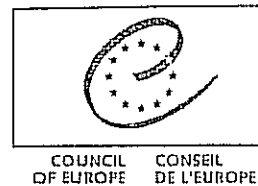




European Directorate for the
Quality of Medicines & HealthCare



Certification of Substances Division

Certificate of suitability No. R1-CEP 2005-191-Rev 00

1 *Name of the substance:*

2 **BOVINE SERUM ALBUMIN**

3 *Name of holder:*

4 **MOREGATE EXPORTS PTY LTD**

5 56 Banya Street

6 Bulimba

7 Australia-4171 Brisbane, Queensland

8 *Site(s) of production:*

9 **MOREGATE EXPORTS PTY LTD**

10 56 Banya Street

11 Bulimba

12 Australia-4171 Brisbane, Queensland

13 THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE

14 **R0-CEP 2005-191-REV 00**

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(s) of~~
17 production mentioned above, we certify that the substance **BOVINE SERUM**
18 **ALBUMIN** meets the criteria described in the current version of the monograph
19 Products with risk of transmitting agents of animal spongiform encephalopathies
20 no. 1483 of the European Pharmacopoeia, current edition including supplements.

21 – country(ies) of origin of source materials: Australia

22 – nature of animal tissues used in manufacture: Bovine blood

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

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

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

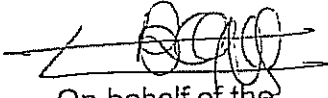
Address: 7, allée Kastner, CS 30026 - F - 67081 Strasbourg (France)
Telephone: 33 (0) 3 88 41 30 30 - Fax: 33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu
Internet : <http://www.edqm.eu>

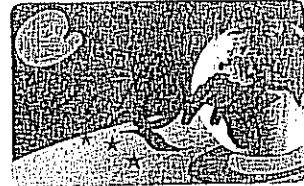


29 The certificate is valid provided there has been no deterioration in the TSE status of the
30 country(ies) of origin of the source material.

31 This certificate is renewed from **22 November 2010** according to the provisions of
32 Resolution AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive
33 2001/82/EC and any subsequent amendment, and the related guidelines.

34 This certificate has:
35 lines.


On behalf of the
Director of EDQM



Strasbourg, 8 November 2010

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

Moregate Exports Pty Ltd, as holder of the certificate of suitability

R1-CEP 2005-191-Rev 00 for BOVINE SERUM ALBUMIN

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)*: