European Directorate for the Quality of Medicines & HealthCare
Direction européenne de la qualité du médicament & soins de santé
COUNCIL OF EUROPE
CONSEIL DE L'EUROPE

Certification of Substances Department

Certificate of suitability
No. R1-CEP 2005-245-Rev 01

Name of the substance:
SOMATOSTATIN

Name of holder:
BACHEM AG
Hauptstrasse 144
Switzerland-4416 Bubendorf

Site(s) of production:
SEE ANNEX 1

THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
R1-CEP 2005-245-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 **SOMATOSTATIN** no. 949 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.

Any unspecified impurity detected by the test for related substances of the monograph is limited to not more than 0.5%.

- Test for residual solvents by gas chromatography (Annex 2)
  Isopropanol not more than 5000 ppm

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

- Test for elemental impurities by inductively coupled plasma-mass spectroscopy (Annex 3)
  Palladium not more than 1 ppm

- Test for residual triethylamine by gas chromatography (Annex 4)
  Triethylamine not more than 7000 ppm

- Test for residual trifluoroacetic acid by ion chromatography (Annex 5)
  Trifluoroacetic acid not more than 0.1%

The re-test period of the substance is 5 years if stored at or below -15°C in amber glass bottles with polypropylene twist-off cap and protected from light.

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 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.

This certificate is renewed from **27 June 2012** 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 five annexes, the first of 1 page, the second of 3 pages, the third of 2 pages, the fourth of 1 page and the fifth of 3 pages.

This certificate has:

lines.

On behalf of the
Director of EDQM

Strasbourg, 19 January 2018

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

Bachem AG, as holder of the certificate of suitability

R1-CEP 2005-245-Rev 01 for Somatostatin

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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