National Organization for Medicines

CERTIFICATE NUMBER :***107407/4-11-2020***

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

Part 1

Issued following an inspection in accordance with :
Art. 111(5) of Directive 2001/83/EC as amended
Art. 15 of Directive 2001/20/EC

The competent authority of Greece confirms the following:
The manufacturer:***RONTIS HELLAS ΑΝΩΝΥΜΗ ΕΜΠΟΡΙΚΗ ΚΑΙ ΒΙΟΜΗΧΑΝΙΚΗ ΕΤΑΙΡΕΙΑ ΙΑΤΡΟΦΑΡΜΑΚΕΥΤΙΚΩΝ ΕΙΔΩΝ / RONTIS HELLAS MEDICAL AND PHARMACEUTICAL PRODUCTS S.A.***
Site address:***Τ.Θ.3012 ΒΙ.ΠΕ. Λάρισας / P.O. BOX 3012 Larisa Industrial Area, Λάρισα / Larisa, 41004, Greece***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***0000010664/20/1*** in accordance with Art. 40 of Directive 2001/83/EC and Art. 13 of Directive 2001/20/EC transposed in the following national legislation:
Δ.ΥΓ 3(α)/Γ.Π. 32221/29-4-2013, art. 57
ΔΥΓ 3/89292/03, Art. 12

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2018-07-05*** , it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC [3]

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.*

Part 2

Human Medicinal Products
Human Investigational Medicinal Products

1 MANUFACTURING OPERATIONS	
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 1.2.1.13 Tablets
	1.2.2 Batch certification
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

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

2020-12-04

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

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Tel :***Confidential***
Fax :***Confidential***