

Certification of Substances Division

**Certificate of suitability**  
**No. R0-CEP 2007-074-Rev 01**

1 *Name of the substance:*  
2 **FOETAL BOVINE SERUM**

3 *Name of holder:*  
4 **BIO WEST SAS**  
5 Rue De La Caille  
6 France-49340 Nuaille

7 *Site(s) of production:*  
8 **BIO WEST SAS**  
9 Rue De La Caille  
10 France-49340 Nuaille

11 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**  
12 **R0-CEP 2007-074-REV 00**

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

19 – country (ies) of origin of source materials: Brazil, Chile, Costa Rica, Mexico,  
20 Panama, Paraguay and Uruguay

21 – nature of animal tissues used in manufacture: Foetal bovine blood

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

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

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