

Certification of Substances Department

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

1 *Name of the substance:*

2 **OX BILE BACTERIOLOGICAL**
3 Cat 184

4 *Name of holder:*

5 **BIOTECNICA INTERNACIONAL, S.A. DE C.V.**
6 Artículo 123 numero 104, Colonia Huertos y Granjas de Brenamiel
7 San Jacinto Amilpas
8 Mexico-68285 Oaxaca

9 *Site(s) of production:*

10 **BIOTECNICA INTERNACIONAL, S.A. DE C.V.**
11 Artículo 123 numero 104, Colonia Huertos y Granjas de Brenamiel
12 San Jacinto Amilpas
13 Mexico-68285 Oaxaca

14 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
15 **R0-CEP 2013-161-REV 00**

16 After examination of the information provided on the origin of raw material(s) and type of tissue(s)
17 used and on the manufacturing process for this substance on the site(s) of production mentioned
18 above, we certify that the substance **OX BILE BACTERIOLOGICAL** meets the criteria described
19 in the current version of the monograph Products with risk of transmitting agents of animal
20 spongiform encephalopathies no. 1483 of the European Pharmacopoeia, current edition including
21 supplements.

22 – Country of origin of source materials:
23 Australia

24 – Nature of animal tissues used in manufacture:
25 Bovine bile

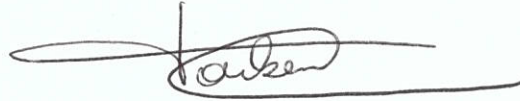
26 The submitted dossier must be updated after any significant change that may alter the quality,
27 safety or efficacy of the substance, or that may alter the risk of transmitting animal spongiform
28 encephalopathy agents.

29 Manufacture of the substance shall take place in accordance with a suitable quality assurance
30 system, and in accordance with the dossier submitted.

31 Failure to comply with these provisions will render this certificate void.
32 The certificate is valid provided that there has been no deterioration in the TSE status of the
33 country(ies) of origin of the source material.

34 This certificate is renewed from **21 March 2019** according to the provisions of Resolution AP-CSP
35 (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment,
36 and the related guidelines.

37 This certificate has:
38 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)*: