

## QUALITY CONTROL DEPARTMENT

LAMOTRIGINE Ph. Eur.

### CERTIFICATE OF ANALYSIS

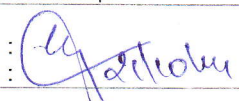
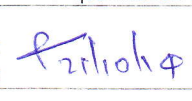
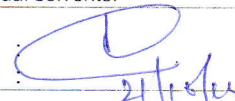
Commercial batch #	: LAM/1410113	Dispatch Qty.	: 250.00 Kg
In-house Batch #	: 4LAM3/14082	Batch Qty.	: 354.50 Kg
Mfg. Date	: October – 2014	Expiry date	: September – 2019
Specification #	: QCD/SP/FP/LAM/001-R <sub>6</sub>	Method #	: QCD/MH/FP/LAM/001-R <sub>6</sub>

Sl. #.	TESTS	OBSERVATIONS	STANDARD LIMIT
1	Characters - Appearance - Solubility	Almost white powder Meets the requirement	White or almost white powder Very slightly soluble in water, Slightly soluble in anhydrous ethanol.
2	Identification by IR absorption	Meets the requirement	IR spectrum in KBR dispersion of sample should be concordant with that of reference/working standard.
3	Heavy metals	Less than 10 ppm	Not more than 10 ppm
4	Loss on drying at 105°C [at a pressure not exceeding 5.25 mmHg (0.7 kPa) for 3 hrs]	0.20%	Not more than 0.5%
5	Sulphated ash	0.04%	Not more than 0.1%
6	Related substances by HPLC - Impurity A - Impurity E - Impurity F - Impurity G - Schiff's base - Single unknown impurity - Total impurities	Below detection limit (0.01%) Below detection limit (0.01%) Below detection limit (0.01%) Below detection limit (0.01%) Below detection limit (0.03%) Below detection limit Below detection limit	Not more than 0.10% Not more than 0.10% Not more than 0.10% Not more than 0.10% Not more than 0.10% Not more than 0.10% Not more than 0.2%
7	Assay by Potentiometry (dry basis)	100.4%	Not less than 99.0% and Not more than 101.0%w/w
8	Additional tests		
a)	Residual solvents - Isopropyl alcohol	Below detection limit ( 10 ppm)	Not more than 1000 ppm
b)	X –Ray diffraction	Meets the requirement	X-Ray diffraction pattern of sample should be concordant with that of reference / working standard.
c)	Particle size by Malvern Mastersizer - Less than 150 µm	100%	Not less than 90%

**Remark:** The product complies with above mentioned specification+ Customer's specification (CSO#CSO/481-R<sub>1</sub>/12).

**Storage condition:** Store in airtight containers below 25°C.

**Note:** The values given in the parenthesis are for limit of detection and limit of quantitation of respective purity and residual solvents.

PREPARED BY : 	CHECKED BY : 	APPROVED BY : 
Date	Date	Date

A Jubilant Pharma Company

#### OUR VALUES



#### Jubilant Generics Limited

(Formerly Jubilant Life Sciences Division)  
# Plot No. 18, 56, 57 & 58  
KIADB Industrial Area, Nanjangud-571 302  
Mysore, Karnataka, India  
Tel: +91 8221 228402-8  
Fax: +91 8221 228410/11  
www.jubilantpharma.com

#### Corporate Office :

I-A, Sector 16-A  
Noida-201 301, UP India  
Tel: +91 120 4361000  
Fax: +91 120 4234895,4234896

#### Regd Office :

I-A, sector 16-A  
Noida-201 301, UP, India  
CIN:U24100UP2013FLC060821