Harman

Harman Finochem Ltd.

FACTORY : PLOT NO. A-100, A-100/1, A-100/2 & D-1,MIDC INDL. AREA, SHENDRA, AURANGABAD - 431 007.
PH.: + 91 (240) 2622001 / 6605500/ 6605580 • TELEFAX+ 91 (240) 2622002 • E-mail:info@harmanfinochem.com

CERTIFICATE OF ANALYSIS

Product	**METFORMIN HYDROCHLORIDE USP**		
NDC NO.	**66064-1100-01**		
Manufacturer	**M/s. HARMAN FINOCHEM LTD.**		
Batch Number	SC0100545	A. R. Number	SFPC00573
Date of Manufacturing	March 2023	Date of Expiry	February 2028
Dispatch Quantity	50.0 Kg.	Drug Lic. No.	AD / 065
Date of Release	06/05/2023		

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)	0.012%	Metformin Related Compound A: NMT 0.02%. (1-Cyanoguanidine) (LOQ – 0.00025%)
	0.015%	Any Other Impurity: NMT 0.1% (LOQ – 0.0005%) (In-house Limit: NMT 0.05%).
	0.05%	Total impurities: NMT 0.5% (In-house Limit: 0.20%).
Loss on Drying	0.2%	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)	100.0%	NLT 98.0% and NMT 102.0%.
Residual Solvents (By GC)		**ICH Limit** **In house Limit**
Isopropyl Alcohol (IPA)	BQL	NMT 5000 ppm NMT 500 ppm (LOQ -40 ppm)
Dimethyl Formamide (DMF)	BQL	NMT 880 ppm NMT 450 ppm (LOQ -40 ppm)
Additional In-house Specification:		
Impurity F Dimethylamine content (DMA) By HPLC	0.003%	NMT 0.05% (LOQ – 0.0011%)
Bulk Density / Tapped density	0.50 g/ml	Untapped : 0.30 to 0.70 g/ml.
	0.70 g/ml	Tapped : 0.50 to 0.90 g/ml.
#Particle Size Distribution (Using Sieve Shaker)	96 % passes through 150 µm	90% should passes through 150 µm (100# mesh)
Nitrosamine Impurity (By GC-MS/MS)	BQL	N-nitrosodimethylamine (NDMA) : NMT 0.032 ppm (LOQ : 0.008 ppm)

Remarks: The Batch Complies as per USP, In-house and Customer Specifications.
*These tests are for information only.
Particle Size Distribution test analysis completed on 20/06/2023 and COA reissued.

Prepared by	Checked by	Approved by
M.R. Shelke	Dilip Bhangale	For Harman Finochem Ltd.
(Jr. Executive QA)	(A.G.M. QC)	Tarun Kumar Mishra
Date : 20/06/23	Date : 20/06/23	(A.G.M. QA)
		Date : 20/06/23

KalChem INTERNATIONAL Compounding Chemicals You Can Trust