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 2001-336-Rev 00

Name of the substance:
BACTERIOLOGICAL BILE
(Product code 10.236)

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

Site(s) of production:
ORGANOTECHNIE SAS
27 Avenue Jean Mermoz
France-93120 La Courneuve

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R0-CEP 2001-336-REV 02

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(s) of production mentioned above, we certify that the substance **BACTERIOLOGICAL BILE** 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.

– countries 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.

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

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

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

This certificate is renewed from **13 February 2008** 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 & HealthCare

Strasbourg, 6 February 2008

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 2001-336-Rev 00 for BACTERIOLOGICAL BILE

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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