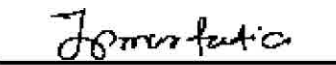


Approved By: Rupesh Kelaskar, Senior Manager, Quality Control

Date: 1/4/2013 8:43:11AM



Approved By: R. Jigar Marfatia, Manager, Quality Assurance

Date: 1/7/2013 10:08:38AM

Version: 1

Effective 07-Jan-2013

Specification and Certificate of Analysis

Material: PREGABALIN
Material #: 327973
Batch No.: KL5525
Storage Precautions: Store in well closed container at controlled room temperature (15 to 30°C)
Manufacturer: SRINI PHARMACEUTICALS LTD
Manufacturing Plant: The site was not provided
Manufacturer Lot No.: PRB/0280313B
Testing Site: Bangalore, India
A.R. No.: 09R1300452

<u>TEST</u>	<u>SPECIFICATION</u>		<u>RESULTS</u>
	<u>METHOD</u>	<u>ACCEPTANCE CRITERIA</u>	
APPEARANCE	G-74	White to off-white powder.	Conforms
IDENTIFICATION	PREG-DS-61-IN	IR Spectrum: Corresponds to standard	Conforms
IDENTIFICATION	PREG-DS-23-IN	HPLC Retention time: Corresponds to standard	Conforms
X-RAY DIFFRACTION	PREG-DS-62-IN	XRD: Corresponds to standard	Conforms
WATER CONTENT	G-18	NMT 0.5%	0.0%
RESIDUE ON IGNITION	G-14	NMT 0.1% w/w	0.0%
HEAVY METALS	GM-7	NMT 10 ppm	Less than 10 ppm

RELATED COMPOUNDS	PREG-DS-22-IN	PRB-I: NMT 0.15% PRB-II: NMT 0.15% PRB-III: NMT 0.15% Unidentified Impurity: NMT 0.10% each Total Impurities: NMT 0.5%	ND ND BRT ND BRT
ENANTIOMERIC PURITY	PREG-DS-23-IN	PRB-IV: NMT 0.20%	ND
RESIDUAL SOLVENTS	PREG-DS-32-IN	Ethanol: NMT 5000 ppm Isopropyl alcohol: NMT 5000 ppm Ethyl acetate: NMT 5000 ppm Isobutyl alcohol: NMT 5000 ppm	ND ND ND ND
RESIDUAL SOLVENTS	PREG-DS-33-IN	Triethylamine: NMT 320 ppm	ND
RESIDUAL SOLVENTS	PREG-DS-34-IN	Chloroform: NMT 60 ppm	ND
ASSAY	PREG-DS-12-IN	98.0 to 102.0% (anhydrous and solvent free basis)	100.3%
BULK AND TAPPED DENSITY	G-64	Bulk density: 0.4 to 0.7 g/mL Tapped density: 0.6 to 0.8 g/mL	0.6g/mL 0.7g/mL

Legend:

BRT: Below Reporting Threshold

ND: None Detected

Reporting Threshold: 0.05%

PRB-I: (R)-(-)-3-Carbamoylmethyl-5-methyl-hexanoic acid (Synthetic Impurity)

PRB-II: 3-Isobutyl glutaric acid (Synthetic Impurity / Degradation Product)

PRB-III: 4-Isobutyl-pyrrolidin-2-one (Degradation Product)

PRB-IV: (R)-(-)-3-Aminomethyl-5-methyl-hexanoic acid (R-Isomer) (Synthetic Impurity)

The sample complies to the above specifications.

Laboratory Approved By:

~~S. N. Santhosh~~

Santhosh S M, Team Leader

Date: 05/16/2013 16:35:40

QA Approved By:

S. Venkatesh

Venkatesh Murthy, Team Leader

Date: 05/16/2013 16:44:06

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Report Date: 16-May-2013
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