Bulgarian Drug Agency

CERTIFICATE NUMBER: ***BG/GMP/2023/240***

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 Bulgaria confirms the following:
The manufacturer: ***Kwality Pharmaceuticals Limited***
Site address: ***I A Industrial Area, Raja Ka Bagh, Tehsil Nurpur Distt, Kangra (H.P.), 176201, India***
OMS Organisation Id. / OMS Location Id.: ***ORG-100048403*** / ***LOC-100080161***

Has been inspected in connection with marketing authorisation(s) listing manufacturers located outside of the European Economic Area in accordance with Art. 111(4) of Directive 2001/83/EC.

From the knowledge gained during inspection of this manufacturer, the latest of which was conducted on ***2023-04-21***, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive (EU) 2017/1572 and Commission Delegated Regulation (EU) 2017/1569 [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 Art. 111(5) of Directive 2001/83/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: 2023.07.22 14:07:04 EEST
Reason: MoldSign Signature
Location: Moldova

Part 2

Human Medicinal Products

1 MANUFACTURING OPERATIONS	
1.1	**Sterile products**
	1.1.1 Aseptically prepared (processing operations for the following dosage forms) 1.1.1.2 Lyophilisates 1.1.1.4 Small volume liquids 1.1.1.6 Other: (powder for injection)(en)
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 1.2.1.8 Other solid dosage forms: oral powder in sachet(en) 1.2.1.13 Tablets
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 1.5.1.8 Other solid dosage forms: oral powder in sachet(en) 1.5.1.13 Tablets Special Requirements 7 Other: non-coated and film-coated tablets(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*

Clarifying remarks (for public users)

Inspection covers manufacturing and testing of medicinal products in Cytotoxic Block and Cephalosporin Block: Cytotoxic Block: Sterile medicinal products; Aseptically prepared (processing operations for the following Dosage forms): Small volume liquids (vial) and Lyophilized Injection. Non-sterile products; Non-sterile products (processing operations for the following Dosage forms): Capsules, hard shell; Tablets: Tablets/Coated tablets. Cephalosporin Block: Sterile medicinal products; Aseptically prepared (processing operations for the following Dosage forms): Small volume Aseptic powders for injection. Non-sterile products; Non-sterile products (processing operations for the following Dosage forms): Capsules, hard shell; Other Solid dosage form - powder for oral suspension in sachets (Oral Dry Syrups); Tablets/Coated tablets. Activities pointed out in p.1.1.1.6, p.1.2.1.8 and p.1.5.1.8 refer only to manufacture of cephalosporin block. It has been distant inspection

2023-06-21

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

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