Bulgarian Drug Agency

CERTIFICATE NUMBER: ***BG/GMP/2021/193***

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: ***Nobel Ilac Sanayii Ve Ticaret A.S.***
Site address: ***Sancaklar Mahallesi, Eski Akcakoca Caddesi No 299, Merkez, Duzce, 81100, Turkey***
OMS Organisation Id. / OMS Location Id.: ***ORG-100010367*** / ***LOC-100062379***

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 ***2021-10-14***, 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. Updates to restrictions or clarifying remarks can be identified through the EudraGMDP website (http://eudragmdp.ema.europa.eu/). 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/ECis also applicable to importers.*

[2] *Guidance on the interpretation of this template can be found in the Interpretation of the Union format for GMP certificate.*

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

Digitally signed by Moraru Grigore
Date: 2024.05.20 10:59:10 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: beta lactam antibiotic-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 1.2.1.5 Liquids for external use Special Requirements 7 Other: spray(en) 1.2.1.6 Liquids for internal use Special Requirements 7 Other: syrups, oral suspensions(en) 1.2.1.8 Other solid dosage forms: powder for oral suspension, granules for oromucosal suspension,effervescent granules(en) 1.2.1.11 Semi-solids Special Requirements 7 Other: cream, ointment, gel(en) 1.2.1.13 Tablets 1.2.1.17 Other: film-coated tablets, coated tablets, gastro-resistant tablets, gastro-resistant capsules, lozenges(en)
1.4	**Other products or manufacturing activity**
	1.4.1 Manufacture of 1.4.1.3 Other: beta-lactam antibiotics – cephalosporines: film-coated tablets; powder for oral suspension(en)

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 1.5.1.11 Semi-solids 1.5.1.13 Tablets 1.5.1.17 Other non-sterile medicinal products: film-coated tablets, coated tablets, gastro-resistant tablets, gastro-resistant capsules, lozenges, powder for oral suspension , granules for oromucosal suspension, effervescent granules, cephalosporines:film-coated tablets, powder for oral suspension(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)

It has been a distant inspection.

2021-12-22

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

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Bulgarian Drug Agency
Tel:***Confidential***
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