



Divi's Laboratories Limited

CERTIFICATE OF ANALYSIS

Product: LEVETIRACETAM				Rev. No.	OS/13/01
Grade	EP	Q.A.R No.	DU1/FP/1308/004233	Sl.No	OS-188S
Batch Number	OS-1200813	Mfg. date	AUG 2013	Total pages	1
Quantity	200 Kg	Retest date	JUL 2018	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	-76° to -82°	-79.77°
	b) IR Spectrum	Conforms with working standard spectrum	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%	0.04%
06	Related substances by HPLC (%w/w) i) (2RS) -2-(2-oxopyrrolidin-1-yl) butanoic acid (Impurity-A)	Not more than 0.3%	Not detected
	ii) (2Z) -2-(2-oxopyrrolidin-1-yl)but-2-enamide(Impurity-B)	Not more than 0.05%	Not detected
	iii) Unspecified impurity	Not more than 0.05%	Not detected
	iv) Sum of Unspecified impurities	Not more than 0.1%	Not detected
	v) Total impurities	Not more than 0.4%	0.04%
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	99.72%w/w
ADDITIONAL TEST			
11	Triethylamine	Not more than 15 ppm	2 ppm
12	Residual solvents i) Methylene chloride	Not more than 100 ppm	Not detected
	ii) Chloroform	Not more than 60 ppm	Not detected
	iii) Ethyl acetate	Not more than 200 ppm	Not detected
	iv) Isopropyl alcohol	Not more than 1000 ppm	149 ppm
13	Particle size	----	10% passes through 20 microns 50% passes through 111 microns 90% passes through 295 microns

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"

	Analyst	Person in-charge of testing
Signature	<i>P. Sub</i> 30/08/13	<i>AP</i> 30/08/13

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

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