

Swissmedic Swiss Agency for Therapeutic Products

CERTIFICATE NUMBER: **GMPEHV-CH-1006282**

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Part 1

Issued under the provisions of the Mutual Recognition Agreement between the European Union and **Switzerland**.

The competent authority of Switzerland confirms the following:

The manufacturer: **F. Hoffmann-La Roche AG**

Site address: **Wurmisweg, Kaiseraugst, 4303, Switzerland**

Additional details on units inspected: **This GMP-Certificate is valid for the site registered with Swissmedic: Kaiseraugst - Herstellung, Verpackung und Prüfung von Arzneimitteln (NCA Reference Key: 1000114)**

OMS Organisation Id. / OMS Location Id.: **ORG-100001445 / LOC-100001980**

Other

(Human) According to Swiss regulations in force: Therapeutic products act, TPA, SR 812.21 and Medicinal products licensing ordinance, MPLO, RS 812.212.1

(Veterinary) According to Swiss regulations in force: Therapeutic products act, TPA, SR 812.21 and Medicinal products licensing ordinance, MPLO, RS 812.212.1

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on **2023-11-30**, it is considered that it complies with:

The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union and **Switzerland**

This certificate reflects the status of the manufacturing site at the time of the inspection noted above and should not be relied upon to reflect the compliance status if more than three years have elapsed since the date of that inspection. This certificate is valid only when presented with all pages and both Parts 1 and 2.

The authenticity of this certificate may be verified in EudraGMDP. If it does not appear, please contact the issuing authority.

Part 2

Human Medicinal Products	
Veterinary Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.1	Sterile products
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids 1.1.1.6 Other: Other aseptically prepared products: Rocephin(en)
	<i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.3 Small volume liquids
	<i>1.1.3 Batch certification</i>
1.2	Non-sterile products
	<i>1.2.1 Non-sterile products (processing operations for the following dosage forms)</i> 1.2.1.1 Capsules, hard shell 1.2.1.8 Other solid dosage forms 1.2.1.13 Tablets
	<i>1.2.2 Batch certification</i>
1.3	Biological medicinal products (list of product types)
	<i>1.3.1 Biological medicinal products (list of product types)</i> 1.3.1.5 Biotechnology products
	<i>1.3.2 Batch Certification (list of product types)</i> 1.3.2.5 Biotechnology products
1.5	Packaging
	<i>1.5.1 Primary Packaging</i> 1.5.1.1 Capsules, hard shell 1.5.1.2 Capsules, soft shell 1.5.1.8 Other solid dosage forms 1.5.1.13 Tablets
	<i>1.5.2 Secondary packaging</i>

1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i> <i>1.6.4 Biological</i>

2024-10-31

Name and signature of the authorised person of the
Competent Authority of Switzerland

Confidential
Swissmedic Swiss Agency for Therapeutic Products
Tel: **Confidential**
Fax: **Confidential**