COUNCIL OF EUROPE CONSEIL DE L'EUROPE

European Directorate for the Quality of Medicines
Certification Unit

Certificate of suitability No. R1-CEP 2000-335-Rev 00

Name of the substance:
DEOXYCHOLIC ACID

Name of holder:
ICE SRL INDUSTRIA CHIMICA EMILIANA
Via Sicilia 8, 10
I - 42100 Reggio Emilia

Site of production:
ICE SRL INDUSTRIA CHIMICA EMILIANA
Via Sicilia 8, 10
I - 42100 Reggio Emilia

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R0-CEP 2000-335-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 of production mentioned above, I - 42100 Reggio Emilia, we certify that the substance **DEOXYCHOLIC ACID** 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:	Argentina, Australia, Brazil, Canada, Colombia, Costa Rica, Paraguay, Uruguay, Venezuela, USA, Mexico, South Africa and India
- nature of animal tissues used in manufacture:	Bovine bile

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 GMP, 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

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

This certificate is renewed from **31 May 2006** 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 35 lines only.

Dr. A. ARTIGES
Director of the Quality of Medicines

Strasbourg, 12 May 2006

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

ICE SRL INDUSTRIA CHIMICA EMILIANA, as holder of the certificate of suitability

R1-CEP 2000-335-Rev 00 for DEOXYCHOLIC ACID

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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