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 2003-037-Rev 03

Name of the substance:
GOSERELIN

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 2003-037-REV 02

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 **GOSERELIN** no. 1636 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)

Ethanol	not more than 5000 ppm
Isopropanol	not more than 2000 ppm

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

The following elemental impurity classified in ICH Q3D is intentionally introduced in the manufacture of the substance: Palladium.

The re-test period of the substance is 60 months if stored at a temperature between 2°C and 8°C and protected from light in a plastic coated amber glass bottle (hydrolytic type III) with a polypropylene 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.

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 **19 November 2008** 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 two annexes, the first of 1 page and the second of 4 pages.
This certificate has:
lines.

On behalf of the
Director of EDQM

Strasbourg, 18 December 2020

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 2003-037-Rev 03 for Goserelin

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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