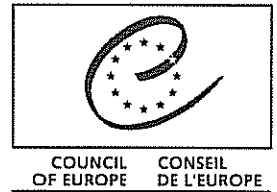




European Directorate for the  
Quality of Medicines & HealthCare



Certification of Substances Division

## Certificate of suitability No. R1-CEP 2001-093-Rev 01

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

3 *Name of holder:*  
4 **MOREGATE EXPORTS LTD**  
5 137 Ward Street  
6 New Zealand- Hamilton

7 *Sites of production:*  
8 **MOREGATE EXPORTS LTD**  
9 137 Ward Street  
10 New Zealand- Hamilton

11 **PPCS/RICHMOND**  
12 Pacific & Teahora Plants  
13 Rangitane And Whakatu Roads  
14 New Zealand- Hastings

15 **WALLACE CORPORATION LIMITED**  
16 New Zealand- Waitoa

17 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**  
18 **R1-CEP 2001-093-REV 00**

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

25 - country of origin of source materials : New Zealand  
26 - nature of animal tissues used in manufacture : Adult bovine blood

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

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

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

34 The certificate is valid provided 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 **7 December 2006** according to the provisions of  
37 Resolution AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive  
38 2001/82/EC and any subsequent amendment, and the related guidelines.

39 This certificate has:  
40 lines.



Dr. A. ARTIGES  
Director of EDQM & HealthCare

Strasbourg, 16 April 2007

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 2001-093-Rev 01 for ADULT 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)*: