



Harman Finochem Limited

FACTORY : PLOT NO. E-7, E-8, E-9 & E-53, M.I.D.C. INDUSTRIAL AREA, CHIKALTHANA,
CHHATRAPATI SAMBAJINAGAR - 431006, MAHARASHTRA, INDIA.
PH.: +91 (240) 6601382 / 6601300 • E-mail : factory@harmanfinochem.com

CERTIFICATE OF ANALYSIS

PRODUCT		METHYLPHENIDATE HYDROCHLORIDE U.S.P.	
MANUFACTURER		M/s. HARMAN FINOCHEM LTD.	
BATCH NUMBER	CE0100114	A. R. NUMBER	HFCHFP25000447
DATE OF MANUFACTURING	MARCH 2025	EXPIRY DATE	FEBRUARY 2030
DISPATCH QUANTITY	60.000 kg	DRUG LIC. NUMBER	AD / 001
DATE OF RELEASE	09.04.2025		
TESTS	RESULTS	SPECIFICATIONS	
#Description	White fine crystalline powder	White, odorless, fine crystalline powder. Its solutions are acid to litmus.	
#Solubility	Complies	Freely soluble in water and in methanol, soluble in alcohol; slightly soluble in chloroform and in acetone.	
Identification	Complies	A. The IR spectrum of sample preparation is concordant with spectrum of Methylphenidate hydrochloride working standard.	
	Complies	B. The retention time of the major peak in the chromatogram of the sample preparation corresponds to that in the chromatogram of the standard preparation as obtained in the Assay by HPLC.	
	Complies	C. Meets the requirement for the silver nitrate Precipitate test for chloride.	
Loss on drying	0.3%	NMT 0.5% (Dry in vacuum at 60°c for 4 hours)	
Residue on ignition	0.07%	NMT 0.1%	
Organic impurities (by HPLC)			
Erythro (R,S) isomer	Below LOQ	Not more than 0.15% (LOQ: 0.0125%)	
Related compound A	0.02%	Not more than 0.5% (LOQ: 0.0125%)	
Unspecified impurity	0.02%	Not more than 0.10% (LOQ: 0.006%)	
Total impurities	0.1%	Not more than 1.0%	
Assay (On Dried Basis)	99.7%	NLT 98.0% and NMT 102.0%	
Residual Solvents (by GC)		Limits	LOQ
Methanol	256 ppm	Not more than 3000 ppm	20 ppm
Ethanol	Below LOQ	Not more than 5000 ppm	40 ppm
Isopropyl chloride	Below LOQ	Not more than 25 ppm	0.4 ppm
Isopropyl alcohol	231 ppm	Not more than 5000 ppm	20 ppm
Methylene chloride	Below LOQ	Not more than 600 ppm	10 ppm
Ethyl acetate	Below LOQ	Not more than 5000 ppm	10 ppm
In-house Tests			
Particle size by Malvern 3000	D (10) - 3.7 µm D (50) - 21 µm D(90) - 77 µm	For information For information For information	
*N-Nitrosopiperidine	Below LOQ	NMT 21 ppm (LOQ: 0.3 ppm)	
*N-Nitroso ritalinic acid	Below LOQ	NMT 21 ppm (LOQ: 0.4 ppm)	
*N-Nitroso methylphenidate	Below LOQ	NMT 21 ppm (LOQ: 0.6 ppm)	
*Summation of impurities	0.04 ppm	NMT 21 ppm	
Remarks: The Batch Complies as per U. S. P. and In-house Specification.			
Note: # These tests are for information only.			
* This test is performed once in 5 th batch or minimum one batch per year if number of batches less than 5.			
Prepared by	Checked by	Approved and Released by For Harman Finochem Ltd.	
 (Mr. B.R.Darkonde) (Executive Q. A.) Date : 09/04/25	 (Dr. S.Chakraborty) (Dy. Manager Q. C.) Date : 09/04/25	 (Mr. A.S.Gaikwad) (D.G.M. Q. A.) Date: 09/04/25	