European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Certification of Substances Department

Certificate of suitability
No. R1-CEP 2013-161-Rev 00

Name of the substance:
OX BILE BACTERIOLOGICAL
Cat 184

Name of holder:
BIOTECNICA INTERNACIONAL, S.A. DE C.V.
Articulo 123 numero 104, Colonia Huertos y Granjas de Brenamiel
San Jacinto Amilpas
Mexico-68285 Oaxaca

Site(s) of production:
BIOTECNICA INTERNACIONAL, S.A. DE C.V.
Articulo 123 numero 104, Colonia Huertos y Granjas de Brenamiel
San Jacinto Amilpas
Mexico-68285 Oaxaca

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R0-CEP 2013-161-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(s) of production mentioned above, we certify that the substance **OX BILE BACTERIOLOGICAL** 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 of origin of source materials:
  Australia

- 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, and in accordance with the dossier submitted.

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)
Tel: +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 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 **21 March 2019** according to the provisions of Resolution AP-CSP (07) 1, 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, 1 March 2019

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

BIOTECNICA INTERNACIONAL, S.A. DE C.V., as holder of the certificate of suitability

R1-CEP 2013-161-Rev 00 for Ox Bile Bacteriological

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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F-67081 Strasbourg (France)
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