Council of Europe
EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES

CERTIFICATION OF SUITABILITY OF MONOGRAPHS OF THE EUROPEAN PHARMACOPOEIA

Certificate No. R0-CEP 2001-093-Rev 00

Name of the substance:
ADULT BOVINE SERUM

Name of holder:
MOREGATE EXPORTS LTD
137 Ward Street
NZ – Hamilton

Site of production:
MOREGATE EXPORTS LTD
127 Ward Street
NZ – Hamilton

MOREGATE EXPORTS LTD
Portage Road
NZ - Auckland

MOREGATE EXPORTS LTD
Main Road
NZ – Thames

After examination of the information provided on the origin of raw material(s) and type of tissue(s) used and on the manufacturing process for this substance on the sites of production mentioned above, NZ - Hamilton, NZ - Auckland and NZ- Thames we certify that the substance **ADULT BOVINE SERUM** meets the criteria described in the monograph Products with risk of transmitting agents of animal spongiform encephalopathies (no. 1483, Ph. Eur. 4th Ed. and any subsequently revised version).

- country of origin of source materials:	New Zealand
- nature of animal tissues used in manufacture:	Adult bovine blood

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

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

Postal Address: 226 Avenue de Colmar (entrance rue Schertz) B.P. 907 - F 67029 Strasbourg Cedex 1
Telephone: 03.88.41.29.47 - Fax 03.88.41.27.71 - E-mail: certification@pheur.org

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 granted within the framework of the procedure established by the European
35 Pharmacopoeia Commission [Resolution AP-CSP (93) 5 as amended] for a period of five years
36 starting from **7 December 2001**. Moreover, it is granted according to the provisions of Directive
37 75/318/EEC amended and Directive 81/852/EEC amended, and the related guidelines.

38 This certificate has 38 lines only.

Dr. A. ARTIGES
Director of the Quality of Medicines

Strasbourg, 7 December 2001

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

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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)*

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

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