

## Certificate of suitability No. R1-CEP 2001-291-Rev 01

1 *Name of the substance:*

2 **MEAT PEPTONES**

3 Product codes: 102, 130, 140, 144 and 147

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 2001-291-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 **MEAT PEPTONES** meets  
19 the criteria described in the current version of the monograph Products with risk of  
20 transmitting agents of animal spongiform encephalopathies no. 1483 of the European  
21 Pharmacopoeia, current edition including supplements.

22 – country (ies) of origin of source materials: New Zealand  
23 – nature of animal tissues used in manufacture: Bovine lungs

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

27 Manufacture of the substance shall take place in accordance with a suitable quality  
28 assurance system such as ISO 9001, and in accordance with the dossier submitted.

29 Failure to comply with these provisions will render this certificate void.

- 30 The certificate is valid provided there has been no deterioration in the TSE status of the  
31 country(ies) of origin of the source material.
- 32 This certificate is renewed from 2 December 2007 according to the provisions of  
33 Resolution AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive  
34 2001/82/EC and any subsequent amendment, and the related guidelines.
- 35 This certificate has:  
36 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 2001-291-Rev 01 for MEAT PEPTONES**

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)  
MEAT PEPTONE; Meat Peptone (Cat. No. 1600); Bacteriological Peptone  
(Cat. No. 1616); Protease Peptone (Cat. 1609); Protease Peptone # 3  
(Cat. No. 1607); Tryptone (Cat. No. 1612) and its application for  
Pronadisa TM 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

