

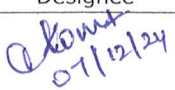
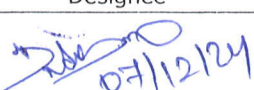
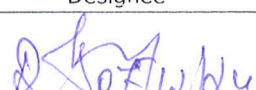
**Safetab Life Science****MASTER COPY****BATCH MANUFACTURING RECORD**

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Product:	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic:	Gliclazide and Metformin Hydrochloride sustained release Tablets	MFC NO:	ST/MFC/130/R2	Supersedes MFC No:	ST/MFC/130/R1
Batch No.:		Mfg. Date:		Exp. Date:	

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 850 mg (in sustained release form) Colour: Approved colours are used.		
STORAGE CONDITION	:	Store in a cool dry and dark place.		
SHELF LIFE	:	36 MONTHS		
CUSTOMER NAME	:	GENERIC HEALTHCARE PVT LTD		
EFFECTIVE BATCH NUMBER	:	617241223	DATE:	07/12/24
MANUFACTURING LICENCE No.	:	21 14 4378		
MFG. DATE:	:		BMR. No	STBMR: 123/02
EXP. DATE:	:		Supersedes BMR. No	STBMR: 123/01
BMR ISSUED BY/DATE (QA)	:			
BMR CHECKED & RECEIVED BY/DATE (PRODUCTION)	:			
Allotted By: QA Executive Sign/Date: _____				
DATE OF COMMENCEMENT:	:	DATE OF COMPLETION:		
This BMR contains 75 Pages + Additional Pages				
Checked by Competent Staff Sign/Date:				

Title	Prepared by:	Checked by:	Approved By:	
Designation	QA Executive / Designee	Production Head / Designee	QA Head / Designee	
Signature with Date	 07/12/24	 07/12/24	 07/12/24	

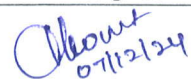
	Safetab Life Science			MASTER COPY	
	BATCH MANUFACTURING RECORD			Page 4 of 75	
Product:	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic:	Gliclazide and Metformin Hydrochloride sustained release Tablets	MFC NO:	ST/MFC/130/R2	Supersedes MFC No:	ST/MFC/130/R1
Batch No.:		Mfg. Date:		Exp. Date:	

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, Dupont, Hyundae
3	Microcrystalline cellulose powder	RMEM0031	60.000	BP	30.000	7.500	7.500	7.500	7.500	Sigachi, RanQ
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, Elite

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	BATCH MANUFACTURING RECORD			Page 5 of 75	
Product:	GLIDE M 60/850 TABLETS	Product ID No.:	1014	Batch Size	5,00,000 Tablets
Generic:	Gliclazide and Metformin Hydrochloride sustained release Tablets	MFC NO:	ST/MFC/130/R2	Supersedes MFC No:	ST/MFC/130/R1
Batch No.:		Mfg. Date:		Exp. Date:	

2.5 INDENT OF ACTIVE PHARMACEUTICAL INGREDIENTS (GLICLAZIDE PART)

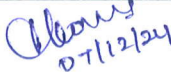
S.No	Name of the Ingredients	Material Code	Label claim per tablet in mg	Overages %	Spec	Std. Qty. per batch (Kg)	Vendor
1	Gliclazide	RMAG0014	60.000	nil	BP	30.000	KIMIA

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/ Innophos
3	Methocel K 100 Premium LVCR	RMEM0036	40.000	BP	20.000	Ami life science, Dupont
4	Iron oxide Red	RMEI0004	1.000	USP/NF	0.500	Neelikon
4	Povidone K30	RMEP0049	9.000	BP	4.500	Haungshan Bonsun, Chanzhou
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, Cabot
8	Purified Talc	RMET0012	5.000	BP	2.500	Neelkanth/Imerys
9	Magnesium stearate	RMEM0033	2.500	BP	1.250	Nitika

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