

Certification of Substances Division

**Certificate of suitability**  
**No. R1-CEP 2005-160-Rev 01**

- 1 *Name of the substance:*  
2 **FLUTICASONE PROPIONATE**
- 3 *Name of holder:*  
4 **HOVIONE FARMACIENCIA S.A.**  
5 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 2005-160-REV 00**

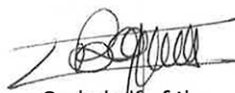
11 After examination of the information provided on the manufacturing method and subsequent

**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**

- 29 This certificate is renewed from **15 December 2011** according to the provisions of Resolution AP-  
30 CSP (07) 1, and of Directive 2001/83/EC and Directive 2001/82/EC and any subsequent  
31 amendment, and the related guidelines.
- 32 This certificate has two annexes, the first of 1 page and the second of 3 pages.  
33 This certificate has:  
34 lines.

  
On behalf of the  
Director of EDQM



Strasbourg, 16 December 2015