European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé
COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Certification of Substances Department

Certificate of suitability
No. R1-CEP 2007-074 - Rev 03

Name of the substance:
FOETAL BOVINE SERUM

Name of holder:
BIO WEST SAS
Rue De La Caille
France-49340 Nuaillé

Site(s) of production:
BIO WEST SAS
Rue De La Caille
France-49340 Nuaillé

BIO NUTRIENTES DO BRASIL LTDA
Avenida Copacabana 177, Sala124
Empresarial 18 Do Forte Barueri
Brazil-06472-001 São Paulo

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R1-CEP 2007-074 - REV 02

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 **FOETAL BOVINE SERUM** 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.

- Countries of origin of source materials:
  Argentina, Brazil, Chile, Colombia, Costa Rica, Denmark, France, Ireland, Italy, Mexico, Panama, Paraguay, Spain, United States of America and Uruguay

- Nature of animal tissues used in manufacture:
  Foetal bovine blood

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.

Address: 7 Allée Kastner, CS 30026
F-67081 Strasbourg (France)
Tel: +33 (0) 3 88 41 30 30 – e-mail: cep@edqm.eu
Internet: https://www.edqm.eu

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.

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

This certificate is renewed from **18 January 2013** according to the provisions of Resolution AP-CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 12 July 2023

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

BIO WEST SAS, as holder of the certificate of suitability

R1-CEP 2007-074 - Rev 03 for Foetal bovine serum

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*):