edqm 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 2007-157-Rev 00

Name of the substance:
DESMOPRESSIN

Name of holder:
BACHEM AMERICAS, INC.
3132 Kashiwa Street
United States Am.-90505 Torrance, California

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R0-CEP 2007-157-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 listed in annex, we certify that the quality of the substance is suitably controlled by the current version of the monograph **DESMOPRESSIN** no. 712 of the European Pharmacopoeia, current edition including supplements, only if it is supplemented by the test(s) mentioned below, based on the analytical procedure(s) given in annex.

- Test for related substances by liquid chromatography (Annex 2)
  Any unspecified impurity not more than 0.5%

- Test for residual solvents by gas chromatography (Annex 3)
  Acetonitrile not more than 400 ppm
  Diisopropylethylamine not more than 1000 ppm
  Piperidine not more than 1000 ppm

  In the last steps of the synthesis water is used as solvent.

- Test for trifluoroacetic acid by liquid chromatography (Annex 4)
  Trifluoroacetic acid not more than 0.25%

The re-test period of the substance is 2 years if stored at a temperature not exceeding -20°C in an amber glass container closed with a polypropylene lid with a polytetrafluoroethylene 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.

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

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.

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

This certificate is renewed from **22 December 2013** 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 four annexes, the first of 1 page, the second of 7 pages, the third of 5 pages and the fourth of 8 pages.
This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 3 January 2014

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

BACHEM AMERICAS, INC. as holder of the certificate of suitability

R1-CEP 2007-157-Rev 00 for Desmopressin

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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