



European Directorate for the Quality of Medicines
Certification Unit

Certificate of suitability
No. R1-CEP 2000-188-Rev 00

1 *Name of the substance:*

2 **FOETAL BOVINE SERUM**

3 *Name of holder:*

4 **MOREGATE EXPORTS LTD**

5 137 Ward Street

6 NZ - Hamilton

7 *Site of production:*

8 **MOREGATE EXPORTS LTD**

9 137 Ward Street

10 NZ - Hamilton

11 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
12 **R0-CEP 2000-188-REV 02**

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 of production
15 mentioned above, NZ - Hamilton, we certify that the substance **FOETAL BOVINE SERUM** meets
16 the criteria described in the current version of the monograph Products with risk of transmitting
17 agents of animal spongiform encephalopathies no. 1483 of the European Pharmacopoeia, current
18 edition including supplements.

19 - country of origin of source materials: New Zealand

20 - nature of animal tissues used in manufacture: Foetal Calf Blood

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

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

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

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

- 29 This certificate is renewed from **27 March 2006** according to the provisions of Resolution AP-
30 CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive 2001/82/EC and any
31 subsequent amendment, and the related guidelines.
32 This certificate has 32 lines only.



Dr. A. ARTIGES
Director of the Quality of Medicines


Strasbourg, 10 March 2006

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

MOREGATE EXPORTS LTD, as holder of the certificate of suitability
R1-CEP 2000-188-Rev 00 for FOETAL BOVINE SERUM
EXAMPLE CERTIFICATE DOWNLOADED FROM WESITE
WWW.TCSBIOSCIENCES.CO.UK
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)*:  14-03-06