






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

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Product	PHENYTOIN SODIUM EP 10		
Manufacturer	M/s. HARMAN FINOCHEM LTD.		
Batch Number	SB0100294	A. R. Number	SFPB00284
Date of Manufacturing	February 2022	Date of Expiry	January 2027
Dispatch Quantity	25.0 Kg.	Drug LIC. Number	AD/065
Date of Release	15/03/2022		
TESTS	RESULTS	SPECIFICATIONS / LIMITS	
Characters	White powder	White or almost white, very hygroscopic, crystalline powder.	
*Appearance			
*Solubility	Complies	Soluble in Purified water and in ethanol (96%), practically insoluble in methylene chloride.	
Identification (First identification : A,C)	Complies	A) FT-IR Spectrum of sample should concordant with the spectrum of Phenytoin Sodium working standard.	
	Complies	C) It gives reaction (b) of sodium.	
Appearance of solution	Complies	The solution is clear and not more intensely coloured than reference solution BY ₆ .	
Related Substances (By HPLC)	0.0% BQL 0.0% BDL 0.1%	Impurity C : NMT 0.2% (LOQ – 0.0125%) Impurity D : NMT 0.15% (LOQ – 0.05%) Impurity E : NMT 0.3% (LOQ – 0.006%) Unspecified impurities : NMT 0.10% (LOQ – 0.006%) Total impurities : NMT 0.5%	
Free Phenytoin	0.3 ml of 0.1M NaOH	NMT 1.0 ml of 0.1M sodium hydroxide is required to change the color of the indicator to pink.	
Water (By KF)	0.5%	Maximum 3.0% (Determined on ~1.00 g).	
Assay (On Anhydrous Basis) By HPLC	99.8%	Between 98.0% and 102.0%	
Residual solvent (By GC)	BQL	Methanol : NMT 3000 ppm (LOQ – 333 ppm)	
Additional In-house Test:			
Particle Size Distribution (Using Malvern Particle Size Analyser-3000, Wet Method)	D(0.1) – 1.8 µm D(0.5) – 11 µm D(0.9) – 54 µm	D(0.1) – For Information D(0.5) – For Information D(0.9) – For Information	
Untapped Density	0.47 g/ml	For Information	
Tapped Density	0.68 g/ml	For Information	
Remarks: The Batch Complies as per EP 10 and In-house Specification.			
*These tests are for information only.			
Prepared by  (Sr. Officer QA) Date: 28/10/22	Checked by  (A.G.M. QC) Date: 28/10/22	Approved by For Harman Finochem Ltd.  (A.G.M. QA) Date: 28/10/22	