REPÚBLICA PORTUGUESA
SAÚDE

SNS SERVIÇO NACIONAL DE SAÚDE

Infarmed
Autoridade Nacional do Medicamento e Produtos de Saúde, I.P.

National Authority of Medicines and Health Products, I.P.

CERTIFICATE NUMBER: ***FI006/001/2019***

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

The competent authority of Portugal confirms the following:
The manufacturer: ***Hetero Labs Limited***
Site address: ***Unit-V, Block V and V-A, TSIIC - Formulation SEZ, S. Nos 439, 440, 441 & 458, Polepally Village, Jadcherla Mandal, Mahaboobnagar District, Telangana State, 509301, India***
DUNS Number: ***65-045-2530***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 8(2) of Regulation (EC) 726/2004 and Art. 111(4) of Directive 2001/83/EC transposed in the following national legislation:
Art.176.º n.º 4 of Decree-Law n.º 176/2006, 30 of August

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2019-01-25*** , 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.*

Digitally signed by Chirtoacă Iurie
Date: 2022.01.17 11:48:25 EET
Reason: MoldSign Signature
Location: Moldova

SYSTEM CERTIFICATION ISO 9001:2008 SGS

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Fernanda Ralha
Diretora da Direção
Inspeção e Licenciamentos

Part 2

Human 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 1.2.1.17 Other: powders(en)
1.5	**Packaging**
	1.5.1 Primary Packing 1.5.1.1 Capsules, hard shell 1.5.1.13 Tablets 1.5.1.17 Other non-sterile medicinal products: powders(en)
	1.5.2 Secondary packing
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Any restrictions related to the scope of this certificate :

Scope of the inspection included Centrally Authorised Products Entecavir 0.5mg film-coated tablets (EU/1/17/1211/001-003) and Entecavir 1mg film-coated tablets (EU/1/17/1211/004-006) 1.2.1.17 - This dosage form is only manufactured in Unit V-A.

Clarifying remarks (for public users)

Scope of the inspection included Centrally Authorised Products Entecavir 0.5mg film-coated tablets (EU/1/17/1211/001-003) and Entecavir 1mg film-coated tablets (EU/1/17/1211/004-006) 1.2.1.17 - This dosage form is only manufactured in Unit V-A.

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2019-04-01

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

Fernanda Ralha
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