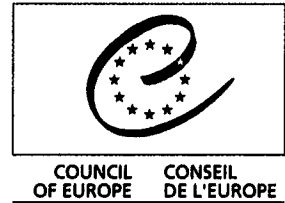


edom



**European Directorate for the Quality of Medicines
Division Certification of Substances**

**Certificate of suitability
No. R1-CEP 2001-134-Rev 00**

1 *Name of the substance:*
2 **HAEMOGLOBIN GLUTAMER 200**
3 Bovine

4 *Name of holder:*
5 **BIOPURE CORPORATION**
6 11 Hurley Street
7 USA - MA 02141 Cambridge

8 *Sites of production:*
9 **BIOPURE CORPORATION**
10 674 Souder Road
11 USA - PA 18964 Souderton

12 **BIOPURE CORPORATION**
13 39 Hurley Street
14 USA - MA 02141 Cambridge

15 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
16 **R0-CEP 2001-134-REV 02**

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, USA - PA 18964 Souderton and USA - MA 02141 Cambridge, we certify that
20 the substance **HAEMOGLOBIN GLUTAMER 200** meets the criteria described in the current version
21 of the monograph Products with risk of transmitting agents of animal spongiform
22 encephalopathies no. 1483 of the European Pharmacopoeia, current edition including
23 supplements.

24 – country of origin of source materials: United States of America
25 – nature of animal tissues used in manufacture: Bovine blood

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

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

- 31 Failure to comply with these provisions will render this certificate void.
32 The certificate is valid provided that there has been no deterioration in the TSE status of the
33 country of origin of the source material.
34 This certificate is renewed from **10 July 2006** according to the provisions of Resolution AP-CSP
35 (93) 5 as amended, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent
36 amendment, and the related guidelines.
37 This certificate has 37 lines only.



Dr. A. ARTIGES
Director of the Quality of Medicines

Strasbourg, 17 July 2006

DECLARATION OF ACCESS *(to be filled in by the certificate holder under their own responsibility)*

BIOPURE CORPORATION, as holder of the certificate of suitability
R1-CEP 2001-134-Rev 00 for HAEMOGLOBIN GLUTAMER 200

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)*: