

ИЗПЪЛНИТЕЛНА АГЕНЦИЯ ПО ЛЕКАРСТВОТА

CERTIFICATE NUMBER: **BG/GMP/2022/210**

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: ***Akums Drugs And Pharmaceuticals Limited***

Site address: ***Plot No 2 3 4 5 Sector 6b lie, Sidcul Ranipur, Haridwar, 249403, India***

OMS Organisation Id. / OMS Location Id.: ***ORG-100023847 / LOC-100071775***

DUNS Number: ***67-760-6032***

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 **2022-05-13**, it is considered that it complies with:

- The principles and guidelines of Good Manufacturing Practice laid down in Directive 2003/94/EC³

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.

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.

Part 2

Human Medicinal Products	
1 MANUFACTURING OPERATIONS	
1.1	Sterile products
	<i>1.1.1 Aseptically prepared (processing operations for the following dosage forms)</i> 1.1.1.4 Small volume liquids 1.1.1.6 Other: Other: Powder for solution for injection(en)
	<i>1.1.2 Terminally Sterilised (processing operations for the following dosage forms)</i> 1.1.2.1 Large volume liquids 1.1.2.3 Small volume liquids
1.5	Packaging
	<i>1.5.2 Secondary packaging</i>
1.6	Quality control testing
	<i>1.6.1 Microbiological: sterility</i> <i>1.6.2 Microbiological: non-sterility</i> <i>1.6.3 Chemical/Physical</i>

Clarifying remarks (for public users)

It has been a distant inspection at Plant III. Based on risk assessment the validity of the certificate is two years. When the travel restrictions are dropped out the on site inspection will be carried out.

2022-06-24

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

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