Certificate of suitability
No. R1-CEP 2005-022-Rev 00

1 Name of the substance:
   GONADORELIN ACETATE

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

3 Site(s) of production:
   BACHEM AG
   Hauptstrasse 144
   Switzerland-4416 Bubendorf

11 THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE
12 R0-CEP 2005-022-REV 00

13 After examination of the information provided on the manufacturing method and
   subsequent processes (including purification) for this substance on the site(s) of
   production mentioned above, we certify that the quality of the substance is suitably
   controlled by the current version of the monograph GONADORELIN ACETATE no. 827
   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.

18 – Test for related substances by liquid chromatography
20 (Annex 1)
21 D-His\(^2\)-Gonadorelin  not more than 0.5%
22 D-Tyr\(^5\)-Gonadorelin  not more than 0.5%
23 Any unspecified impurity  not more than 0.5%
24 Sum of impurities  not more than 1.0%

25 – Test for residual solvents by gas chromatography
26 (Annex 2)
27 n-Butanol  not more than 5000 ppm

28 In the last steps of the synthesis water is used as solvent.
The re-test period of the substance is 36 months if stored at a temperature between 2°C and 8°C in a plastic-coated amber glass bottle (hydrolytic type III soda lime silica glass) with a white polypropylene twist off 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.


This certificate has two annexes, the first of 3 pages and the second of 2 pages. This certificate has:

lines.

On behalf of the Director of EDQM

Strasbourg, 17 May 2011

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 2005-022-Rev 00 for GONADORELIN ACETATE

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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