

Certification of Substances Department

Certificate of suitability
No. R1-CEP 1996-066-Rev 06

- 1 *Name of the substance:*
2 **DOXYCYCLINE HYCLATE**
- 3 *Name of holder:*
4 **HOVIONE PHARMASCIENCE LIMITED**
5 Estrada Coronel Nicolau De Mesquita
6 Macao- Taipa
- 7 *Site(s) of production:*
8 **SEE ANNEX 1**

9 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
10 **R1-CEP 1996-066-REV 05**

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

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

33 This certificate is renewed from **26 May 2002** according to the provisions of Resolution AP-CSP
34 (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent amendment,
35 and the related guidelines.

36 This certificate has four annexes, the first of 1 page, the second and the third of 3 pages each and
37 the fourth of 1 page.

38 This certificate has:
39 lines.



On behalf of the
Director of EDQM



Strasbourg, 5 October 2020