European Directorate for the
Quality of Medicines & HealthCare

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Certification of Substances Division

Certificate of suitability
No. R1-CEP 2001-032-Rev 01

Name of the substance:
FOETAL BOVINE SERUM
Gamma-irradiated and non gamma-irradiated
(Product codes: S 0410, S 0413, S 0415, S 4110, S 4113 and S 4115)

Name of holder:
BIOCHROM AG
Leonorenstr 2-6
Germany-12247 Berlin

Site(s) of production:
BIOCHROM AG
Leonorenstr 2-6
Germany-12247 Berlin

BIOCHROM AUSTRALIA PTY LTD.
A.C.N. 133 388 511
2/14 Pearl Street
Australia-3012 Brooklyn, Victoria

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R1-CEP 2001-032-REV 00

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 site(s) of production mentioned above, we certify that the substance **FOETAL BOVINE SERUM** meets the criteria described in the current version of the monograph Products with risk of transmitting agents of animal spongiform encephalopathies no. 1483 of the European Pharmacopoeia, current edition including supplements.

- country(ies) of origin of source materials: Australia
- nature of animal tissues used in manufacture: Foetal bovine blood

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

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

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.

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

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

This certificate is renewed from **7 December 2006** according to the provisions of Resolution AP-CSP (93) 5 as amended, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 3 May 2010

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

Biochrom AG, 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)*

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)*:

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