

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

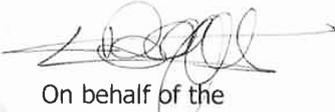
**"For filing purposes please contact
Hovione to obtain a complete
"controlled copy" of this CEP.
Maintaining proper records will
enable you to receive "updates" and
enable us to comply with our change
control requirements"**

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