Medicines And Healthcare Products Regulatory Agency

CERTIFICATE NUMBER: ***UK MIA 20075 Insp GMP 20075/16488800-0002***

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

Part 1

Issued following an inspection in accordance with :

The competent authority of United Kingdom confirms the following:
The manufacturer: ***ACCORD HEALTHCARE LIMITED***
Site address: ***EDGEFIELD AVENUE, NEWCASTLE UPON TYNE, NE3 3NB, United Kingdom***

Has been inspected under the national inspection programme in connection with manufacturing authorisation no. ***UK MIA 20075*** in accordance with Art. 40 of Directive 2001/83/EC transposed in the following national legislation:
The Human Medicines Regulations 2012 (SI 2012/1916)

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2020-05-05***, 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: 2023.04.05 09:21:22 EEST
Reason: MoldSign Signature
Location: Moldova

Part 2

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 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**
	1.6.3 Chemical/Physical

2 IMPORTATION OF MEDICINAL PRODUCTS	
2.1	**Quality control testing of imported medicinal products**
	2.1.3 Chemical/Physical
2.2	**Batch certification of imported medicinal products**
	2.2.2 Non-sterile products
2.3	**Other importation activities**
	2.3.2 Importation of intermediate which undergoes further processing

Clarifying remarks (for public users)

This certificate is issued based on a remote inspection of GMP compliance during COVID-19 travel restrictions. A risk-based site inspection programme remains in force.

2020-07-14

Name and signature of the authorised person of the Competent Authority of United Kingdom

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