



**European Directorate for the Quality of Medicines
Certification Unit**

Certificate No. R0-CEP 2005-191-Rev 00

1 *Name of the substance:*

2 **BOVINE SERUM ALBUMIN**

3 *Name of holder:*

4 **MOREGATE EXPORTS PTY LTD**

5 Banya Street 56

6 Bulimba

7 AUS - 4171 Brisbane, Queensland

8 *Site of production:*

9 **MOREGATE EXPORTS PTY LTD**

10 Banya Street 56

11 Bulimba

12 AUS - 4171 Brisbane, Queensland

13 After examination of the information provided on the origin of raw material(s) and type of
14 tissue(s) used and on the manufacturing process for this substance on the site of production
15 mentioned above, AUS - 4171 Brisbane, Queensland, we certify that the substance **BOVINE**
16 **SERUM ALBUMIN** meets the criteria described in the current version of the monograph Products
17 with risk of transmitting agents of animal spongiform encephalopathies no. 1483 of the European
18 Pharmacopoeia, current edition including supplements.

19 - country(ies) of origin of source materials:

Australia

20 - nature of animal tissues used in manufacture:

Bovine blood

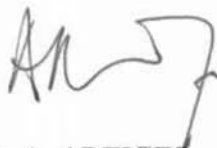
21 The submitted dossier must be updated every five years or after any significant modification of
22 the manufacturing method, the country(ies) of origin or the nature of the tissues used that may
23 alter the risk of transmitting animal spongiform encephalopathy agents or require changing the
24 specifications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

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

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

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

- 30 This certificate is granted within the framework of the procedure established by the European
31 Pharmacopoeia Commission [Resolution AP-CSP (93) 5 as amended] for a period of five years
32 starting from **22 November 2005**. Moreover, it is granted according to the provisions of
33 Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related
34 guidelines.
35 This certificate has 35 lines only.



Dr. A. ARTIGES
Director of the Quality of Medicines

Strasbourg, 22 November 2005

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

R0-CEP 2005-191-Rev 00 for BOVINE SERUM ALBUMIN

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)*

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