

MSN Pharmachem Pvt. Ltd.

Factory : Plot no: 212,A,B,C,D, IDA Phase-II, Pashamylaram,
Patancheru (Mandal), Medak Dist-502 307, Andhra pradesh, India
Tel:+91-8455-224116, Fax:+91-8455-224115



WORKING STANDARD CERTIFICATE OF ANALYSIS

Product	: PREGABALIN	Evaluated with	: PEBVIIIARS0801
Working STD No.	: PVWS1201	Date of Manufacture	: June 2012
Source B.No	: PV0240612	To be Retested on	: June 2014
A.R. No.	: BP120276	Date of Analysis	: 17.07.2012
Reference	: In-House	Specification No.	: QC-FPPV-001/02
Storage: Preserve in well closed containers and store at controlled room temperature			
S.No	TEST	RESULT	SPECIFICATION
8.0	Related substances by HPLC		
8.1	Highest individual unspecified impurity	0.02%	Not more than 0.10%
8.2	Total impurities	0.03%	Not more than 0.50%
9.0	Enantiomeric Purity by HPLC		
9.1	R-Isomer	0.04%	Not more than 0.15%
10.0	Assay by HPLC (On anhydrous basis)	99.8%w/w	Not less than 98.0% and Not more than 102.0% w/w
11.0	Residual Solvents by GC		
11.1	Methanol	167 ppm	Not more than 3000 ppm
11.2	2-Propanol	Less than LOQ(115 ppm)	Not more than 5000 ppm
11.3	Dichloromethane	Not detected	Not more than 600 ppm
11.4	Toluene	Not detected	Not more than 890 ppm

Note : This material can be used as Working standard for Regular analysis.

Compiled by : *[Signature]*

Checked by : *[Signature]*

Head, Quality Control : *[Signature]*

Date : 17.07.12

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