Digitally signed by Chirtoacă Iurie
Date: 2023.04.11 10:16:50 EEST
Reason: MoldSign Signature
Location: Moldova

Hessisches Landesamt für Gesundheit und Pflege - Abteilung Pharmazie (Humanarzneimittel)

CERTIFICATE NUMBER: ***DE_HE_01_GMP_2021_0099***

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

Part 1

Issued following an inspection in accordance with :

The competent authority of Germany confirms the following:
The manufacturer: ***Hemofarm A.D.***
Site address: ***Hajduk Veljkova bb, Sabac, 15000, Serbia***

Other
wurde im Rahmen der in der Zulassung aufgefuehrten Hersteller mit Sitz ausserhalb des Europaeischen Wirtschaftsraumes einer Fernbewertung unterzogen gemaess - Art. 111 (4) der Richtlinie 2001/83/EG umgesetzt in deutsches Recht durch: SECT. 72a Abs. 1 Arzneimittelgesetz
Distant Assessment

From the knowledge gained during Distant Assessment of this manufacturer, the latest of which was conducted on ***2021-05-28***, 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.

---

[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.*

Part 2

1 MANUFACTURING OPERATIONS	
1.2	**Non-sterile products**
	1.2.1 Non-sterile products (processing operations for the following dosage forms) 1.2.1.1 Capsules, hard shell 1.2.1.6 Liquids for internal use 1.2.1.11 Semi-solids 1.2.1.13 Tablets 1.2.1.17 Other: granules and granules for oral suspensions(en)
1.5	**Packaging**
	1.5.1 Primary Packaging 1.5.1.1 Capsules, hard shell 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: granules and granules for oral suspensions(en)
	1.5.2 Secondary packaging
1.6	**Quality control testing**
	1.6.2 Microbiological: non-sterility *1.6.3 Chemical/Physical*

Clarifying remarks (for public users)

distant assessment, in addition video conference / virtual site tour of selected production and storage areas This certificate is valid until 27.05.2023. This certificate is in case of importation into the European Union only valid in connection with the current confirmation according to para 72a section 1 sentence 1 number 2 Medicinal Products Act, the German Drug Law (Arzneimittelgesetz - AMG), issued to the importing company STADA Arzneimittel AG, Stadastr. 2-18, 61118 Bad Vilbel after the inspection according to para 72a section 1 sentence 3 number 1 Medicinal Products Act, and after confirming the validity of the inputs using the database according to para 67a Medicinal Products Act. Scope of inspection: - Acetylsalicylic Acid/Pseudoephedrine 500mg/30mg granules (Handelsname: Grippostad (R) complex - granules for oral suspension); BPS - Aciclovir 50mg/g ointment; BPS - Allopurinol 100 mg and 300 mg tablets; BPS - Amitriptylin 25mg film-coated tablets; (text missing)

2021-09-30

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

---

Confidential
Regierungspräsidium Darmstadt
Tel:***Confidential***
Fax:***Confidential***