					
23	16.15	1.80	14.35	Gopi	11/06/2020	53					
24	16.75	1.80	14.95	Gopi	11/06/2020	54					
25	16.60	1.80	14.80	Gopi	11/06/2020	55					
26	17.63	1.80	15.83	Gopi	11/06/2020	56					
27	18.35	1.80	16.55	Gopi	11/06/2020	57					
28	16.90	1.80	15.10	Gopi	11/06/2020	58					
29	18.70	1.80	16.90	Gopi	11/06/2020	59					
30	17.10	1.80	15.30	Gopi	11/06/2020	60					
Total weight of inspected tablets:						644.64 kg		kg			

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

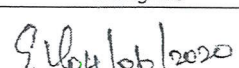
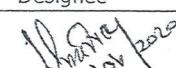
CONTROLLED COPY

	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	11 of 41
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.:	C-2200604	Mfg. Date:	06/2020	Exp. Date:	05/2023

6.0 MACHINE PARAMETERS:

Parameters	Standard and Limits		Observation		
	Machine-1* ST/PPB/001	Machine-2* ST/PPB2/001	Date:	Date:	Date:
Temperature of forming Roller	165° C to 175° C	145° C to 160° C	10/06/2020 170°C	11/06/2020 170°C	
Temperature of Sealing Roller	195° C to 210° C	195° C to 210° C	200°C	200°C	
Stereo impression quality	OK / NOT OK (Should be legible)		OK	OK	
Overprinting details:	Code no:		PON/DRUGS/071319ab	PON/DRUGS/071319ab	
	Batch No.:		CID 200604	CID 200604	
	MFG. Date:		06/2020	06/2020	
	EXP. Date:		05/2023	05/2023	
Leak test to be performed on Blister	OK / Not OK (No blister should fail in leak test)		OK	OK	
Checked by Packing Sign / Date			02/06/2020	11/06/2020	
Verified by IPQA Sign / Date			JPR 10/06/2020	JPR 11/06/2020	

11/06/2020

	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 PACKING RECORD		Page No.:	12 of 41
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.:	GDD00604	Mfg.Date:	06/2020	Exp.Date:	05/2023

7.0 PRIMARY PACKING LINE IN-PROCESS CONTROL:

Date	10/06/2020								10/06/2020							
Machine Operator Name	Gopi								Gopi, P.k.mallik							
EVERY ONE HOUR																
Checked by	P	Q	P	Q	P	Q	P	Q	P	Q	P	Q	P	Q	P	Q
Time of inspection	06:40	06:45	07:45	08:45	09:20	09:25	10:30	10:40	11:35	11:45	12:35	12:40	13:30	13:35	14:35	14:40
Sealing temperature	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C
Forming temperature	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C
Leak test on strip* (2 strips per check)	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Knurling quality	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Horizontal cutting quality	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Vertical cutting quality	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Quality of over printing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK
Code no:	P0N1DRUGS 09131906															
Batch No.	GDD00604															
Mfg.Date	06/2020															
Exp.Date	05/2023															
Machine Speed (strips per min)	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40	40
Packing Supervisor / IPQA Signature	               															

- If vacuum test fails perform every 15 minutes for next one hour and all the shippers to be checked for leak test from the last successful leak test. All the shippers packed from the time of last successful leak test shall be segregated and random checked by QA and will be released after approval from IPQA.
- OK / Not OK mention to particular process.
- P - Production
- Q - Quality Assurance

	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 PACKING RECORD		Page No.:	13 of 41
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.:	G2200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

7.0A PRIMARY PACKING LINE IN-PROCESS CONTROL:

Date	10/06/2020								10/06/2020							
Machine Operator Name	P.K. Mallik, Jygnar.								Jygnar.							
EVERY ONE HOUR																
Checked by	P	Q	P	Q	P	Q	P	Q	P	Q	P	Q	P	Q	P	Q
Time of inspection	15:28	16:35	16:35	16:40	17:35	17:40	18:40	18:45	20:15	20:20	21:30	21:35				
Sealing temperature	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C				
Forming temperature	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C				
Leak test on strip* (2 strips per check)	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Knurling quality	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Horizontal cutting quality	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Vertical cutting quality	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Quality of over printing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Code no:	P0N1DR005	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Batch No.	G2200604	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Mfg.Date	06/2020	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Exp.Date	05/2023	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK				
Machine Speed (strips per min)	40	40	40	40	40	40	40	40	40	40	40	40				
Packing Supervisor / IPQA Signature	T	E	L	E	T	E	T	E	T	E	T	E				

- If vacuum test fails perform every 15 minutes for next one hour and all the shippers to be checked for leak test from the last successful leak test. All the shippers packed from the time of last successful leak test shall be segregated and random checked by QA and will be released after approval from IPQA.
- OK / Not OK mention to particular process.

P - Production

Q - Quality Assurance

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	P. K. Mallik 10/06/2020	P. K. Mallik 10/06/2020	P. K. Mallik 10/06/2020	

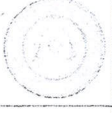
		Safetab Life Science			
		BATCH PACKING RECORD		Page No.:	14 of 41
Product:	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	0200604 <u>0200604</u> <u>04/06/20</u>	Mfg.Date:	06/2020	Exp.Date:	05/2022

7.0B PRIMARY PACKING LINE IN-PROCESS CONTROL:

Date	11/06/2020								11/06/2020							
Machine Operator Name	Gopi								Gopi							
EVERY ONE HOUR																
Checked by	P	Q	P	Q	P	Q	P	Q	P	Q	P	Q	P	Q	P	Q
Time of inspection	06:40	06:45	07:45	07:50	08:25	08:35	09:30	10:40	11:40	11:45	12:35	12:40	13:35	13:40		
Sealing temperature	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C	200°C		
Forming temperature	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C	170°C		
Leak test on strip* (2 strips per check)	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Knurling quality	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Horizontal cutting quality	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Vertical cutting quality	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Quality of over printing	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Code no:	07/13/906	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Batch No.	0200604	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Mfg.Date	06/2020	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Exp.Date	05/2022	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK	OK		
Machine Speed (strips per min)	40	40	40	40	40	40	40	40	40	40	40	40	40	40		
Packing Supervisor / IPQA Signature	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>	<i>[Signature]</i>		

- If vacuum test fails perform every 15 minutes for next one hour and all the shippers to be checked for leak test from the last successful leak test. All the shippers packed from the time of last successful leak test shall be segregated and random checked by QA and will be released after approval from IPQA.
- OK / Not OK mention to particular process.
- P - Production
- Q - Quality Assurance

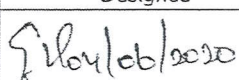
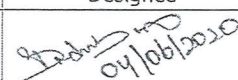
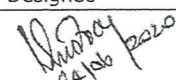
Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	CONTROLLED COPY
Signature with Date	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020	<i>[Signature]</i> 04/06/2020	

	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	15 of 41
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.:	20000604 200. G. R. 04/06/20	Mfg. Date:	06/2020	Exp. Date:	05/2023

7.0C PRIMARY PACKING LINE IN-PROCESS CONTROL:

Date																
Machine Operator Name																
EVERY ONE HOUR																
Checked by	P	Q	P	Q	P	Q	P	Q	P	Q	P	Q	P	Q	P	Q
Time of inspection																
Sealing temperature																
Forming temperature																
Leak test on strip* (2 strips per check)																
Knurling quality																
Horizontal cutting quality																
Vertical cutting quality																
Quality of over printing																
Code no:																
Batch No.																
Mfg. Date																
Exp. Date																
Machine Speed (strips per min)																
Packing Supervisor / IPQA Signature																

- If vacuum test fails perform every 15 minutes for next one hour and all the shippers to be checked for leak test from the last successful leak test. All the shippers packed from the time of last successful leak test shall be segregated and random checked by QA and will be released after approval from IPQA.
- OK / Not OK mention to particular process.
- P - Production
- Q - Quality Assurance

	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 PACKING RECORD		Page No.:	16 of 41
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.:	G0200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

7.0D PRIMARY PACKING LINE IN-PROCESS CONTROL:

Date																
Machine Operator Name																
EVERY ONE HOUR																
Checked by	P	Q	P	Q	P	Q	P	Q	P	Q	P	Q	P	Q	P	Q
Time of inspection																
Sealing temperature																
Forming temperature																
Leak test on strip* (2 strips per check)																
Knurling quality																
Horizontal cutting quality																
Vertical cutting quality																
Quality of over printing																
Code no:																
Batch No.																
Mfg.Date																
Exp.Date																
Machine Speed (strips per min)																
Packing Supervisor / IPQA Signature																

- If vacuum test fails perform every 15 minutes for next one hour and all the shippers to be checked for leak test from the last successful leak test. All the shippers packed from the time of last successful leak test shall be segregated and random checked by QA and will be released after approval from IPQA.
- OK / Not OK mention to particular process.

P - Production

Q - Quality Assurance

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

		Safetab Life Science			
		BATCH PACKING RECORD		Page No.:	17 of 41
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.:	6D200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

8.0 DEFOILING: Inspection of De-foiled tablets:

Date	Inspection Started at	Inspection Completed at	Weight of tablets taken for Inspection	Inspected by	Quantity of good tablets		Packed in Shipper No.	Weight of rejected tablets	Checked by
					Kg	No's			
11/06/2020	12:00	13:45	1.500	Mangjule	1.300	956	64	0.200	h
						na			h
Total			1.500		1.300	956	64	0.200	h
Total quantity of rejected tablets destroyed: 147 Nos.			Done by/Date (Packing)			Checked. By/Date (IPQA)			
			h/11/06/2020			JRC 11/06/2020			

9.0 LINE CLEARANCE CHECKS - SECONDARY PACKING:

S.No	Checks	Observation	
		Production	IPQA
1	Inspect the packaging area and the packing line for cleanliness. The area and packing line should be visibly clean.	✓	✓
2	Batch Packing record checked.	✓	✓
3	Check the status labels of the area/packing line and ensure their correctness with respect to product name, batch number, date, signature of production personnel.	✓	✓
4	Removal of Previous Secondary Packing Material.	✓	✓
5	Removal of Previous Documents.	✓	✓
6	Ensure that the balances are cleaned and it's calibration status.	✓	✓
7	Check whether the balance to be used are within calibration due date.	✓	✓
CONVEYOR BELT			
8	Cleanliness of the Conveyor Belt Checked	✓	✓
9	Cleanliness of guard checked	✓	✓
10	Check & ensure that the area is free from dosage units (strips, etc.)/packaging components (labels, leaflets, cartons etc.) & documents of the previous batch/product.	✓	✓
11	Ensure that any tools/materials required for equipment maintenance/operation are kept properly under control.	✓	✓
12	Check and ensure that labeled bins are available for disposal of rejects of each packing material.	✓	✓
Note: Tick mark (✓) if Complies and (X) if Does not comply.			
Checked by packing sign /date..... h/06/2020		Verified by IPQA sign /Date..... JRC 11/06/2020	

9.1 PACKING INSTRUCTIONS:

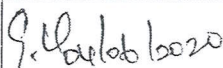
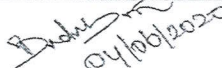
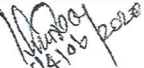
Pack 10 tablets in one strip and check the quality of sealing.
At the end of packing operation remove rejected capsules and destroy in presence of IPQA.
Pack 3 strips into the carton. Pack cartons per row and cartons per column as per profile given in 12.1.1. Seal the 5 ply shipper using tape and carry out the Inprocess checks as listed in the batch record. Weigh and record the weight of individual shipper in BPR.
Destroy the rejected printed packing materials at the end of the shift in presence of IPQA.

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

	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	18 of 41
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.:	600200604	Mfg.Date:	06/06/2020	Exp.Date:	05/2023

10.0 SECONDARY PACKING LINE CONTROLS:

Date / Time	ACTIVITIES	DONE BY	Date / Time	ACTIVITIES	DONE BY
10/06/2020 06:50	Strip checking	I. Parameeswari Sarala.S	10/06/2020 11:15	Strip checking	Sasirekha .Sarasu
	Printing checking	Saravijammal		Printing checking	P. Rama
	Packing of 3 strips and leaflet per carton Packing carton	Sumathi, Shanthi.B Elavarasi, Sivarani Sivaranjini, Revathiasei		Packing of 3 strips and leaflet per carton	M. Mohalakshmi Kodivalli Sivagami.
	Cartons weighing	B. Selvi		Cartons weighing	M. Rajavalli
	De foiling	-		De foiling	-
	Carton put into 5 ply shipper	B. Selvi		Carton put into 5 ply shipper	M. Rajavalli
	Shipper weighing	B. Selvi		Shipper weighing	M. Rajavalli
	Shipper label pasting	B. Selvi		Shipper label pasting	M. Rajavalli
	Others if any	-		Others if any	-
	Checked by packing supervisor sign/date	 10/06/2020		Checked by packing supervisor sign/date	 10/06/2020

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

	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	19 of 41
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.:	G0200604	Mfg.Date:	06/02/20	Exp.Date:	05/02/23

10.0A SECONDARY PACKING LINE CONTROLS:

Date / Time	ACTIVITIES	DONE BY	Date / Time	ACTIVITIES	DONE BY
10/06/2020 14:05	Strip checking	S. Selvi. Sarasua Nagammal	11/06/2020 06:40	Strip checking	Bavathiasa, Soraola I. Parameswari
	Printing checking	Kasamma Chinnelugolm		Printing checking	B. Shanthi D. Saravammal
	Packing of 3 strips and leaflet per carton Packing carton	Sridoni. Sarguna Gomathi. Saravathi Kannila		Packing of 3 strips and leaflet per carton	Blavasi Sivazani, Sraani B. Santhi, B. Selvi
	Cartons weighing	V. Saravathi		Cartons weighing	P. Sumathi
	De foiling	-		De foiling	Manjula
	Carton put into 5 ply shipper	V. Saravathi		Carton put into 5 ply shipper	P. Sumathi
	Shipper weighing	V. Saravathi		Shipper weighing	P. Sumathi
	Shipper label pasting	V. Saravathi		Shipper label pasting	P. Sumathi
	Others if any	-		Others if any	-
	Checked by packing supervisor sign/date	L 10/06/2020		Checked by packing supervisor sign/date	Q 11/06/2020

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

 Safetab Life Science		BATCH PACKING RECORD		Page No.:	20 of 41
				Product:	GLIDE M 60/850 TABLETS
Generic:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	C2000604	Mfg.Date:	06/2020	Exp.Date:	05/2023

10.0B SECONDARY PACKING LINE CONTROLS:

Date / Time	ACTIVITIES	DONE BY	Date / Time	ACTIVITIES	DONE BY
11/06/2020 14:05	Strip checking	Nagammal. S. Selvi Saraswathi. Saravang		Strip checking	
	Printing checking	Keesam mal Ananthi		Printing checking	
	Packing of 3 strips and leaflet per carton Packing carton	Saraswathi Elavaran Ananthasethi		Packing of 3 strips and leaflet per carton	
	Cartons weighing	V. Saravathi		Cartons weighing	
	De foiling	—		De foiling	
	Carton put into 5 ply shipper	V. Saravathi		Carton put into 5 ply shipper	
	Shipper weighing	V. Saravathi		Shipper weighing	
	Shipper label pasting	V. Saravathi		Shipper label pasting	
	Others if any	—		Others if any	
	Checked by packing supervisor sign/date	11/06/2020		Checked by packing supervisor sign/date	

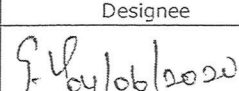
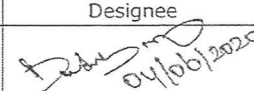
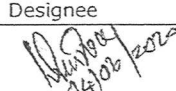
11/06/2020

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

	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	21 of 41
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.:	LS200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

10.0C SECONDARY PACKING LINE CONTROLS:

Date / Time	ACTIVITIES	DONE BY	Date / Time	ACTIVITIES	DONE BY
	Strip checking			Strip checking	
	Printing checking			Printing checking	
	Packing of 3 strips and leaflet per carton Packing carton			Packing of 3 strips and leaflet per carton	
	Cartons weighing			Cartons weighing	
	De foiling			De foiling	
	Carton put into 5 ply shipper			Carton put into 5 ply shipper	
	Shipper weighing			Shipper weighing	
	Shipper label pasting			Shipper label pasting	
	Others if any			Others if any	
	Checked by packing supervisor sign/date			Checked by packing supervisor sign/date	

	Prepared by:	Checked by:	Approved By:	   CONTROLLED COPY
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	9/4/06/2020	9/4/06/2020	9/4/06/2020	

	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	22 of 41
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.:	C.0200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

11.0 SECONDARY PACKING LINE IN-PROCESS CONTROLS: Frequency: Every One-Hour

Checked by		P	Q	P	Q	P	Q	P	Q
Date		10/06/2020	10/06/2020	10/06/2020	10/06/2020	10/06/2020	10/06/2020	10/06/2020	10/06/2020
Time		06:50	06:55	07:45	07:50	09:35	09:42	10:30	10:40
Parameter	Standards and Limits								
CARTON									
strip in monocarton	3X10's	OK	OK	OK	OK	OK	OK	OK	OK
Leaflet in carton		OK	OK	OK	OK	OK	OK	OK	OK
Print Quality	Clear & Legible	OK	OK	OK	OK	OK	OK	OK	OK
Overprinting Details	Batch No:								
	Mfg.Dt:	OK	OK	OK	OK	OK	OK	OK	OK
	Exp.Dt:								
SHIPPERS									
Shipper No.		01	01	03	03	06	06	08	08
Print Quality of Shipper Label	Clear & Legible	OK	OK	OK	OK	OK	OK	OK	OK
Overprinting Details	Batch No:								
	Mfg.Dt:	OK	OK	OK	OK	OK	OK	OK	OK
	Exp.Dt:								
	Qty:	OK	OK	OK	OK	OK	OK	OK	OK
Shipper sealing quality	Uniform	OK	OK	OK	OK	OK	OK	OK	OK
Packing Supervisor/ IPQA Signature		h	JPR	h	JPR	h	JPR	h	JPR

- OK / Not OK mention to particular process.
- P – Production Q – Quality Assurance

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	04/06/2020	04/06/2020	

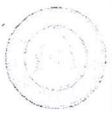
	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	23 of 41
Product:	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	C0200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

11.0A SECONDARY PACKING LINE IN-PROCESS CONTROLS: Frequency: Every One-Hour

Checked by		P	Q	P	Q	P	Q	P	Q
Date		10/06/2020	10/06/20	10/06/20	10/06/20	10/06/20	10/06/20	10/06/20	10/06/20
Time		11:35	11:40	12:27	12:32	13:30	13:35	14:35	14:40
Parameter	Standards and Limits								
CARTON									
strip in monocarton	3X10's	OK	OK	OK	OK	OK	OK	OK	OK
Leaflet in carton		OK	OK	OK	OK	OK	OK	OK	OK
Print Quality	Clear & Legible	OK	OK	OK	OK	OK	OK	OK	OK
Overprinting Details	Batch No:								
	Mfg.Dt:	06/2020	OK	OK	OK	OK	OK	OK	OK
	Exp.Dt:	05/2023	OK	OK	OK	OK	OK	OK	OK
SHIPPERS									
Shipper No.		11	12	13	13	17	18	19	19
Print Quality of Shipper Label	Clear & Legible	OK	OK	OK	OK	OK	OK	OK	OK
Overprinting Details	Batch No:								
	Mfg.Dt:	06/2020	OK	OK	OK	OK	OK	OK	OK
	Exp.Dt:	05/2023	OK	OK	OK	OK	OK	OK	OK
	Qty:	240 x 3 x 10's	OK	OK	OK	OK	OK	OK	OK
Shipper sealing quality	Uniform	OK	OK	OK	OK	OK	OK	OK	OK
Packing Supervisor/ IPQA Signature		Q	JARs	Q	JARs	Q	JARs	F	Q

- OK / Not OK mention to particular process.
- P - Production Q - Quality Assurance

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee	
Signature with Date	G. V. 10/06/2020	J. V. 10/06/2020	M. V. 10/06/2020	

	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	24 of 41
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.:	G0000604	Mfg.Date:	06/2020	Exp.Date:	05/2028

11.0B SECONDARY PACKING LINE IN-PROCESS CONTROLS: Frequency: Every One-Hour

Checked by		P	Q	P	Q	P	Q	P	Q
Date		10/06/2020	10/06/2020	10/06/2020	10/06/2020	10/06/2020	10/06/2020	10/06/2020	10/06/2020
Time		15:30	15:35	16:33	16:40	17:35	17:40	18:40	18:45
Parameter	Standards and Limits								
CARTON									
strip in monocarton	3X10's	OK	OK	OK	OK	OK	OK	OK	OK
Leaflet in carton		OK	OK	OK	OK	OK	OK	OK	OK
Print Quality	Clear & Legible	OK	OK	OK	OK	OK	OK	OK	OK
Overprinting Details	Batch No:	OK	OK	OK	OK	OK	OK	OK	OK
	Mfg.Dt:								
	Exp.Dt:								
SHIPPERS									
Shipper No.		21	22	24	25	26	26	28	28
Print Quality of Shipper Label	Clear & Legible	OK	OK	OK	OK	OK	OK	OK	OK
Overprinting Details	Batch No:	OK	OK	OK	OK	OK	OK	OK	OK
	Mfg.Dt:								
	Exp.Dt:								
	Qty:								
Shipper sealing quality	Uniform	OK	OK	OK	OK	OK	OK	OK	OK
Packing Supervisor/ IPQA Signature		f	R	f	R	f	R	f	R

- OK / Not OK mention to particular process.
- P - Production Q - Quality Assurance

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	G.R. 04/06/20	04/06/20	04/06/20	

	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	25 of 41
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.:	G2000604	Mfg.Date:	06/2020	Exp.Date:	05/2023

11.0C SECONDARY PACKING LINE IN-PROCESS CONTROLS: Frequency: Every One-Hour

Checked by		P	Q	P	Q	P	Q	P	Q
Date		10/06/2020	10/06/20	10/06/2020	10/06/20	11/06/2020	11/06/20	11/06/2020	11/06/20
Time		20:20	20:25	21:30	21:35	06:40	06:50	07:45	07:50
Parameter	Standards and Limits								
CARTON									
strip in monocarton	3X10's	OK	OK	OK	OK	OK	OK	OK	OK
Leaflet in carton		OK	OK	OK	OK	OK	OK	OK	OK
Print Quality	Clear & Legible	OK	OK	OK	OK	OK	OK	OK	OK
Overprinting Details	Batch No: G2000604	OK	OK	OK	OK	OK	OK	OK	OK
	Mfg.Dt: 06/2020								
	Exp.Dt: 05/2023								
SHIPPERS									
Shipper No.		31	31	38	38	39	39	42	42
Print Quality of Shipper Label	Clear & Legible	OK	OK	OK	OK	OK	OK	OK	OK
Overprinting Details	Batch No: G2000604	OK	OK	OK	OK	OK	OK	OK	OK
	Mfg.Dt: 06/2020								
	Exp.Dt: 05/2023								
	Qty:								
Shipper sealing quality	Uniform	OK	OK	OK	OK	OK	OK	OK	OK
Packing Supervisor/ IPQA Signature		L	R	L	R	R	ZR	R	JR

- OK / Not OK mention to particular process.
P - Production Q - Quality Assurance

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

	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	26 of 41
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.:	C20200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

11.0D SECONDARY PACKING LINE IN-PROCESS CONTROLS: Frequency: Every One-Hour

Checked by		P	Q	P	Q	P	Q	P	Q
Date		11/06/2020	11/06/2020	11/06/2020	11/06/2020	11/06/2020	11/06/2020	11/06/2020	11/06/2020
Time		09:20	09:30	10:30	10:35	11:25	11:35	12:30	12:40
Parameter	Standards and Limits								
CARTON									
strip in monocarton	3X10's	ok	ok	ok	ok	ok	ok	ok	ok
Leaflet in carton		ok	ok	ok	ok	ok	ok	ok	ok
Print Quality	Clear & Legible	ok	ok	ok	ok	ok	ok	ok	ok
Overprinting Details	Batch No:	ok	ok	ok	ok	ok	ok	ok	ok
	C20200604								
	Mfg.Dt:								
	06/2020								
	Exp.Dt:								
	05/2023								
SHIPPERS									
Shipper No.		49	49	53	55	56	57	59	60
Print Quality of Shipper Label	Clear & Legible	ok	ok	ok	ok	ok	ok	ok	ok
Overprinting Details	Batch No:	ok	ok	ok	ok	ok	ok	ok	ok
	C20200604								
	Mfg.Dt:								
	Exp.Dt:								
	06/2020								
	05/2023								
	Qty:								
	240x3x10's	ok	ok	ok	ok	ok	ok	ok	ok
Shipper sealing quality	Uniform	ok	ok	ok	ok	ok	ok	ok	ok
Packing Supervisor/ IPQA Signature		Q	JR	Q	JR	Q	JR	Q	JR

- OK / Not OK mention to particular process.
- P - Production Q - Quality Assurance

Designation	Prepared by: QA Executive / Designee	Checked by: Production Head / Designee	Approved By: QA Head / Designee
Signature with Date	G. B. 04/06/20	04/06/20	04/06/20

CONTROLLED COPY

	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	27 of 41
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.:	G.D200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

11.0E SECONDARY PACKING LINE IN-PROCESS CONTROLS: Frequency: Every One-Hour

Checked by		P	Q	P	Q	P	Q	P	Q
Date		11/06/2020	11/06/20	11/06/2020	11/06/2020	11/06/2020	11/06/2020		
Time		13:30	13:35	14:40	14:45	15:35	15:40		
Parameter	Standards and Limits								
CARTON									
Strip in moncarton	3X10's	OK	OK	OK	OK	OK	OK		
Leaflet in carton		OK	OK	OK	OK	OK	OK		
Print Quality	Clear & Legible	OK	OK	OK	OK	OK	OK		
Overprinting Details	Batch No: G.D200604	OK	OK	OK	OK	OK	OK		
	Mfg.Dt: 06/2020								
	Exp.Dt: 05/2023								
SHIPPERS									
Shipper No.		b2	b3	b4	b5	b5	b5		
Print Quality of Shipper Label	Clear & Legible	OK	OK	OK	OK	OK	OK		
Overprinting Details	Batch No: G.D200604	OK	OK	OK	OK	OK	OK		
	Mfg.Dt: 06/2020								
	Exp.Dt: 05/2023								
	Qty: 240 x 3 x 10's								
Shipper sealing quality	Uniform	OK	OK	OK	OK	OK	OK		
Packing Supervisor/ IPQA Signature		Q	IPR	V	Q	L	Q		

- OK / Not OK mention to particular process.
- P - Production Q - Quality Assurance

11/06/2020

	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	G. B 04/06/20	04/06/2020	04/06/2020	

	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	28 of 41
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.:	G0200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

11.OF SECONDARY PACKING LINE IN-PROCESS CONTROLS: Frequency: Every One-Hour

Checked by		P	Q	P	Q	P	Q	P	Q
Date									
Time									
Parameter	Standards and Limits								
CARTON									
Strip in mon carton	3X10's								
Leaflet in carton									
Print Quality	Clear & Legible								
Overprinting Details	Batch No:								
	Mfg.Dt:								
	Exp.Dt:								
SHIPPERS									
Shipper No.									
Print Quality of Shipper Label	Clear & Legible								
Overprinting Details	Batch No:								
	Mfg.Dt:								
	Exp.Dt:								
	Qty:								
Shipper sealing quality	Uniform								
Packing Supervisor/ IPQA Signature									

- OK / Not OK mention to particular process.
- P - Production Q - Quality Assurance

11/06/2020

	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 PACKING RECORD			Page No.:	29 of 41
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.:	G0200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

11.0G SECONDARY PACKING LINE IN-PROCESS CONTROLS: Frequency: Every One-Hour

Checked by		P	Q	P	Q	P	Q	P	Q
Date									
Time									
Parameter	Standards and Limits								
CARTON									
strip in monocarton	3X10's								
Leaflet in carton									
Print Quality	Clear & Legible								
Overprinting Details	Batch No:								
	Mfg.Dt:								
	Exp.Dt:								
SHIPPERS									
Shipper No.									
Print Quality of Shipper Label	Clear & Legible								
Overprinting Details	Batch No:								
	Mfg.Dt:								
	Exp.Dt:								
	Qty:								
Shipper sealing quality	Uniform								
Packing Supervisor/ IPQA Signature									

- OK / Not OK mention to particular process.
- P - Production Q - Quality Assurance

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

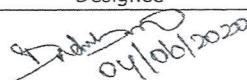
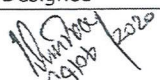
	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	30 of 41
Product:	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic:	Gliclazide and Metformin Hydrochloride sustained release Tablets 60/850mg	MFC NO:	ST/MFC/130/R0	Supersedes MFC No:	NIL
Batch No.:	6.2200604	Mfg.Date:	06/2020	Exp.Date:	05/2023

11.0H SECONDARY PACKING LINE IN-PROCESS CONTROLS: Frequency: Every One-Hour

Checked by	P	Q	P	Q	P	Q	P	Q
Date								
Time								
Parameter	Standards and Limits							
CARTON								
strip in monocarton	3X10's							
Leaflet in carton								
Print Quality	Clear & Legible							
Overprinting Details	Batch No:							
	Mfg.Dt:							
	Exp.Dt:							
SHIPPERS								
Shipper No.								
Print Quality of Shipper Label	Clear & Legible							
Overprinting Details	Batch No:							
	Mfg.Dt:							
	Exp.Dt:							
	Qty:							
Shipper sealing quality	Uniform							
Packing Supervisor/ IPQA Signature								

- OK / Not OK mention to particular process.
P - Production Q - Quality Assurance

11/06/2020

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

	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	31 of 41
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.:	62200604	Mfg.Date:	06/2020	Exp.Date:	05/2028

12.0 WEIGHT CHECKS ON SHIPPERS: SALES

12.1 LIMITS

Per carton packed qty:	3 X 10's	Per shipper packed qty:	240X3X10's
Dimension of 5 ply shipper in mm: Length (L), Width (W), Height (H) (L X W X H)			345X390X395
Weight of ten filled carton:	573.19 gm	Average weight of a filled carton (A):	57.32 gm
Weight of ten empty shippers:	11.760 kg	Average weight of an empty shipper (B):	1.176 + 0.008 kg
Weight of one filled shipper (C): (A X 240 + B)		14.940 kg	
Checked by packing : ✓ Date : 10/06/2020		Verified by IPQA: [Signature] Date : 10/06/2020	
Limits:	Strip : Strip weight $\pm \frac{1}{2}$ tablet weight. (15.07 gm to 16.92 gm)		
	Carton: Average weight of filled carton $\pm \frac{1}{2}$ strip weight. (49.45 gm to 65.19 gm)		
	Shipper: Weight of filled shipper $\pm \frac{1}{2}$ carton weight. (14.911 kg to 14.969 kg)		

12.1.1 PACKING PROFILE:

Pack 10 tablets in 1 strip → 3 strip into 1 carton → 240 cartons in one 5ply shipper

	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	

		Safetab Life Science			
		BATCH PACKING RECORD		Page No.:	32 of 41
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.:	C0200604	Mfg. Date:	06/2020	Exp. Date:	05/2023

12.2 WEIGHT CHECKS:

Date: 10/06/2020 Date: 10/06/2020 Date: 11/06/2020 Date: -

Shipper No.	Gross weight (kg)	Checked by Packing	Shipper No.	Gross weight (kg)	Checked by Packing	Shipper No.	Gross weight (kg)	Checked by Packing	Shipper No.	Gross weight (kg)	Checked by Packing
01	14.924	Q	26	15.016	L	51	15.108	Q			
02	14.898	Q	27	14.982	V	52	15.1048	Q			
03	14.878	Q	28	14.986	L	53	15.054	Q			
04	14.894	Q	29	14.918	V	54	15.046	Q			
05	14.920	Q	30	14.982	V	55	14.916	Q			
06	14.876	Q	31	14.920	V	56	14.988	Q			
07	14.906	Q	32	14.978	L	57	15.002	Q			
08	14.908	Q	33	14.920	L	58	15.024	Q			
09	14.916	Q	34	14.904	V	59	15.034	Q			
10	14.982	Q	35	14.940	L	60	15.024	Q			
11	14.886	Q	36	15.058	V	61	15.034	Q			
12	14.878	Q	37	15.036	V	62	14.950	Q			
13	14.966	Q	38	15.072	L	63	14.972	L			
14	14.960	Q	39	15.052	Q	64	15.040	L			
15	14.854	Q	40	15.044	Q	65	15.042	L			
16	14.852	Q	41	15.062	Q						
17	14.862	Q	42	14.950	Q						
18	14.906	V	43	15.036	Q						
19	14.840	V	44	15.024	Q						
20	14.922	V	45	15.038	Q						
21	14.942	V	46	15.186	Q						
22	14.930	V	47	14.996	Q						
23	15.018	V	48	15.024	Q						
24	14.904	V	49	15.046	Q						
25	14.896	V	50	15.084	Q						

Verified by IPQA sign/date: 11/06/2020

Date	Packed in Shipper No.		Weighed by / Date	Checked by / Date	Packed quantity	Loose pack details	
	From	To				Shipper No:	
10/06/2020	01	38	B. Selvi	10/06/2020	273 boxes	Quantity:	
11/06/2020	39	65	Sassirelce	11/06/2020	19490 boxes	Total packed quantity:	468000
Remarks (If any):							

Note - If any shipper weight found out of limit, the same shall be checked physically by opening the shipper.

	Prepared by:	Checked by:	Approved By:
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee
Signature with Date	G. V. 10/06/2020	D. 04/06/2020	11/06/2020

CONTROLLED COPY

	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	34 of 41
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.:	60200604	Mfg.Date:	06/2020	Exp.Date:	05/2028

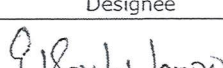
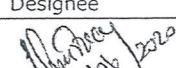
13.0 PACKING MATERIALS RECONCILIATION:

S. No	Material	Sales						
		Printed Aluminium Foil (Kg)	Plain PVC clear Foil (Kg)	carton (no's)	leaflet (No's)	5 Ply Shipper (No's)	Transparent t GHPL printed Bopp Tape 2"	Labels (No's)
A	Quantity received for the batch	37.46	129.30	16665	16665	70	7	70
B	Quantity packed	33.50	121.00	15600	15600	65	7	65
C	Quantity rejected (Online) & Destroyed	0.36	0.60	879	231	5	-	4
D	Unused printed packing material	-	-	-	-	-	-	-
E	Quantity Returned materials	3.60	7.70	850	800	-	-	-
F	Sample affixed on BPR	-	-	3	1	-	-	1
G	QC samples	-	-	7	7	-	-	-
H	Other samples (If any)	-	-	26	26	-	-	-
I	Total accountable Quantity (B + C + E + F + H)	37.46	129.30	16665	16665	70	7	70
J	Variation (A - I)	-	-	-	-	-	-	-
K	%Variation $(\frac{J \times 100}{A})$	0%	0%	0%	0%	0%	0%	0%
L	Acceptable limit	± 2 %			± 1%			

If % Variation is out of the acceptable limit, investigate & specify the reason:

14.0 DESTRUCTION OF REJECTED PACKING MATERIALS AND STEREOS:

Date	Stereos (No's)	Printed Aluminium Foil (Kg)	Plain PVC foil (Kg)	Printed Cartons (No's)	LEAFLET (NO's)	Shipper Labels (No's)	Shipper (No's)	Destroyed by Packing	Verified by IPQA
11/06/2020	15	3.60	0.60	879	231	4	5	1	Q
Total Qty. Destroyed	15	0.360	0.60	879	231	4	5		

	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 PACKING RECORD		Page No.:	35 of 41
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:	05/2023

15.0 PACKING LABEL PASTE:

SHIPPING MARK	
Product Name	: GLIDE – M 60/850
Batch No.	: GD200604
Mfg.Date	: 06/2020
Exp.Date	: 05/2023
Quantity	: 240 X 3 X 10'S
Gross Weight	: kgs
Net Weight	: kgs
Case No.	:
Supplier. Generic Healthcare Pvt. Ltd.	



	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 PACKING RECORD			Page No.:	36 of 41
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.:	CND200604	Mfg.Date:	06/2020	Exp.Date:	05/2022

16.0 TOTAL BATCH RECONCILIATION REPORT:

A	Batch Size	5, 00,000 No's
B	Quantity received for packing	474000
C	Total quantity packed	468000
D	Control samples	200
E	Analytical Samples	3018
F	In process samples	840
G	Others samples if any (Stability, Regulatory Samples, etc) P.A + M.C.	60 + 700 + 10
H	In process loss	-
I	Packing Loss = B - (C + D + E + F + G + H)	4160
J	Total Loss = A - (C + D + E + F + G + H)	30160
K	Packing yield % (C + D + E + F + G + H) / B X 100 (Limit: NLT 99.0%)	99.12 %
L	Total batch yield % (Limit: NLT 93.00%)*	93.97 %

*Tentative limit

17.0 TRANSFER OF FINISHED GOODS:

Date	FGR No.	Pack Size of per shipper	Quantity transferred	No. of Shippers	Quantity sent to FGR	Issued by Packing	Checked by IPQA
11/06/2020	179	240	468000	65	15600x325	L	Q

18.0 RELEASE FOR DISPATCH:

Total batch Quantity released by (packing) : 11/06/2020

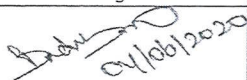
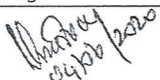
Checked by QA Head : 11/06/2020

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

	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	37 of 41
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.:	CDS 200604	Mfg.Date:	06/06/2020	Exp.Date:	05/2022

19.0 PROCESS HISTORY

Refer designation no: ST/DR/20/070

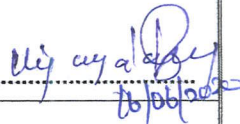
	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	G.L. 04/06/2020	 04/06/2020	 04/06/2020	

	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	38 of 41
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.:	C.D200604	Mfg.Date:	06/20/20	Exp.Date:	05/20/23

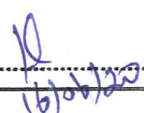
20.0 Following the BPR records in additional attached.		Checked by Production Head	Reviewed by QA Head
1	Stereo Impression approval sheet	✓	✓
2	Approved Specimen of Aluminium foil with the batch stereo overprinting	✓	✓
3	Approved Specimen of overprinting carton	✓	✓
4	Checked in Packing label paste	✓	✓
5	FGR transferred slip attached	✓	✓
6	Finished product Certificate of Analysis attached	✓	✓
7	Any other items attached.	✓	✓

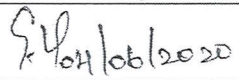
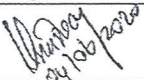
Note: Tick mark (✓) if Complies and (X) if Does not comply.

This Batch Packing Record submitted to QA Head on date.....16/06/2020

Production Head sign/date..... 16/06/20

This Batch Packing Record received, reviewed and batch is released for distribution on date.....16/06/20

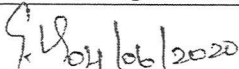
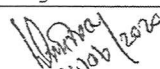
Reviewed by QA Head..... 16/06/20

	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 PACKING RECORD			Page No.:	39 of 41
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.:	CDD200604	Mfg.Date:	06/20/20	Exp.Date:	05/2023

21.0 ABBREVIATIONS

S.No.	Short Form	Abbreviation	S.No.	Short Form	Abbreviation
1	BPR	Batch Packing Record	16	Tab	Tablet
2	MFG	Manufacturing	17	Std	Standard
3	EXP	Expiry	18	Avg	Average
4	MRP	Maximum Retail Price	19	rpm	Rotation Per Minute
5	QA	Quality Assurance	20	No's	Numbers
6	Kg	Kilogram	21	Sign	Signature
7	g	Gram	22	IPQA	In Process Quality Assurance
8	Min	Minutes	23	SOP	Standard Operating Procedure
9	Hrs	Hours	24	mm	Millimeter
10	M/C	Machine	25	NLT	Not Less Than
11	Prod	Production	26	NMT	Not More Than
12	B.No	Batch number	27	QC	Quality Control
13	FGR	Finished Good Receipt	28	A.R.No.	Analytical Report Number
14	mg	Milligram	29	L	Lakhs
15	Qty	Quantity			

	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 PACKING RECORD			Page No.:	40 of 41
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/RO	Supersedes MFC No:	NIL
Batch No.:	C2D200601	Mfg.Date:	06/06/20	Exp.Date:	05/06/23

22.0 BATCH PACKING RECORD REVIEW CHECK LIST		
S. No.	CHECK POINTS	Status
1	The entire Page no: <u>01</u> to <u>41</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 packing activities.	Yes / No
7	Dispensing is carried out as per indent of packing materials and are correct.	Yes / No
8	Environmental conditions comply during all the packing stages.	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	Individual specimen of Printed foil, Printed carton and shipper label, Inspected tablets container label is attached with signature, verified and are correct.	Yes / No
12	Destruction record of rejected packing material is filled and destruction is verified by IPQA.	Yes / No
13	Surplus packing materials return request is filled and surplus quantity of packing material is returned and verified.	Yes / No / NA
14	Packing material reconciliation is filled and variance is within acceptance limit.	Yes / No
15	In shipper weighing record none of the shippers are out of limit. Where any shipper weight is out of limit, has been opened and quantity verified and signed against that particular shipper number and correct.	Yes / No
16	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 Packing record review it should be brought to the notice of QA Head.	

Batch Packing Record reviewed by IPQA Sign/Date: [Signature] 16/06/2020

QA Head Sign/Date: [Signature] 16/06/20

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

	Safetab Life Science				
	BATCH PACKING RECORD			Page No.:	41 of 41
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.:	C02200604	Mfg.Date:	06/02/20	Exp.Date:	05/2023

23.0 REVISION HISTORY:

Revision No.	Date of Revision	Changes Made	Effective Date
00	--	1. New product introduced refer change control No: ST/CC/20/021.	04/06/2020

	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	