



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) 2822001 / 6605500/ 6605580 • TELEFAX+ 91 (240) 2822002 • E-mail: info@harmanfinochem.com

CERTIFICATE OF ANALYSIS

CERTIFICATE OF ANALYSIS			
Product	PHENYTOIN SODIUM EP		
Manufacturer	M/s. HARMAN FINOCHEM LTD.		
Batch Number	PS/1819009	A. R. Number	PS/009/1819
Date of Manufacturing	July 2018	Date of Expiry	June 2023
Dispatch Quantity	50.0 kg	Drug LIC. Number	AD/065
Date of Release	19/02/2019		
TESTS	RESULTS	SPECIFICATIONS / LIMITS	
Characters	White hygroscopic 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)	BQL	Impurity C : NMT 0.2% (LOD - 0.006% & LOQ – 0.0125%)	
	BQL	Impurity D : NMT 0.15% (LOD - 0.025% & LOQ – 0.05%)	
	0.019%	Impurity E : NMT 0.3% (LOD - 0.003% & LOQ – 0.006%)	
	BDL	Unspecified impurities : NMT 0.10% (LOD - 0.003% & LOQ – 0.006%)	
	0.027%	Total impurities : NMT 0.5%	
Free Phenytoin	0.10 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)	0.62%	Maximum 3.0% (Determined on- 1.00 g).	
Assay (On Anhydrous Basis) By HPLC	100.2%	Between 98.0% and 102.0%	
Residual solvent (By GC)	23 ppm	Methanol : NMT 3000 ppm (LOD – 167 ppm & LOQ – 333 ppm)	
Additional In-house Test:			
Particle Size (By Malvern Particle Size Analyser)	d(0.1) – 4.7 µm d(0.5) – 17 µm d(0.9) – 48 µm	d(0.1) – For Information d(0.5) – For Information d(0.9) – For Information	
Untapped Density	0.36 g/ml	For Information	
Tapped Density	0.54 g/ml	For Information	
Remarks: The Batch Complies as per EP and In-house Specification.			
*These tests are for information only.			
Prepared by S.B. Shejul (Officer QA) Date: 14/10/20	Checked by Santosh Pande (A.G.M. QC) Date: 14/10/20	Approved by For Harman Finochem Ltd. Tarun Kumar Mishra (Sr. Manager QA) Date: 14/10/20	

REGD. OFFICE : 107 - A, VINAY BHAVYA COMPLEX, 159 - A, C.S.T. ROAD, KALINA, SANTACRUZ (E), MUMBAI - 400 098. INDIA
PHONES : (022) 2652 8080 / 67330100 / 67330101 • FAX: 91-22-2652 8285 • E-mail : info@harmanfinochem.com

Betr.: 25 kgs. netto PHENYTOINE NATRIUM EP 9.6, NON CEP MATERIAAL VAN ONZE PRINCIPAAL
HARMAN FINOCHEM LTD. (UW ART. CODE 9200102) zoals geleverd met onze factuur No. 21036-1.008
d.d. 02.03.2021.



“UTAG” B.V.