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 2005-003-Rev 02

Name of the substance:
PROPOFOL
code number 22270

Name of holder:
BACHEM S.A.
Succursale de Vionnaz
Route du Simplon 22
Switzerland-1895 Vionnaz

Site(s) of production:
BACHEM S.A.
Succursale de Vionnaz
Route du Simplon 22
Switzerland-1895 Vionnaz

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R1-CEP 2005-003-REV 01

After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site(s) of production mentioned above, we certify that the quality of the substance is suitably controlled by the current version of the monograph **PROPOFOL** no. 1558 of the European Pharmacopoeia, current edition including supplements.

The re-test period of the substance is 36 months if stored under nitrogen in aluminium bottles coated with an epoxy phenolic resin, closed with a polypropylene screw cap with Teflon liner.

The holder of the certificate has declared the absence of use of material of human or animal origin in the manufacture of the substance.

The submitted dossier must be updated after any significant change that may alter the quality, safety or efficacy of the substance.

Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice and in accordance with the dossier submitted.

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

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

This certificate is renewed from **19 December 2010** 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, 8 August 2011

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

BACHEM S.A., as holder of the certificate of suitability

R1-CEP 2005-003-Rev 02 for PROPOFOL

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