



**AI Andalous**

Pharmaceutical Ind.

Product name: Glimepiride plus 4/30 mg Tablets

Reference protocol number: PVP040-II

Report number: PVR1-040/300kg

**Process validation report**

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Reference Protocol version:1

Report Version:02

**Glimepiride plus 4/30 mg tablets**

**PROCESS VALIDATION REPORT**

**240772, 240773, 240880**



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VALIDATION REPORT APPROVAL		
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Reference protocol number: PVP040-II		Reference Protocol version:1	
Report number: PVR1-040/300kg		Report Version:02	

**1.OBJECTIVES:**

- To provide documented evidence that the predetermined process of Glimpiride plus 4/30 mg tablets is still capable of reliably and repeatedly rendering a product of the required quality after adding new supplier of API glimepiride (Glenmark) and pioglitazone (MSN) according to CC-SC-20-056 and preparation optimization

**2.SCOPE:**

**Product Name:** Glimpiride plus 4/30 mg tablets

**Bulk Code:** 10101026

**Semi-Finish Code (Goods):** 201010260110

**Finished product code:** 301010260110

**Shelf life:**24 month.

**Type of validation:** prospective

**Manufacturing Line:** Solid

**Batch size:** 300 kg Powder = 1000,000 tab = 100,000 Blister

**Status of product:** valid

**Production steps to be valid:** All process

S.N.	Batch Record	Mfg. Date	Exp. Date	Batch size
1.	240772	09/2024	09/2026	300 Kg 1000,000 tabs
2.	240773	09/2024	09/2026	
3.	240880	10/2024	10/2026	



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**3. LIST OF MACHINE & EQUIPMENT AND ITS QUALIFICATION/CALIBRATION STATUS:**

Machine	Machine code	Batch No. 240772	Batch No. 240773	Batch No. 240880
Weighing Booth	DS001	Calibration date: 02/2025 Qualified	Calibration date: 02/2025 Qualified	Calibration date: 02/2025 Qualified
Diosna Binder tank	SON14T013	NA	NA	NA
Russel sifter	SO013	NA	NA	NA
Comasa HSM	SO008	Calibration date: 02/2025 Qualified	Calibration date: 02/2025 Qualified	Calibration date: 02/2025 Qualified
Comasa FBD	SO007	Calibration date: 02/2025 Qualified	Calibration date: 02/2025 Qualified	Calibration date: 02/2025 Qualified
Cone mill	SO009	02/2025	02/2025	02/2025
Kern balance 15 kg	DSN04B003	01/2025	01/2025	01/2025
Kern balance 60 kg	DSN04B004	01/2025	01/2025	01/2025
CMS Bin Blender	SO010	02/2025	02/2025	02/2025
FEITE tablet compression machine	SO037	Calibration date: 03/2025 Qualified	Calibration date: 03/2025 Qualified	Calibration date: 03/2025 Qualified
Metal detector of Fette machine	SO037MD01 SO037MD02	NA	NA	NA
Blistering Machine (CAM)	PA012	Calibration date: 02/2025 Qualified	Calibration date: 02/2025 Qualified	Calibration date: 02/2025 Qualified
OHAUS Balance	SON04B005	01/2025	01/2025	01/2025



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Machine	Machine code	Batch No. 240772	Batch No. 240773	Batch No. 240880
KERN Balance	SON04B009	01/2025	01/2025	01/2025
Shimadzu Balance	SON04B013	01/2025	01/2025	01/2025
KERN Balance	SON04B015	01/2025	01/2025	01/2025
Moisture analyser	SO025	01/2025	01/2025	01/2025



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**3.1. List of equipment used: (IPC/QC laboratories)**

Equipment name	Equipment code	Batch No. 240772	Batch No. 240773	Batch No. 240880
HPLC	QC009	06/2025-Qulified	06/2025-Qulified	06/2025-Qulified
HPLC	QC010	08/2025-Qulified	08/2025-Qulified	08/2025-Qulified
HPLC	QC011	07/2025-Qulified	07/2025-Qulified	07/2025-Qulified
HPLC	QC012	07/2025-Qulified	07/2025-Qulified	07/2025-Qulified
HPLC	QC013	01/2025-Qulified	01/2025-Qulified	01/2025-Qulified
HPLC	QC014	06/2025-Qulified	06/2025-Qulified	06/2025-Qulified
HPLC	QC015	01/2025-Qulified	01/2025-Qulified	01/2025-Qulified
Dissolution tester	QC070	10/2025-Qulified	10/2025-Qulified	10/2025-Qulified
Dissolution tester	QC006	01/2025-Qulified	01/2025-Qulified	01/2025-Qulified
Dissolution tester	QC007	04/2025-Qulified	04/2025-Qulified	04/2025-Qulified
Dissolution tester	QC008	02/2025-Qulified	02/2025-Qulified	02/2025-Qulified
Digital caliber	QC076	02/2025-Qulified	02/2025-Qulified	02/2025-Qulified
Hardness tester	QAN06K002	02/2025	02/2025	02/2025
Friability tester	QA002	02/2025	02/2025	02/2025
Disintegration tester	QA004	02/2025	02/2025	02/2025
Leakage tester	QA010	02/2025	02/2025	02/2025
Kern balance ABS2204N	QA008	02/2025	02/2025	02/2025
Sartorius balance	QAN04B001	02/2025	02/2025	02/2025
Karl Fischer Titroline	QAN04B004	02/2025	02/2025	02/2025
Mettler Toledo balance	QC049	08/2025	08/2025	08/2025
Mettler Toledo balance	QCN04B005&QCN04B006,	01/2025	01/2025	01/2025
ADAM balance	QCN04B007	03/2025	03/2025	03/2025
PHARMA TEST Disintegration Tester	QCN04B002	01/2025	01/2025	01/2025
	QC027	07/2025	07/2025	07/2025

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#### 4. MATERIALS SUPPLIERS LIST:


Sr.#	Code No.	Item Name	B.n:240772	B.n:240773	B.n:240880
1.	R0067-01	Glimepiride micronized (Glenmark)*	Glenmark	Glenmark	Glenmark
2.	R0123-02	Pioglitazone HCl (D <sub>90</sub> NMT 10 um) (MSN)	MSN	MSN	MSN
3.	R0632	Hydroxy propyl cellulose - LXF	Klucel	Klucel	Ashlad
4.	R0175	Polysorbate 80	croda	croda	croda
5.	R0086	Lactose monohydrate	Kerry	Kerry	Kerry
6.	R0109	Microcrystalline cellulose PH 102	Dupont	Dupont	Dupont
7.	R0041	Croscarmellose sodium	IFF	IFF	IFF
8.	R0475	Magnesium stearate	Nimbasia	Nimbasia	Nimbasia

\*5% excess to added as manufacturing overage.

\*Conclusion: All materials are dispensed according to supplier list F-QA/S109-02-00

N.B: All RC dispensed are attached in BMR



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Processing steps	Parameters (Critical, key and non-key)	Control parameter
<b>Blending speed</b>  <b>Sieving of magnesium stearate</b>  <b>Lubrication</b>	Blending speed	12 rpm
	Blending time	15 min
	Bin capacity	600 L
	Sieve size	250 µm
	Blending speed	12 rpm
	Blending time	5 min
	Bin capacity	600 L
	Bulk density	0.4724±0.05
	Tapped density	0.6466±0.05
	Punches	9 mm round biconcave non scored tablet with small (a) letter on one side
<b>Compression</b>  <b>FETTE</b>	Av. Weight first layer	Control limit (180.0 mg +3, -1%) Release limit (180±5%)
	Av. Weight tablet	Release limit (300.0 mg ± 5%) Control limit(299-304)mg
	Hardness	4-7 Kp
	Thickness	4.39-4.75mm
	Feeder speed (1)	15 rpm
	Feeder speed (2)	25-38 rpm
	Machine speed	50000 TPH
	Pre compression cycle Hight first layer	(2.5-3) mm
	Pre compression cycle Hight second layer	(3-3.5) mm
	Main Compression Hight first layer	(1.65-1.75) mm
	Main Compression Hight second layer	(2.1-2.4) mm
	Pre compression force second layer	(2-4) KN (As reference)
	Main Compression force first layer	(1.2-1.5) KN (As reference)
	Main Compression force second	(6-11) KN (As reference)
	Cam size first layer (fixed cam)	10mm
	Cam size second layer	8mm
<b>Blistering</b>	Sealing temp.	200-220 °C
	Machine speed	4347-5555 blister/hr


#### 16. RECOMMENDED ONGOING PROCESS VERIFICATION FOR VALIDATION STUDY

**STAGE III:** Monitoring 10 Batches in phase 2 according to statistical results 3 batches

Recommended.

#### 17. FINAL CONCLUSION

The process is validated and capable of reliably and repeatedly rendering a product of the required quality.

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#### 18. HISTORY OF CHANGES

Version number	Month/Year	Changes
1	09/2022	Change composition
2	12/2024	New supplier of pioglitazone (MSN) and glimepiride (Glenmark) and preparation optimization