

Certification of Substances Department

Certificate of suitability
No. R0-CEP 2020-229 - Rev 01

1 *Name of the substance:*

2 **OCTREOTIDE**

3 *Name of holder:*

4 **BACHEM AG**

5 Hauptstrasse 144

6 Switzerland-4416 Bubendorf

7 *Site(s) of production:*

8 **SEE ANNEX 1**

9 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
10 **R0-CEP 2020-229 - REV 00**

11 After examination of the information provided on the manufacturing method and subsequent
12 processes (including purification) for this substance on the site(s) of production listed in annex, we
13 certify that the quality of the substance is suitably controlled by the current version of the
14 monograph **OCTREOTIDE** no. 2414 of the European Pharmacopoeia, current edition including
15 supplements, only if it is supplemented by the test(s) mentioned below, based on the analytical
16 procedure(s) given in annex.

17 – Test for residual solvents by gas chromatography (Annex 2)
18 Acetonitrile not more than 410 ppm

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

20 No elemental impurity classified in ICH Q3D is intentionally introduced in the manufacture of
21 the substance.

22 The re-test period of the substance is 24 months if stored at a temperature between 2°C and
23 8°C in a polyethylene bag, placed in an aluminium bag.

24 The holder of the certificate has declared the absence of use of material of human or animal
25 origin in the manufacture of the substance.

26 The submitted dossier must be updated after any significant change that may alter the quality,
27 safety or efficacy of the substance.

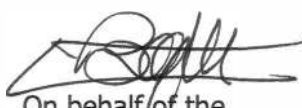
28 Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice
29 and in accordance with the dossier submitted.

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

31 This certificate is granted within the framework of the procedure established by the European
32 Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from
33 **31 March 2021**. Moreover, it is granted according to the provisions of Directive 2001/83/EC and
34 Directive 2001/82/EC and any subsequent amendment, and the related guidelines.

35 This certificate has two annexes, the first of 1 page and the second of 2 pages.

36 This certificate has:
37 lines.


On behalf of the
Director of EDQM

Strasbourg, 18 July 2022

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

Bachem AG, as holder of the certificate of suitability

R0-CEP 2020-229 - Rev 01 for Octreotide

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)*: