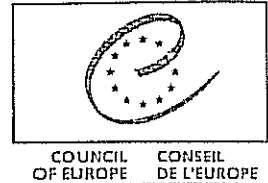




European Directorate for the
Quality of Medicines & HealthCare



Certification of Substances Division

Certificate of suitability
No. R1-CEP 2005-192-Rev 00

1 *Name of the substance:*
2 **ADULT BOVINE PLASMA**

3 *Name of holder:*
4 **MOREGATE EXPORTS PTY LTD**
5 **56 Banya Street**
6 **Bulimba**
7 **Australia-4171 Brisbane, Queensland**

8 <i>Site(s) of production:</i>	
9 MOREGATE EXPORTS PTY LTD	MOREGATE EXPORTS PTY LTD.
10 175 Riverview Road	4830 D'Aguilar Highway
11 Dinmore	Kilcoy
12 Australia-4303 Brisbane, Queensland	Australia-4515 Kilcoy, Queensland
13 MOREGATE EXPORTS PTY LTD.	MOREGATE EXPORTS PTY LTD
14 117 Colmslie Road	56 Banya Street
15 Cannon Hill	Bulimba
16 Australia-4170 Brisbane, Queensland	Australia-4171 Brisbane, Queensland

17 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
18 **R0-CEP'2005-192-REV 00**

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

25 - country(ies) of origin of source materials: **Australia**
26 - nature of animal tissues used in manufacture: **Bovine blood**

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



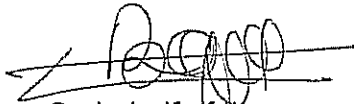
30 Manufacture of the substance shall take place in accordance with a suitable quality
31 assurance system such as GMP, and in accordance with the dossier submitted.

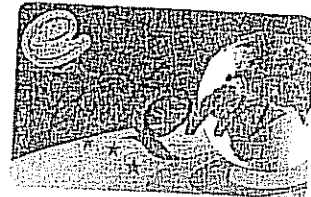
32 Failure to comply with these provisions will render this certificate void.

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

35 This certificate is renewed from **22 November 2010** according to the provisions of
36 Resolution AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive
37 2001/82/EC and any subsequent amendment, and the related guidelines.

38 This certificate has:
39 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 2005-192-Rev 00 for ADULT BOVINE PLASMA

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):*

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>

