

Hetero Drugs Limited

S.No.s, 213, 214 & 255, Bonthapally Village, Jinnaram Mandal, Medak District, Telangana state, INDIA.

Phone : + 091-8458-275314/ 275777, Fax: +91-8458-275271



CERTIFICATE OF ANALYSIS

Product : Topiramate
Batch No : TA0170515
Date of Manufacture : May - 2015
Analytical Report No. : TA0018/15

Reference STP No. : TA-005-02, TA-003-02
Reference : In-House
Batch Quantity : 226.68 Kg
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-I 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°	(-) 32°	USP < 781 > In-House
6	Water content	Not more than 0.50 % w/w	0.10 % 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 %	0.02%	
		Total impurities : Not more than 0.40 %	0.05%	
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	169 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	169 ppm	

Compiled by : *Buuz*

Checked by : *R. Beey*

Authorised signatory : *MM*

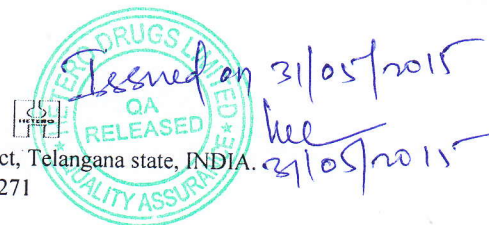
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S.No.	Test	Specifications	Results	Reference
12	Assay by HPLC (on anhydrous and solvent free basis)	Should be between 98.5 % w/w and 101.5 % w/w	99.9 % w/w	USP < 621 > In-House
13	Melting Range	Between 122°C and 126°C.	123°C and 125°C	USP < 741 > In-House
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	15.8 µm	
		d (0.9) : Not more than 100 µm	59.4 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-I 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 : *Ram*
Date : 31/05/2015

Checked by : *R. Healy*
Date : 31/05/15

Authorised signatory : *MM*
Date : 31/05/15