Agen□ia Na□ională a Medicamentului □i a Dispozitivelor Medicale din România

CERTIFICATE NUMBER: ***026/2021/RO***

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER [1, 2]

Part 1

Issued following an inspection in accordance with :

The competent authority of Romania confirms the following:
The manufacturer: ***ROMPHARM COMPANY SRL***
Site address: ***Str. Eroilor, nr.1Aclădiri Rompharm 1 □i Rompharm 2, Oraş Otopeni, Jude□ul Ilfov, cod po□tal 075100, Romania***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***1F*** in accordance with Art. 40 of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2021-06-16***, it is considered that it complies with:

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. However, this period of validity may be reduced or extended using regulatory risk management principles by an entry in the Restrictions or Clarifying remarks field. 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.

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[1] *The certificate referred to in paragraph 111(5) of Directive 2001/83/EC and 80(5) of Directive 2001/82/EC, shall also be required for imports coming from third countries into a Member State.*

[2] *Guidance on the interpretation of this template can be found in the Help menu of EudraGMDP database.*

[3] *These requirements fulfil the GMP recommendations of WHO.*

Digitally signed by Chirtoacă Iurie
Date: 2022.09.30 17:17:52 EEST
Reason: MoldSign Signature
Location: Moldova

Part 2

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.4 Small volume liquids
	1.1.2 Terminally Sterilised (processing operations for the following dosage forms) 1.1.2.3 Small volume liquids
	1.1.3 Batch certification
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.5 Liquids for external use 1.2.1.6 Liquids for internal use 1.2.1.8 Other solid dosage forms: granules and powders (unit dose and multidose)(en)
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.5 Liquids for external use 1.5.1.6 Liquids for internal use 1.5.1.8 Other solid dosage forms: granules and powders (unidose and multidose)(en)
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.1 Microbiological: sterility *1.6.2 Microbiological: non-sterility* *1.6.3 Chemical/Physical* *1.6.4 Biological*

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.2 Microbiological: non-sterility *2.1.3 Chemical/Physical*
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products
2.3	**Other importation activities**

	2.3.1 Site of physical importation
	2.3.2 Importation of intermediate which undergoes further processing
	2.3.4 Other: release for sale of imported medicinal products(en)

Clarifying remarks (for public users)

total manufacturing operations are carried out for sterile prod.–aseptically prepared small vol.liquids:eye drops(sol.,suspensions) and injectable liq.(sol.,suspensions),respectively for sterile prod.-small vol. liq.-terminally sterilized-injectable sol.; sterile and non-sterile liq. prod. are manufactured in bldg.RPH 1;solid prod.are manufactured in bldg.RPH 2;central warehouse is located in bldg.RPH 3;sec.packaging is performed in bldg.RPH 2, including for prod. manufactured in bldgs.RPH 1 and RPH 3;quality control tests are carried out in bldg.RPH 2(chemical/physical) and RPH1(microbiological);batch certification of the series of prod.manufactured in RPH 3 is performed in Str.Eroilor,nr.1A,Oraş Otopeni,Jud.IF,cod po□tal 075100.Importation of intermediate prod.from India (Itraconazol pelete 22,0 %,Itraconazole pellets 22,0%,Omeprazole pellets 8.5 %), China(Omeprazole pellets 8.5%);central warehouse is located in building Rompharm 3.This GMP certificate is valid up to June 2024

2021-10-05

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

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Confidential
National Agency for Medicines and Medical Devices of Romania
Tel:***Confidential***
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