Harman Finochem Limited

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CERTIFICATE OF ANALYSIS

Product	**METFORMIN HYDROCHLORIDE USP**		
NDC NO.	**66064-1100-01**		
Manufacturer	**M/s. HARMAN FINOCHEM LTD.**		
Batch Number	SE0102246	A. R. Number	HFSAFP26000624
Date of Manufacturing	November 2025	Date of Expiry	October 2030
Dispatch Quantity	350.000 Kg	Drug Lic. No.	AD / 065
Date of Release	28/02/2026		

TESTS	**RESULTS**	**SPECIFICATIONS / LIMITS**
Description	White Crystalline Powder.	White, crystalline powder.
Solubility	Complies	Freely soluble in purified water, slightly soluble in alcohol, practically insoluble in acetone and in methylene chloride.
Identification	Complies Complies Complies	A. FT-IR spectrum of sample should concordant with the spectrum of Metformin HCl working standard. B. Meets the requirements of the tests for chloride. C. The retention time of the principal peak of the sample solution corresponds to that of the standard solution as obtained in the Assay (By HPLC) test.
Organic Impurities (By HPLC)	0.005%	Metformin Related Compound A: NMT 0.02%. (1-Cyanoguanidine) (LOQ – 0.00025%)
	0.016%	Any Other Impurity: NMT 0.1% (In-house Limit: NMT 0.05%). (LOQ – 0.0005%)
	0.04%	Total impurities: NMT 0.5% (In-house Limit: 0.20%).
Loss on Drying	0.18%	NMT 0.5% (Determined on~1.0 g sample at 105 °C for 5 hrs.)
Residue on Ignition	0.02%	NMT 0.1% (Determined on~1.0 g sample).
Assay (On Dried Basis) (By HPLC)	100.1%	NLT 98.0% and NMT 102.0%.
Residual Solvents (By GC)	ND (< LOQ: 200 ppm)	H-Solvent: NMT 5000 ppm (In-house) (LOD: 60 ppm & LOQ – 200 ppm)
Additional In-house Specification:		
Impurity F Dimethylamine content (DMA) By HPLC As per Ph. Eur.	0.006%	NMT 0.05% (LOQ – 0.0011%)
Bulk Density / Tapped density	0.51 g/ml	Untapped : 0.30 to 0.70 g/ml.
	0.74 g/ml	Tapped : 0.50 to 0.90 g/ml.
Particle Size Distribution (Using Sieve Shaker)	99 % passes through 150 µm	90% should passes through 150 µm (100# mesh)
*Nitrosamine Impurity (By GC-MS/MS)	Not Detected	N-nitrosodimethylamine (NDMA): NMT 0.032 ppm (LOQ : 0.008 ppm)

Remarks: The Batch Complies as per USP, In-house and Customer Specifications.
*Nitrosamine Impurity (By GC-MS/MS) test to be performed every 10th batch of sample and is a part of skip testing based on trend. However, if tested shall confirm to specifications.

Prepared by	Checked by	Approved by For Harman Finochem Ltd.
Rushikesh Mule (Officer QA) Date : 28/02/2026	Aniket Patil (Asst. Manager QC) Date : 28/02/26	Pravin Bhonde (Jr. Manager QA) Date : 28/02/26

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