



European Directorate for the Quality of Medicines  
Certification Unit

Certificate of suitability  
No. R1-CEP 2000-174-Rev 00

1 *Name of the substance:*

2 **ADULT BOVINE SERUM**

3 Defibrinated

4 *Name of holder:*

5 **MOREGATE EXPORTS LTD**

6 137 Ward Street

7 NZ - Hamilton

8 *Sites of production:*

9 **MOREGATE EXPORTS LTD**

10 137 Ward Street

11 NZ - Hamilton

12 **AUCKLAND MEAT PROCESSORS**

13 131 Portage Road

14 NZ - Auckland

15 **RICHMOND PACIFIC**

16 Rangitane Rd., Whakatu Rd.

17 NZ - Hastings

18 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**

19 **R0-CEP 2000-174-REV 02**

20 After examination of the information provided on the origin of raw material(s) and type of  
21 tissue(s) used and on the manufacturing process for this substance on the sites of production  
22 mentioned above, NZ – Hamilton, NZ – Auckland and NZ – Hastings we certify that the  
23 substance **ADULT BOVINE SERUM** meets the criteria described in the current version of the  
24 monograph Products with risk of transmitting agents of animal spongiform encephalopathies  
25 no. 1483 of the European Pharmacopoeia, current edition including supplements.

26 - country of origin of source materials: New Zealand

27 - nature of animal tissues used in manufacture: Bovine blood

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

- 31 Manufacture of the substance shall take place in accordance with a suitable quality assurance  
32 system such as GMP, and in accordance with the dossier submitted.
- 33 Failure to comply with these provisions will render this certificate void.
- 34 The certificate is valid provided that there has been no deterioration in the TSE status of the  
35 country(ies) of origin of the source material.
- 36 This certificate is renewed from **19 February 2006** according to the provisions of Resolution  
37 AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive 2001/82/EC and any  
38 subsequent amendment, and the related guidelines.
- 39 This certificate has 39 lines only.



Dr. A. ARTIGES  
Director of the Quality of Medicines

Strasbourg, 6 February 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 2000-174-Rev 00 for ADULT BOVINE SERUM**

EXAMPLE CERTIFICATE DOWNLOADED FROM WEBSITE

hereby authorises WWW.TCSBIOSCIENCES.CO.UK  
*(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)*: