

Certification of Substances Department

Certificate of suitability
No. R0-CEP 2019-281-Rev 00

- 1 *Name of the substance:*
2 **ZOLEDRONIC ACID MONOHYDRATE**
- 3 *Name of holder:*
4 **SCINOPHARM TAIWAN, LTD.**
5 No. 1, Nan-Ke 8th Road
6 Taiwan-74144 Shan-Hua, Tainan
- 7 *Site(s) of production:*
8 **SEE ANNEX 1**

9 A
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Notice
NOT FOR REGISTRATION PURPOSES
For filing purposes please contact ScinoPharm Taiwan
to obtain a complete "controlled copy" of this CEP.

ScinoPharm Taiwan- Regulatory Technical Services
(SPT.RTS@scinopharm.com.tw)

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- 18 In the last steps of the synthesis water is used as solvent.
- 19 No elemental impurity classified in ICH Q3D is intentionally introduced in the manufacture of
20 the substance.
- 21 The re-test period of the substance is 60 months if stored in double polyethylene bags under
22 nitrogen, placed in a polyethylene bottle or drum.
- 23 The holder of the certificate has declared the absence of use of material of human or animal
24 origin in the manufacture of the substance.
- 25 The submitted dossier must be updated after any significant change that may alter the quality,
26 safety or efficacy of the substance.
- 27 Manufacture of the substance shall take place in accordance with the Good Manufacturing Practice
28 and in accordance with the dossier submitted.

- 29 Failure to comply with these provisions will render this certificate void.
- 30 This certificate is granted within the framework of the procedure established by the European
31 Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from
32 **7 April 2021**. Moreover, it is granted according to the provisions of Directive 2001/83/EC and
33 Directive 2001/82/EC and any subsequent amendment, and the related guidelines.
- 34 This certificate has three annexes, the first of 1 page, the second and the third of 2 pages each.
35 This certificate has:
36 lines.



On behalf of the
Director of EDQM



Strasbourg, 7 April 2021

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

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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)*: