

Certification of Substances Department

Certificate of suitability No. CEP 2020-229 - Rev 02

1 *Name of the substance:*

2 **OCTREOTIDE**

3 *Details of holder:*

4 **BACHEM AG**

5 Hauptstrasse 144

6 Switzerland-4416 Bubendorf

7 SPOR ORG ID: 100011626

8 SPOR LOC ID: 100021354

9 After examination of the information provided on the production method and control strategy for the
10 substance, we certify that its quality is suitably controlled by the current version of the European
11 Pharmacopoeia monograph for **OCTREOTIDE** No. 2414 and any supplementary tests deemed
12 necessary. The approved site(s) of production, specification and any supplementary test
13 procedure(s) are included on the following pages, which constitute an integral part of this certificate.

14 In the last steps of the process, purified water is used as solvent.

15 No elemental impurity classified in ICH Q3D is intentionally introduced in the production of the
16 substance.

17 The re-test period of the substance is 60 months if stored at a temperature not exceeding -15°C
18 in a polyethylene bag, placed in an aluminium bag.

19 No material of human or animal origin is used in the production of the substance.

20 The holder of the certificate should fulfil the following conditions in order to maintain the validity of
21 this certificate.

22 The dossier submitted must be updated in accordance with EDQM guidance on the requirements
23 for revision of certificates of suitability.

24 Production of the substance shall take place in accordance with the dossier submitted and Good
25 Manufacturing Practice.

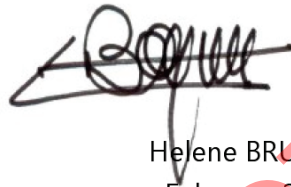
26 Necessary information from the submitted dossier shall be shared with authorised users in order
27 to enable them to evaluate the suitability of this substance for its intended use. This includes
28 informing them of any relevant change in the associated dossier.

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

30 This certificate is granted within the framework of Resolution AP-CSP (07) 1 adopted by the Council
31 of Europe Public Health Committee (Partial Agreement) (CD-P-SP) in February 2007. With regard
32 to its use in the member states of the European Union/European Economic Area, it is granted in
33 accordance with the provisions of Directive 2001/83/EC and Regulation (EU) 2019/6 as amended,
34 and the related guidelines.

35 This certificate is valid from 23 February 2026.

On behalf of the
Director of EDQM



Helene BRUGUERA
February 23, 2026

THIS COPY IS NOT VALID
FOR REGULATORY PURPOSES