3.2.R.3 Certificate(s) of Suitability

edqm
European Directorate for the Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Certification of Substances Division

Certificate of suitability No. R1-CEP 2004-056-Rev 00

Name of the substance:
MESALAZINE

Name of holder:
SYNTESE A/S
Industriholmen 11-13
Denmark-2650 Hvidovre

Site(s) of production:
HY-GRO CHEMICALS PHARMTEK PRIVATE LIMITED (crude substance)
Plot No. 174, Progressive Industrial Society
Narsapur Taluq, Medak District
India-502 325 Miyapur, Bollaram, Andhra Pradesh

BEC CHEMICALS PRIVATE LIMITED (crude substance)
Plot No. 24, M.I.D.C.
Dhatav, Raigad District
India-402 116 Roha, Maharashtra

SYNTESE A/S (whole process)
Industriholmen 11-13
Denmark-2650 Hvidovre

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R0-CEP 2004-056-REV 03

After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site(s) of production mentioned above, we certify that the quality of the substance is suitably controlled by the current version of the monograph **MESALAZINE** no. 1699 of the European Pharmacopoeia, current edition including supplements.

Any other impurity than those mentioned in the monograph and detected by the test for related substances of the monograph is individually limited to not more than 0.05%.

In the last steps of the synthesis water, ethanol and isopropanol 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%.

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Internet : http://www.edqm.eu

AFAQ ISO 9001

The re-test period of the substance is 36 months if stored in a LDPE bag placed inside either a stainless steel drum or millboard drum lined with a plastic bag, or in a LDPE/Al/PET laminated film in a PP bag placed inside a cardboard box.

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.

This certificate is renewed from **3 August 2010** according to the provisions of Resolution AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 29 June 2010

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

Syntese A/S, as holder of the certificate of suitability

R1-CEP 2004-056-Rev 00 for MESALAZINE

hereby authorises FERRING
(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)*

Drug products containing mesalazine drug substance

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)*: 06.09.2010

Rasmus Turin, Regulatory Officer

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