



# 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

## METAPHARMACEUTICAL

N DE LOTE:

0130724

12/07/2024

CERTIFICATE OF ANALYSIS			
Product	PHENYTOIN SODIUM EP		
Manufacturer	M/s. HARMAN FINOCHEM LTD.		
Batch Number	SC0100637A	A. R. Number	SFPC01218
Date of Manufacturing	May 2023	Date of Expiry	April 2028
Dispatch Quantity	10.0 kg	Drug LIC. Number	AD/065
Date of Release	15/09/2023		
TESTS	RESULTS	SPECIFICATIONS / LIMITS	
Characters	White crystalline 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 <sub>6</sub> .	
Related Substances (By HPLC )	0.0% BQL 0.1% 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	0.4 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)	0.6%	Maximum 3.0% (Determined on ~1.00 g).	
Assay (On Anhydrous Basis) By HPLC	100.6%	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) – 1.2 µm D(0.5) – 13 µm D(0.9) – 80 µm	D(0.1) – For Information D(0.5) – For Information D(0.9) – For Information	
Untapped Density	0.43 g/ml	For Information	
Tapped Density	0.68 g/ml	For Information	
Remarks: The Batch Complies as per EP and In-house Specification.			
*These tests are for information only.			
Prepared by   (Sr. Officer QA) Date: 21/06/24	Checked by   (Dy. Manager QC) Date: 21/06/24	Approved by For Harman Finochem Ltd.   (A.G.M. QA) Date: 21/06/24	