

## Certificate of suitability No. R1-CEP 2001-299-Rev 01

1 *Name of the substance:*

2 **BEEF EXTRACT POWDER**

3 Product code 150

4 *Name of holder:*

5 **BIOTECNICA INTERNACIONAL SA DE CV**

6 Artículo 123 # 104, Col. Huertos y Granjas de Brenamiel

7 San Jacinto Amilpas

8 Mexico-68285 Oaxaca

9 *Site(s) of production:*

10 **BIOTECNICA INTERNACIONAL SA DE CV**

11 Artículo 123 # 104, Col. Huertos y Granjas de Brenamiel

12 San Jacinto Amilpas

13 Mexico-68285 Oaxaca

14 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**  
15 **R1-CEP 2001-299-REV 00**

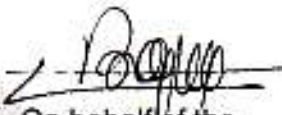
16 After examination of the information provided on the origin of raw material(s) and type of  
17 tissue(s) used and on the manufacturing process for this substance on the site(s) of  
18 production mentioned above, we certify that the substance **BEEF EXTRACT POWDER**  
19 meets the criteria described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

22 – countries of origin of source materials: Mexico, United States of  
23 America and New Zealand

24 – nature of animal tissues used in manufacture: Bovine skeletal muscle and  
25 bovine bones (free from skulls,  
26 spinal cord and vertebrae)

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

- 30 Manufacture of the substance shall take place in accordance with a suitable quality  
31 assurance system such as ISO 9001, and in accordance with the dossier submitted.
- 32 Failure to comply with these provisions will render this certificate void.
- 33 The certificate is valid provided there has been no deterioration in the TSE status of the  
34 country(ies) of origin of the source material.
- 35 This certificate is renewed from **23 October 2007** according to the provisions of  
36 Resolution AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive  
37 2001/82/EC and any subsequent amendment, and the related guidelines.
- 38 This certificate has:  
39 lines.

  
On behalf of the  
Director of EDQM & HealthCare



Strasbourg, 11 February 2008

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

**Biotechnica Internacional Sa de CV**, as holder of the certificate of suitability

**R1-CEP 2001-299-Rev 01 for BEEF EXTRACT POWDER**

hereby authorises LABORATORIOS CONDA, S.A.  
*(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)*

BEEF EXTRACT POWDER, - Extract (Cat. No. 1700); Casein C.C Peptone  
(Cat. No. 1603) and its application for Pronadisa<sup>TM</sup> Micro and  
Molecular Biology Dehydrated Culture Media.

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)*: MARCH 5, 2008