

Certification of Substances Department

Certificate of suitability
No. R1-CEP 2004-111 - Rev 02

- 1 *Name of the substance:*
2 **MOMETASONE FUROATE**
- 3 *Name of holder:*
4 **HOVIONE FARMACIENCIA S.A.**
5 Quinta Sao Pedro, Sete Casas
6 Portugal-2674-506 Loures
- 7 *Site(s) of production:*
8 **SEE ANNEX 1**

9 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**
10 **R1-CEP 2004-111 - REV 01**

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

NOT FOR REGISTRATION PURPOSES

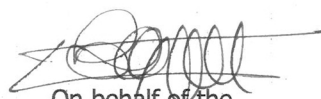
**"For filing purposes please contact
Hovione to obtain a complete
"controlled copy" of this CEP.
Maintaining proper records will
enable you to receive "updates" and
enable us to comply with our change
control requirements"**

Hovione - Regulatory Affairs Department

30 This certificate is renewed from **12 September 2010** according to the provisions of Resolution
31 AP-CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent
32 amendment, and the related guidelines.

33 This certificate has three annexes, the first of 1 page, the second of 4 pages, and the third of
34 1 page.

35 This certificate has:
36 lines.


On behalf of the
Director of EDQM



Strasbourg, 29 October 2021