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Certification of Substances Division

Certificate of suitability

No.

Name of the substance.

Micronised

Name of holder:

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 no. 1121 of the European Pharmacopoeia, current edition including supplements, only if it is supplemented by the test(s) mentioned below, based on the analytical procedure(s) given in annex

In the last steps of the synthesis acetone and ethyl acetate are used as solvents. Their residual content is limited by the test for loss on drying described in the monograph, with a limit of not more than 0.5%

(Annex 2)

The substance is packed in double polyethylene bags placed in a fibre 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.

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Internet : http://www.edqm.eu

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.

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 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 two annexes, the first of 6 pages and the second of 4 pages.

This certificate has:

lines

Strasbourg, 7 August 2013

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

M/S LAKE CHEMICALS PRIVATE LIMITED, as holder of the certificate of suitability

hereby authorises

mpany)

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 h of the certificate

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