European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
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Certification of Substances Division

IOL CHEMICALS AND PHARMACEUTICALS LTD
Mr Vijay SINGLA
Village Fatehgarh Channa, Trident Complex
Mansa Road
India-148101 Barnala, Punjab

CEP_RZ_PH_2013-066-0757705
LF / av

Strasbourg, 5 February 2015

Re: R0-CEP 2013-066-Rev 00 / Lamotrigine

Dear Mr SINGLA,

Please find enclosed the certificate granted for **Lamotrigine** following the evaluation of the dossier.

If you find a mistake on the CEP, you should notify EDQM within 3 months. After this deadline, any complaint will no longer be considered valid.

You are informed that the EDQM may share the assessment reports for this application with the National Competent Authorities of the Ph. Eur. Member states, and with the EMA including all CHMP and CVMP members and their experts.

In accordance with Resolution AP-CSP (07) 1, and as mentioned on the certificate, the submitted dossier must be updated after any change to its content, and this must be reported to EDQM.

This certificate is valid 5 years. It is your responsibility to ask for the renewal of the certificate in due time.

Yours faithfully,

Annick DEGARDIN
Scientific Officer

Hélène BRUGUERA
Head of Division

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 – Fax: +33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
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Certification of Substances Division

Certificate of suitability
No. R0-CEP 2013-066-Rev 00

Name of the substance:
LAMOTRIGINE

Name of holder:
IOL CHEMICALS AND PHARMACEUTICALS LTD
Village Fatehgarh Channa, Trident Complex
Mansa Road
India-148 101 Barnala, Punjab

Site(s) of production:
SEE ANNEX 1

After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site(s) of production listed in annex, we certify that the quality of the substance is suitably controlled by the current version of the monograph **LAMOTRIGINE** no. 1756 of the European Pharmacopoeia, current edition including supplements.

In the last steps of the synthesis ethanol is used as solvent. Its residual content is limited by the test for loss on drying described in the monograph with a limit of not more than 0.5%.

The re-test period of the substance is 18 months if stored in a double polyethylene bag with silica gel sachets in between placed in a polyethylene drum.

The holder of the certificate has declared the absence of use of material of human or animal origin in the manufacture of the substance.

The submitted dossier must be updated after any significant change that may alter the quality, safety or efficacy of the substance.

Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice and in accordance with the dossier submitted.

Failure to comply with these provisions will render this certificate void.

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F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 – Fax: +33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
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This certificate is granted within the framework of the procedure established by the European Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from **5 February 2015**. Moreover, it is granted according to the provisions of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has one annex of 1 page.
This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 5 February 2015

DECLARATION OF ACCESS *(to be filled in by the certificate holder under their own responsibility)*

IOL CHEMICALS AND PHARMACEUTICALS LTD, as holder of the certificate of suitability

R0-CEP 2013-066-Rev 00 for Lamotrigine

hereby authorises .....
(*name of the pharmaceutical company*)

to use the above-mentioned certificate of suitability in support of their application(s) for the following Marketing Authorisation(s): (*name of product(s) and marketing number(s), if known*)

The holder also certifies that no significant changes to the operations as described in the CEP dossier have been made since the granting of this version of the certificate.

Date and Signature (*of the CEP holder*):

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F-67081 Strasbourg (France)
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Internet: http://www.edqm.eu

Certification of Substances Division

Annex 1: Site(s) of production for R0-CEP 2013-066-Rev 00

Production of Lamotrigine:
IOL CHEMICALS AND PHARMACEUTICALS LTD
Village Fatehgarh Channa, Trident Complex
Mansa Road
India-148 101 Barnala, Punjab