



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

**Certificate No. R0-CEP 2005-192-Rev 00**

1 *Name of the substance:*

2 **ADULT BOVINE PLASMA**

3 *Name of holder:*

4 **MOREGATE EXPORTS PTY LTD**

5 Banya Street 56

6 Bulimba

7 AUS - 4171 Brisbane, Queensland

8 *Sites of production:*

9 **MOREGATE EXPORTS PTY LTD**

10 175 Riverview Road

11 Dinmore

12 AUS - 4303 Brisbane, Queensland

**MOREGATE EXPORTS PTY LTD**

4830 D'Aguilar Highway

Kilcoy

AUS - 4515 Kilcoy, Queensland

13 **MOREGATE EXPORTS PTY LTD**

14 117 Colmslie Road

15 Cannon Hill

16 AUS - 4170 Brisbane, Queensland

**MOREGATE EXPORTS PTY LTD**

Banya Street 56

Bulimba

AUS - 4171 Brisbane, Queensland

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 sites of production  
19 mentioned above, AUS - 4303 Brisbane, Queensland, AUS - 4170 Brisbane, Queensland,  
20 AUS - 4515 Kilcoy, Queensland and AUS - 4171 Brisbane, Queensland we certify that the  
21 substance **ADULT BOVINE PLASMA** meets the criteria described in the current version of the  
22 monograph Products with risk of transmitting agents of animal spongiform encephalopathies  
23 no. 1483 of the European Pharmacopoeia, current edition including supplements.

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

Australia

25 - nature of animal tissues used in manufacture:

Bovine blood

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

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

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

- 33 The certificate is valid provided that there has been no deterioration in the TSE status of the  
34 country(ies) of origin of the source material.
- 35 This certificate is granted within the framework of the procedure established by the European  
36 Pharmacopoeia Commission [Resolution AP-CSP (93) 5 as amended] for a period of five years  
37 starting from **22 November 2005**. Moreover, it is granted according to the provisions of  
38 Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related  
39 guidelines.
- 40 This certificate has 40 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 2005-192-Rev 00 for ADULT BOVINE PLASMA**

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)*: