

**Certification of Substances Department**

**Certificate of suitability  
No. R0-CEP 2018-057-Rev 02**

- 1 *Name of the substance:*  
2 **SALMETEROL XINAFOATE**  
3 Process II
- 4 *Name of holder:*  
5 **HOVIONE FARMACIENCIA S.A.**  
6 Sete Casas  
7 Portugal-2674-506 Loures
- 8 *Site(s) of production:*  
9 **SEE ANNEX 1**

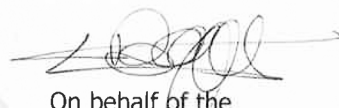
10 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**  
11 **R0-CEP 2018-057-REV 01**

**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**

- 35 Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from  
36 **18 March 2019**. Moreover, it is granted according to the provisions of Directive 2001/83/EC and  
37 Directive 2001/82/EC and any subsequent amendment, and the related guidelines.
- 38 This certificate has three annexes, the first of 1 page, the second of 3 pages and the third of  
39 2 pages.
- 40 This certificate has:  
41 lines.

  
On behalf of the  
Director of EDQM



Strasbourg, 5 July 2019