Certification of Substances Division

Certificate of suitability
No. R1-CEP 2005-250-Rev 01

Name of the substance:
ETOMIDATE

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

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R1-CEP 2005-250-REV 00

After examination of the information provided on the manufacturing method and subsequent processes (including purification) for this substance on the site(s) of production listed in annex, we certify that the quality of the substance is suitably controlled by the current version of the monograph **ETOMIDATE** no. 1514 of the European Pharmacopoeia, current edition including supplements.

Any unspecified impurity detected by the test for related substances of the monograph is limited to not more than 0.10%.

In the last steps of the synthesis *t*-butylmethylether and *n*-heptane are used as solvents. Their residual content is limited by the test for loss on drying described in the monograph, with a limit of not more than 0.5%.

The re-test period of the substance is 60 months if stored in an aluminium bottle coated with an epoxy phenolic resin, closed with a polyethylene plug and finally sealed with a polypropylene screw cap.

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)
Tel: +33 (0) 3 88 41 30 30 – Fax: +33 (0) 3 88 41 27 71 - e-mail: cep@edqm.eu

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

This certificate is renewed from **18 December 2011** according to the provisions of Resolution AP-CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has one annex of 1 page.
This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 8 October 2014

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 2005-250-Rev 01 for Etomidate

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)
Tel: +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

Certification of Substances Division

Annex 1: Sites of manufacture for R1-CEP 2005-250-Rev 01

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