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Harman Finochem Ltd.

FACTORY : PLOT NO. A-100, A-100/1, A-100/2 & D-1, MIDC INDL. AREA, SHENDRA, AURANGABAD-431 007.
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CERTIFICATE OF ANALYSIS			
Product	DIPHENYLHYDANTOIN SODIUM U.S.P. 38 (PHENYTOIN SODIUM U.S.P. 38)		
Manufacturer	M/s. HARMAN FINOCHEM LTD.		
Batch Number	PS/1516014	A. R. Number	PS/014/1516
Date of Manufacturing	January 2016	Date of Expiry	December 2020
Dispatch Quantity	1000.0 kg	Drug LIC. Number	AD/065
Date of Release	03.02.2016		
TESTS	RESULTS	SPECIFICATIONS / LIMITS	
Description	White powder	White, odorless powder. Is some what hygroscopic and on exposure to air gradually absorbs carbon dioxide.	
Solubility	Complies	Freely soluble in water, the solution usually being somewhat turbid due to partial hydrolysis and absorption of carbon dioxide. Soluble in alcohol. Practically insoluble in ether and in chloroform.	
Identification	Complies Complies Complies	A. I. R. Spectrum of sample is concordant with the spectrum of Phenytoin sodium working standard. B. Responds to general test for sodium. C. The retention time of the major peak of the sample solution corresponds to that of the standard solution as obtained in the Assay.	
Loss on drying	0.48%	NMT 2.5 % (Dry it for 105 °C for 4 hours).	
Organic Impurities (By HPLC)	Below LOQ 0.044% Below LOQ 0.023% 0.124%	Phenytoin Related Compound A: NMT 0.5 %. (Diphenyl glycine) Phenytoin Related Compound B: NMT 0.9 %. (Diphenyl hydantoic acid) Benzophenone : NMT 0.1 % (LOQ - 0.006%). Any individual unspecified impurity: NMT 0.10 %. Total Impurities : NMT 0.9 %. (Excluding Benzophenone)	
Heavy Metals	Complies	NMT 20 ppm.	
Assay (On Dried Basis) (By HPLC)	99.7%	NLT 98.0% and NMT 102.0% of $C_{15}H_{11}N_2NaO_2$.	
Residual solvent (By GC)	39 ppm	Methanol : NMT 3000 ppm	
Additional In-house Test:			
Related Compounds (By HPLC)	Below LOQ	Impurity D (In-house): NMT 0.15% (Ph. Eur. Impurity D) (LOQ. 0.05%)	
Particle size	90% - 66 µm 100% - 163 µm	90% < 75 µm 100% < 400 µm	
Remarks: The Batch Complies as per U.S.P 38 and In-house Specification.			
Prepared by (Officer Q. A.) Date: 05/02/16	Checked by (Executive Q. C.) Date: 05/02/16	Approved by For Harman Finochem Ltd. (D.G.M. Q. A.) Date: 05/02/16	

Genehmigt Schütz & Co

Kirsten Lühring, 11-14, 09-02 2016, Schütz & Co. (GmbH & Co. KG)

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