

Approved By: Praveen SM, Deputy Manager

Date: 4/12/2016 12:24:57PM



Approved By: Raghavendra Maiya, Manager, Product Release & Logistics

Date: 4/12/2016 4:37:42PM

Specification and Certificate of Analysis

Material: PREGABALINA CAPSULAS 75 MG APO 30 BLS RFF
Material #: 64452
Batch No.: NE2641
Storage Precautions: Store at temperature not exceeding 25°C
Date Manufactured: 02/20/2017
Package Type: 10's Blister Pack (ALU-PVC), three such blisters packed in a carton (1 x 3 x 10's)
Batch Size: 22221 EA
Expiry Date: 01/31/2019
Testing Site: Bangalore, India
A.R. No.: 09F1700335

<u>TEST</u>	<u>SPECIFICATION</u>		<u>RESULTS</u>
	<u>METHOD</u>	<u>ACCEPTANCE CRITERIA</u>	
APPEARANCE	G-74	Hard gelatin capsules with opaque orange cap and opaque white body. Imprinted APO P75 in black ink. Filled with white powder.	Conforms
IDENTIFICATION	PREG-IMCP-10-IN	HPLC Retention Time: Corresponds to standard	Conforms
IDENTIFICATION	PREG-IMCP-60-IN	UV Spectrum: Corresponds to standard	Conforms
AVERAGE WEIGHT	G-23	Average Fill Weight: 116.4 to 123.6 mg Average Weight: 143.0 to 175.0 mg	119.6mg 158.9mg
ASSAY	PREG-IMCP-10-IN	95.0 to 105.0 % (% of claim)	102.9%
DISSOLUTION	PREG-IMCP-40-IN	As per USP/EP Q = 80% Time = 15 minutes	Mean: 98% %RSD: 0.8% Minimum: 97% Maximum: 99% PASS STAGE1

UNIFORMITY OF DOSAGE UNITS	G-28	As per USP/EP	Mean: 102.9% % RSD: 3.5% Minimum: 97.1% Maximum: 108.3% AV: 10.0 PASS STAGE1
DEGRADATION PRODUCTS	PREG-IMCP-20-IN	PRB-II: NMT 0.2% PRB-III: NMT 0.2% PRB-V: NMT 0.2% Unidentified Impurity: NMT 0.2% each Total Impurities: NMT 1.0%	BRT BRT ND ND BRT

Legend:

BRT: Below Reporting Threshold

ND: None Detected

Reporting Threshold: 0.1%

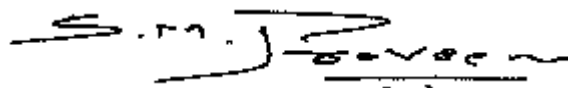
PRB-II: 3-Isobutyl glutaric acid (Synthetic impurity/Degradation product)

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

PRB-V: 1-((2S,3R,4R,5R,6R)-4,5-dihydroxy-6-(hydroxymethyl)-2-((2R,3S,4R,5R,6S)-4,5,6-trihydroxy-2-(hydroxymethyl)tetrahydro-2H-pyran-3-yloxy)tetrahydro-2H-pyran-3-yl)-4-isobutylpyrrolidin-2-one

The sample complies to the above specifications.

Laboratory Approved By:



Praveen SM, Manager

Date: 03/27/2017 10:54:07

QA Approved By:



Adithya M V, Senior Reviewer I

Date: 03/27/2017 11:49:44

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