COUNCIL OF EUROPE CONSEIL DE L'EUROPE

European Directorate for the Quality of Medicines
Division Certification of Substances

Certificate of suitability
No. R1-CEP 2001-118-Rev 01

Name of the substance:
MEAT EXTRACT M1
Ref. 19022

Name of holder:
ORGANOTECHNIE SAS
27 Avenue Jean Mermoz
F - 93120 La Courneuve

Site of production:
ORGANOTECHNIE SAS
27 Avenue Jean Mermoz
F - 93120 La Courneuve

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R1-CEP 2001-118-REV 00

After examination of the information provided on the origin of raw material(s) and type of tissue(s) used and on the manufacturing process for this substance on the site of production mentioned above, F - 93120 La Courneuve, we certify that the substance **MEAT EXTRACT M1** meets the criteria described in the current version of the monograph Products with risk of transmitting agents of animal spongiform encephalopathies no. 1483 of the European Pharmacopoeia, current edition including supplements.

- country(ies) of origin of source materials:
- nature of animal tissues used in manufacture:

The submitted dossier must be updated after any significant change that may alter the quality, safety or efficacy of the substance, or that may alter the risk of transmitting animal spongiform encephalopathy agents.

Manufacture of the substance shall take place in accordance with a suitable quality assurance system such as ISO 9001, and in accordance with the dossier submitted.

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

Postal Address: 226 Avenue de Colmar (entrance rue Schertz) B.P. 907 — F 67029 Strasbourg Cedex 1
Telephone: 03.88.41.30 30 - Fax 03.88.41.27.71 – Web site : http://www.pheur.org

28 The certificate is valid provided that there has been no deterioration in the TSE status of the
29 country(ies) of origin of the source material.

30 This certificate is renewed from **7 March 2006** according to the provisions of Resolution AP-
31 CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive 2001/82/EC and any
32 subsequent amendment, and the related guidelines.

33 This certificate has 33 lines only.

Dr. A. ARTIGES
Director of the Quality of Medicines

Strasbourg, 13 July 2006

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

ORGANOTECHNIE SAS, as holder of the certificate of suitability

R1-CEP 2001-118-Rev 01 for MEAT EXTRACT M1

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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