

**Certification of Substances Department**

**Certificate of suitability**  
**No. R1-CEP 2013-161 - Rev 01**

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 Granjas y Huertos 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 Granjas y Huertos Brenamiel

12 San Jacinto Amilpas

13 Mexico-68285 Oaxaca

14 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**  
15 **R1-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

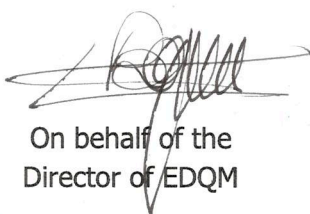
24 – Nature of animal tissues used in manufacture:

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, 7 April 2022

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 01 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)*: