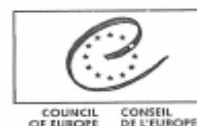


3.2.R.3 Certificate(s) of Suitability

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European Directorate for the
Quality of Medicines & HealthCare

Certification of Substances Division



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

1 *Name of the substance:*
2 **MESALAZINE**

3 *Name of holder:*
4 **SYNTESE A/S**
5 Industriholmen 11-13
6 Denmark-2650 Hvidovre

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

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

16 **SYNTESE A/S** (whole process)
17 Industriholmen 11-13
18 Denmark-2650 Hvidovre

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

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

26 Any other impurity than those mentioned in the monograph and detected by the test
27 for related substances of the monograph is individually limited to not more than
28 0.05%.

29 In the last steps of the synthesis water, ethanol and isopropanol are used as
30 solvents. Their residual content is limited by the test for loss on drying described in
31 the monograph, with a limit of not more than 0.5%.

Address: 7, allée Kastner, CS 30026 - F - 67081 Strasbourg (France)
Telephone: 33 (0) 3 88 41 30 30 - Fax: 33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
Internet : <http://www.edqm.eu>



- 32 The re-test period of the substance is 36 months if stored in a LDPE bag placed
33 inside either a stainless steel drum or millboard drum lined with a plastic bag, or in a
34 LDPE/Al/PET laminated film in a PP bag placed inside a cardboard box.
- 35 The holder of the certificate has declared the absence of use of material of human or
36 animal origin in the manufacture of the substance.
- 37 The submitted dossier must be updated after any significant change that may alter the
38 quality, safety or efficacy of the substance.
- 39 Manufacture of the substance shall take place in accordance with the Good
40 Manufacturing Practice and in accordance with the dossier submitted.
- 41 Failure to comply with these provisions will render this certificate void.
- 42 This certificate is renewed from **3 August 2010** according to the provisions of
43 Resolution AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive
44 2001/82/EC and any subsequent amendment, and the related guidelines
- 45 This certificate has:
46 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): <u>06.07.2010</u>  Rasmus Turin, Regulatory Officer
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