Hetero Drugs Limited

S.No.s, 213, 214 & 255, Bonthapally Village, Jinnaram Mandal, Medak District, Telangana state, INDIA.
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HETERO DRUGS LIMITED QA RELEASED QUALITY ASSURANCE

Issued on 31/05/2015 hee 31/05/2015

CERTIFICATE OF ANALYSIS

Product	: Topiramate	Reference STP No.	: TA-005-02, TA-003-02
Batch No	: TA0180515	Reference	: In-House
Date of Manufacture	: May - 2015	Batch Quantity	: 227.28 Kg
Analytical Report No.	: TA0019/15	Date of Analysis	: 31/05/2015
		Expiry date	: April - 2017
		Status	: Initial certification

S.No.	Test	Specifications	Results	Reference
1	Description	An off-white to white crystalline powder	White crystalline powder	Visual inspection
2	Solubility	Soluble in methanol and in aqueous 0.1N aqueous Sodium hydroxide solution and slightly soluble in water	Complies	Visual inspection
3	Identification by	IR : The infra red absorption spectrum of the finely ground sample in KBr dispersion compressed into a disc should exhibit maxima only at the same wave numbers as that of a similar preparation of Topiramate Working Standard.	Matches with the standard spectrum	USP < 197 K > In-House
		HPLC: The retention time of the major peak in the chromatogram of the assay preparation-1 corresponds to that in the chromatogram of the standard preparation, as obtained in the assay.	Matches with the standard	USP < 621 > In-House
4	pH test	Should be between 4.50 and 6.00	4.9	USP < 791 > In-House
5	Specific Rotation (on anhydrous and solvent free basis)	Should be between -29° and -35°	(-) 31°	USP < 781 > In-House
6	Water content	Not more than 0.50 % w/w	0.09 % w/w	USP < 921 > In-House
7	Residue on ignition	Not more than 0.10 % w/w	0.06 % w/w	USP < 281 > In-House
8	Heavy Metals	Not more than 0.001 % w/w	Less than 0.001%w/w	USP < 231 > In-House
9	Chromatographic purity by HPLC	D-Fructose (Impurity-A) : Not more than 0.10 %	Below QL (QL=0.005%)	USP < 621 > In-House
		2,3,4,5-Bis-O-(1-methylethylidene)-β-D-fructopyranose. (Impurity-B) : Not more than 0.10%	0.02% (QL=0.007%)	
		2,3,4,5-Bis-O-(1-methylethylidene)-β-D-fructopyranosyl Sulphonyl chloride. (Impurity-C) : Not more than 0.10%	Below QL (QL=0.034%)	
		Max.single unknown impurity : Not more than 0.10 %	0.01%	
		Total impurities : Not more than 0.40 %	0.04%	
10	Sulphate & Sulphamate content by HPLC	Sulphamate content : Not more than 50 ppm	Below QL (QL=4.3ppm)	USP < 621 > In-House
		Sulphate content : Not more than 50 ppm	Below QL (QL=4.7ppm)	
11	*Residual solvents by GC	Isopropyl alcohol : Not more than 800 ppm	172 ppm (QL=29ppm)	USP < 467 > In-House
		Dichloromethane : Not more than 200 ppm	Below QL (QL=50ppm)	
		n-Hexane : Not more than 100 ppm	Below QL (QL=18ppm)	
		Ethyl acetate : Not more than 200 ppm	Below QL (QL=35ppm)	
		Pyridine : Not more than 100 ppm	Below QL (LQ=14ppm)	
		Toluene : Not more than 200 ppm	Below QL (QL=9ppm)	
		Total Residual Solvents : Not more than 1200 ppm	172 ppm	

Compiled by : Date : 31/05/15

Checked by : Date : 31/05/15

Authorised signatory : Date : 31/05/15

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S.No.	Test	Specifications	Results	Reference
12	Assay by HPLC (on anhydrous and solvent free basis)	Should be between 98.5 % w/w and 101.5 % w/w	100.1 % w/w	USP < 621 > In-House
13	Melting Range	Between 122°C and 126°C.	123°C and 125°C	USP < 741 > In-House
14	Particle size analysis	d (0.1) : Not more than 10 µm	3.8 µm	USP < 429 > In-House
		d (0.5) : Not more than 50 µm	15.4 µm	
		d (0.9) : Not more than 100 µm	59.3 µm	
15	Bulk density	Untapped : 0.3 g/mL to 0.6 g/mL	0.34 g/mL	USP < 616 > In-House
		Tapped : 0.5 g/mL to 0.9 g/mL	0.69 g/mL	

* No potential for the class-1 solvents as specified by ICH or < 467 > USP to be present in Topiramate,as they are not used in the manufacturing process. The material if tested for these solvents, will comply with the established standards.

The product **conforms** to the above Specifications.

Compiled by : Date : 31/05/15

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