

Certification of Substances Department

Certificate of suitability
No. R1-CEP 1997-078 - Rev 07

1 *Name of the substance:*
2 **MINOCYCLINE HYDROCHLORIDE DIHYDRATE**
3 Grade B

4 *Name of holder:*
5 **HOVIONE FARMACIENCIA S.A.**
6 Quinta Sao Pedro, Sete Casas
7 Portugal-2674-506 Loures

8 *Site(s) of production:*
9 **SEE ANNEX 1**

10 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
11 **R1-CEP 1997-078 - REV 06**

12 After examination of the information provided on the manufacturing method and subsequent
13 processes (including purification) for this substance on the site(s) of production listed in annex, we
14 certify that the quality of the substance is suitably controlled by the current version of the

NOT FOR REGISTRATION PURPOSES

**"For filing purposes please contact
Hovione to obtain a complete
"controlled copy" of this CEP.
Maintaining proper records will
enable you to receive "updates" and
enable us to comply with our change
control requirements"**

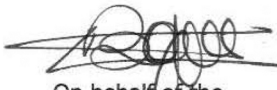
Hovione - Regulatory Affairs Department

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

37 This certificate is renewed from **1 June 2003** according to the provisions of Resolution AP-CSP
38 (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment,
39 and the related guidelines.

40 This certificate has four annexes, the first of 1 page, the second and the third of 3 pages each, the
41 fourth of 4 pages.

42 This certificate has:
43 lines.


On behalf of the
Director of EDQM



Strasbourg, 16 December 2021

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