



European Directorate for the Quality of Medicines
Certification Unit

Certificate of suitability
No. R1-CEP 2000-187-Rev 00

1 *Name of the substance:*

2 **FOETAL BOVINE SERUM**

3 *Name of holder:*

4 **MOREGATE BIOTECH (MOREGATE EXPORTS PTY LTD)**

5 56 Banya Street

6 Bulimba

7 AUS - 4171 Brisbane, Queensland

8 *Site of production:*

9 **MOREGATE EXPORTS PTY LTD**

10 56 Banya Street

11 Bulimba

12 AUS - 4171 Brisbane, Queensland

13 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
14 **R0-CEP 2000-187-REV 02**

15 After examination of the information provided on the origin of raw material(s) and type of
16 tissue(s) used and on the manufacturing process for this substance on the site of production
17 mentioned above, AUS - 4171 Brisbane, Queensland, we certify that the substance **FOETAL**
18 **BOVINE SERUM** meets the criteria described in the current version of the monograph Products
19 with risk of transmitting agents of animal spongiform encephalopathies no. 1483 of the European
20 Pharmacopoeia, current edition including supplements.

21 - country of origin of source materials: Australia

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

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

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

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

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

- 31 This certificate is renewed from **9 March 2006** according to the provisions of Resolution AP-
32 CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive 2001/82/EC and any
33 subsequent amendment, and the related guidelines.
34 This certificate has 34 lines only.



Dr. A. ARTIGES
Director of the Quality of Medicines

Strasbourg, 6 March 2006

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

MOREGATE BIOTECH (MOREGATE EXPORTS PTY LTD), as holder of the certificate of suitability

R1-CEP 2000-187-Rev 00 for FOETAL BOVINE SERUM

EXAMPLE CERTIFICATE DOWNLOADED FROM WEBSITE

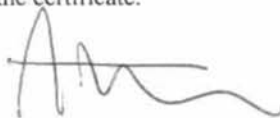
WWW.TCSBIOSCIENCES.CO.UK

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)*:



13 - 03 - 2006