



Divi's Laboratories Limited

CERTIFICATE OF ANALYSIS

Product: LEVETIRACETAM				Rev. No.	OS/13/01
Grade	EP	Q.A.R No.	DUI/FP/1301/000484	Sl.No	OS-049S
Batch Number	OS-0070113	Mfg. date	JAN 2013	Total pages	1
Quantity	650 KG	Retest date	DEC 2017	Page No.	1

STANDARD (PHARMACOPOEIAL)			
Sl.No.	Test	Specification	Observation
01	Appearance	White or almost white powder	White crystalline powder
02	Solubility	Very soluble in water, soluble in Acetonitrile and practically insoluble in Hexane	Complies
03	Identification by a) Specific Optical Rotation b) IR Spectrum	-76° to -82° Conforms with working standard spectrum	-79.91° Concordant with WS
04	Appearance of solution	The solution is clear and not more intensely colored than reference solution BY ₆	Complies
05	Enantiomeric Purity by HPLC (Area%) (2R)-2-(2-oxopyrrolidin-1-yl) butanamide ((R)-etiracetam)- (Impurity-D)	Maximum 0.8%	0.02%
06	Related substances by HPLC (%w/w) i) (2RS)-2-(2-oxopyrrolidin-1-yl) butanoic acid (Impurity-A) ii) (2Z)-2-(2-oxopyrrolidin-1-yl)but-2-enamide (Impurity-B) iii) Unspecified impurity iv) Sum of Unspecified impurities v) Total impurities	Not more than 0.3% Not more than 0.05% Not more than 0.05% Not more than 0.1% Not more than 0.4%	Not detected Not detected Not detected Not detected <0.01%
07	Heavy metals	Not more than 10 ppm	Less than 10 ppm
08	Water	Maximum 0.5%w/w	0.04%w/w
09	Sulphated ash	Not more than 0.1%w/w	0.05%w/w
10	Assay by HPLC (Anhydrous substance)	Between 98.0%w/w and 102.0%w/w	99.73%w/w
ADDITIONAL TEST			
11	Triethylamine	Not more than 15 ppm	5 ppm
12	Residual solvents i) Methylene chloride ii) Chloroform iii) Ethyl acetate iv) Isopropyl alcohol	Not more than 100 ppm Not more than 60 ppm Not more than 200 ppm Not more than 1000 ppm	Not detected Not detected Not detected 180 ppm

Remarks: "The above material fully conforms to the Pharm.Eur. Specification and the additional requirements of the European Certificate of Suitability R0 - CEP 2011 - 219-REV 00"

Signature	Analyst	Person in charge of testing
	<i>[Signature]</i> 25/02/13	<i>[Signature]</i> 25/02/13

"An ISO-9001, ISO-14001 and OHSAS-18001 Triple certified company"

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