



European Directorate for the
Quality of Medicines & HealthCare



Certification of Substances Division

Certificate of suitability No. R1-CEP 2003-205-Rev 00

1 *Name of the substance:*

2 **BOVINE SERUM ALBUMIN**

3 *Name of holder:*

4 **MOREGATE EXPORTS LTD**

5 137 Ward Street

6 New Zealand- Hamilton

7 *Site(s) of production:*

8 **MOREGATE EXPORTS LTD**

9 56 Banya Street

10 Bulimba

11 Australia-4171 Brisbane

MOREGATE EXPORTS LTD

131 Portage Road

New Zealand- Auckland

12 **MOREGATE EXPORTS LTD**

13 137 Ward Street

14 New Zealand- Hamilton

MOREGATE EXPORTS LTD

Main Road

New Zealand- Thames

15 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**

16 **R0-CEP 2003-205-REV 01**

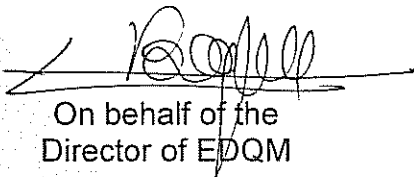
17 After examination of the information provided on the origin of raw material(s) and type of
18 tissue(s) used and on the manufacturing process for this substance on the site(s) of
19 production mentioned above, we certify that the substance **BOVINE SERUM ALBUMIN**
20 meets the criteria described in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

23 — country(ies) of origin of source materials: New Zealand

24 — nature of animal tissues used in manufacture: Bovine blood

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

- 28 Manufacture of the substance shall take place in accordance with a suitable quality
29 assurance system such as GMP, and in accordance with the dossier submitted.
- 30 Failure to comply with these provisions will render this certificate void.
- 31 The certificate is valid provided there has been no deterioration in the TSE status of the
32 country(ies) of origin of the source material.
- 33 This certificate is renewed from **26 May 2009** according to the provisions of Resolution
34 AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive 2001/82/EC
35 and any subsequent amendment, and the related guidelines.
- 36 This certificate has:
37 lines.


On behalf of the
Director of EDQM



Strasbourg, 26 May 2009

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 2003-205-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)*: