

Certification of Substances Department

**Certificate of suitability**  
**No. R0-CEP 2017-055-Rev 01**

- 1 *Name of the substance:*  
2 **SALMETEROL XINAFOATE**  
3 Process I
- 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**

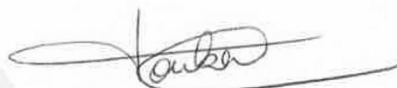
10 **THIS CERTIFICATE SUPERSEDES THE PREVIOUS CERTIFICATE**  
11 **R0-CEP 2017-055-REV 00**

**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 This certificate is granted within the framework of the procedure established by the European  
37 Pharmacopoeia Commission [Resolution AP-CSP (07) 1] for a period of five years starting from  
38 **25 October 2017**. Moreover, it is granted according to the provisions of Directive 2001/83/EC  
39 and Directive 2001/82/EC and any subsequent amendment, and the related guidelines.
- 40 This certificate has three annexes, the first of 1 page, the second and the third of 3 pages each.  
41 This certificate has:  
42 lines.



On behalf of the  
Director of EDQM



Strasbourg, 7 March 2018