

Certification of Substances Department

Certificate of suitability
No. R1-CEP 2001-291 - Rev 04

Name of the substance:

MEAT PEPTONES

Product codes: 102, 130, 144, 147 and 310

Name of holder:

BIOTECNICA INTERNACIONAL S.A. DE C.V.

Articulo 123 numero 104, Colonia Granjas y Huertos Brenamiel

San Jacinto Amilpas

Mexico-68285 Oaxaca

Site(s) of production:

BIOTECNICA INTERNACIONAL S.A. DE C.V.

Articulo 123 numero 104, Colonia Granjas y Huertos Brenamiel

San Jacinto Amilpas

Mexico-68285 Oaxaca

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R1-CEP 2001-291 - REV 03

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 **MEAT PEPTONES** 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:
New Zealand

– Nature of animal tissues used in manufacture:
Bovine lungs

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.

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

31 The certificate is valid provided that there has been no deterioration in the TSE status of the
32 country(ies) of origin of the source material.

33 This certificate is renewed from **2 December 2007** according to the provisions of Resolution AP-
34 CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent
35 amendment, and the related guidelines.

36 This certificate has:
37 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 2001-291 - Rev 04 for Meat peptones

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)*: