



Council of Europe
EUROPEAN DIRECTORATE FOR
THE QUALITY OF MEDICINES

CERTIFICATION OF SUITABILITY OF MONOGRAPHS
OF THE EUROPEAN PHARMACOPOEIA

Certificate No. RO-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 NZ - Hamilton

7 *Sites of production:*

8 **MOREGATE EXPORTS LTD**

9 137 Ward Street

10 NZ - Hamilton

MOREGATE EXPORTS LTD

Portage Road

NZ - Auckland

11 **MOREGATE EXPORTS LTD**

12 Main Road

13 NZ - Thames

MOREGATE EXPORTS LTD

56 Banya Street

Bulimba

AUS - 4171 Brisbane

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 sites of production
17 mentioned above, NZ - Hamilton, NZ - Auckland, NZ - Thames, AUS - 4171 Brisbane, we
18 certify that the substance **BOVINE SERUM ALBUMIN** meets the criteria described in the
19 monograph Products with risk of transmitting agents of animal spongiform encephalopathies
20 (no. 1483, Ph. Eur. 4th Ed. and any subsequently revised version).

21 - country(ies) of origin of source materials: New Zealand

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

23 The submitted dossier must be updated every five years or after any significant modification of
24 the manufacturing method, the country(ies) of origin or the nature of the tissues used that may
25 alter the risk of transmitting animal spongiform encephalopathy agents or require changing the
26 specifications of the monograph.

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

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

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

32 This certificate is granted within the framework of the procedure established by the European
33 Pharmacopoeia Commission [Resolution AP-CSP (93) 5 as amended] for a period of five years
34 starting from **26 May 2004**. Moreover, it is granted according to the provisions of Directive
35 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related
36 guidelines.

37 This certificate has 37 lines only.



Dr. A. ARTIGES
Director of the Quality of Medicines

Strasbourg, 26 May 2004

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

R0-CEP 2003-205-Rev 00 for BOVINE SERUM ALBUMIN

EXAMPLE CERTIFICATE DOWNLOAD 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)*

Date and Signature *(of the CEP holder)*: