

Certificate in accordance with the Royal Decree of 19/12/1997 regarding the control and analysis of Pharmaceutical ingredients used by pharmacists

The Federal Agency for Medicines and Health Products herewith certifies that **FAC SECUNDUM ARTEM (FSA) - Oostmalsebaan 1c (U5), 2960 Sint-Lenaarts** (Belgium), has obtained, in accordance with the Royal Decree of 19th December 1997 regarding the control and analysis of Pharmaceutical ingredients used by pharmacists, the authorizations numbers **1890R**.

This authorization was obtained following an inspection performed according the Art. 8 of the Royal decree 19th December 1997. Art. 8 specifies that suppliers (as defined in Article 6, § 2), are required to carry out operations on raw materials destined for use by pharmacists. in accordance with the principles and guidelines of good manufacturing practice for medicinal products for human use, established by Directive 91/356/EU of the European commission of the 13th June 1991 which establish the principles and guidelines of good manufacturing practice for medicinal products for human use,

The most recent inspection took place on **04 november 2016**.

Any further information regarding this issue can be obtained directly from FAMHP at industry@afmps.be

This certificate may not be reproduced.

Requesting country: **All members states of the European Union.**

SEEN BY THE NATIONAL COMPETENT AUTHORITY		
Address of certifying authority:	Federal agency for medicines and health products - famhp, Eurostation II, Victor Hortaplein 40/40, 1060 Brussels (Belgium)	
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Date and stamp: 8.3.12.2019		Name of authorized person: Xavier De Cuyper Chief Executive Officer - CEO  Karin PROIDEN Director of Inspection Department of Medicines and Health Products
Number of certificate:		