

QUALITY CONTROL DEPARTMENT

LAMOTRIGINE Ph. Eur.







CERTIFICATE OF ANALYSIS

Commercial batch #	: LAM/1308087	Dispatch Qty.	: 100.00 Kg
In-house Batch #	: 4LAM3/13068	Batch Qty.	: 362.00 Kg
Mfg. Date	: August – 2013	Expiry date	: July – 2018
Specification #	: QCD/SP/FP/LAM/001-R ₆	Method #	: QCD/MH/FP/LAM/001-R ₆
Sl. #.	TESTS	OBSERVATIONS	STANDARD LIMIT
1	Characters - Appearance - Solubility	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	0.03%	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)	99.7%	Not less than 99.0% and Not more than 101.0%w/w
8	Additional tests a) Residual solvents - Isopropyl alcohol b) X –Ray diffraction c) Particle size by Malvern Mastersizer - Less than 150 µm	Below detection limit (10 ppm) Meets the requirement 100%	Not more than 1000 ppm X-Ray diffraction pattern of sample should be concordant with that of reference / working standard. Not less than 90%

Remark: The product complies with above mentioned specification+ Customer's specification (CSO#CSO/481-R₁/12).

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 Bhartia Company

OUR VALUES



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