Certification of Substances Division

Certificate of suitability
No. R0-CEP 2014-150-Rev 00

Name of the substance:
ZOLPIDEM TARTRATE

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

Site(s) of production:
SEE ANNEX 1

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 **ZOLPIDEM TARTRATE** no. 1280 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 NMR spectroscopy (Annex 2)
  Tolualdehyde isomers not more than 0.10%
- Test for residual solvents by gas chromatography (Annex 3)
  Methanol not more than 3000 ppm

The substance is packed in an epoxy-phenolic resin coated aluminium bottle with a polyethylene plug, 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.

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

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

This certificate is granted within the framework of the procedure established by the European Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from **25 January 2016**. Moreover, it is granted according to the provisions of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

This certificate has three annexes, the first and the second of 1 page each, the third of 2 pages.
This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 25 January 2016

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

R0-CEP 2014-150-Rev 00 for Zolpidem tartrate

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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