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i medicinska sredstva Srbije
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Žiro račun: 840-712667-07

Agencija za lekove i medicinska sredstva Srbije

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Reason: MoldSign Signature
Location: Moldova

Republika Srbija
Agencija za lekove i
medicinska sredstva Srbije
Br.: 515-00-06053-2017-4
Datum: 17.08.2017.
Beograd

Republic of Serbia
Medicines and Medical Devices
Agency of Serbia
No.: 515-00-06053-2017-4
Date: 08/17/2017
Belgrade

CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

SERTIFIKAT O FARMACEUTSKOM PROIZVODU[1]

This certificate conforms to the format recommended by the World Health Organization. Ovaj sertifikat odgovara formatu preporučenom od strane Svetske zdravstvene organizacije.	
No. of certificate: Br. sertifikata:	515-00-06053-2017-4 515-00-06053-2017-4
Exporting (certifying country): Zemlja izvoznik (davalac sertifikata):	REPUBLIC OF SERBIA REPUBLIKA SRBIJA
Importing (requesting country): Zemlja uvoznik (podnosilac zahteva):	REPUBLIC OF ARMENIA REPUBLIKA JERMENIJA
1. Name and dosage form of the product: **1.** Naziv i farmaceutski oblik proizvoda:	Hemomycin®, Powder for solution for infusion, 1 x 500mg. Hemomycin®, prašak za rastvor za infuziju, 1 x 500mg.
1.1. Active ingredient(s)[2] and amount(s) per unit dose[3]: *For complete composition including excipients, see attached[4].* **1.1.** Aktivna supstanca(e)[2] i količina po pojedinačnoj dozi[3]: *Za kompletan sastav, uključujući pomoćne supstance, videti u prilogu[4].*	Azithromycin 500.0mg (in the form of azythromycin dihydrate) Citric Acid Monohydrate 110.0mg Mannitol 146.0mg Sodium Hydroxide q.s. Water for injection* q.s. to 5ml *Water for injection is used for preparation of the solution. It disappeared during freeze-drying process. Azitromicin 500,0mg (u obliku azitromicin, dihidrata) Limunska kiselina, monohidrat 110,0mg Manitol 146,0mg Natrijum-hidroksid q.s. Voda za injekcije* do 5ml *Voda za injekcije se koristi za pripremu rastvora. Nestaje tokom procesa liofilizacije.
1.2. Is this product licensed to be placed on the market for use in the exporting country?[5] *(Key in as appropriate ☒)* **1.2.** Da li ovaj proizvod ima odobrenje za puštanje na tržište zemlje izvoznika?[5] *(Označiti odgovarajući odgovor ☒)*	☒ yes ☐ no ☒ da ☐ ne
1.3. Is this product actually on the market in the exporting country? *(Key in as appropriate ☒)* **1.3.** Da li se ovaj proizvod zaista nalazi na tržištu zemlje izvoznika? *(Označiti odgovarajući odgovor ☒)*	☒ yes ☐ no ☒ da ☐ ne

If the answer to 1.2. is yes, continue with section 2A and omit section 2B. If the answer to 1.2. is no, omit section 2 A and continue with section 2B.[6] Ukoliko je odgovor na 1.2. da, nastavite popunjavanje dela 2A izostavljajući deo 2B. Ukoliko je odgovor na 1.2. ne, izostavite deo 2 A i nastavite popunjavanje dela 2B.[6]	
2.A.1. Number of product licence[7] and date of issue: **2.A.1.** Broj licence[7] i datum izdavanja:	515-01-4089-12-001 ; 02/04/2013. 515-01-4089-12-001 ; 04.02.2013.
2.A.2. Product licence holder: (*name and address*) **2.A.2.** Vlasnik licence: (*naziv i adresa*)	HEMOFARM AD VRSAC Beogradski put bb, Vrsac, Republic of Serbia HEMOFARM AD VRŠAC Beogradski put bb, Vršac, Republika Srbija
2.A.3. Status of product licence holder:[8] *(Key in appropriate category as defined in footnote 8)* **2.A.3.** Status vlasnika licence:[8] *(Ukucajte odgovarajuću kategoriju, kao što je definisano u fusnoti 8)*	a a
2.A.3.1. For categories b and c the name and address of the manufacture producing the dosage form is:[9] **2.A.3.1.** Za kategorije b i c naziv i adresa proizvodjača koji proizvodi farmaceutski oblik je:[9]	
2.A.4. Is a summary basis for approval appended?[10] *(Key in as appropriate ☒)* **2.A.4.** Da li se u prilogu nalazi kratak pregled karakteristika proizvoda na osnovu kojeg je dobijeno odobrenje?[10] *(Označiti odgovarajući odgovor ☒)*	☐ **yes** ☒ **no** ☐ **da** ☒ **ne**
2.A.5. Is the attached, officially approved product information complete and consonent with the licence[11]? *(Key in as appropriate ☒)* **2.A.5.** Da li je dokument u prilogu, zvanično odobrena infomacija o proizvodu kompletna i u skladu sa licencom[11]? *(Označiti odgovarajući odgovor ☒)*	☐ **yes** ☐ **no** ☒ **not provided** ☐ **da** ☐ **ne** ☒ **nije dostavljena**
2.A.6. Applicant for certificate, if different from licence holder: [12](*name and address*) **2.A.6.** Podnosilac zahteva za dobijanje sertifikata, ukoliko se razlikuje od vlasnika licence:[12](*naziv i adresa*)	
2.B.1. Applicant for certificate: (*name and address*) **2.B.1.** Podnosilac zahteva:(*naziv i adresa*)	
2.B.2. Status of applicant: *(Key in appropriate category as defined in footnote 8)* **2.B.2.** Status podnosioca zahteva:*(Ukucajte odgovarajuću kategoriju, kao što je definisano u fusnoti 8)*	
2.B.2.1. For categories b and c the name and address of the manufacturer producing the dosage form is:[9] **2.B.2.1.** Za kategorije b i c naziv i adresa proizvođača farmaceutskog oblika je:[9]	
2.B.3. Why is marketing authorization lacking? *(Key in as appropriate ☒)* **2.B.3.** Razlog zbog koga nedostaje odobrenje za puštanje u promet? *(Označiti odgovarajući odgovor ☒)*	☐ not required ☐ not requested ☐ under consideration ☐ refused ☐ nije potrebno ☐ nije traženo ☐ u razmatranju ☐ odbijeno
2.B.4. Remarks[13]: **2.B.4.** Primedbe[13]:	
3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? [14] *(Key in as appropriate)*	☒ **yes** ☐ **no** ☐ **not applicable**

3.Da li ovlašćeni organ vrši periodičnu inspekciju proizvodnog pogona u kome se proizvodi farmaceutski oblik? [14] *(Označiti odgovarajući odgovor ☒)*	☒**da**	☐**ne**	☐**nije primenljivo**
If not or not applicable, proceed to question 4. Ukoliko je odgovor negativanili nije primenljivopreći na pitanje 4.			
3.1. Periodicity of rountine inspections: **3.1.** Interval obavljanja redovnih inspekcija:	3 (three) *years* 3 (tri) *godine*		
3.2. Has the manufacture of this type of dosage form been inspected? *(Key in as appropriate ☒)* **3.2.** Da li je izvršena inspekcija proizvodnje ove vrste farmaceutskog oblika? *(Označiti odgovarajući odgovor ☒)*	☒**yes** ☒**da**	☐**no** ☐**ne**	
3.3. Do the facilities and operations conform to GMP as recommended by the World Health Organization? [15] *(Key in as appropriate ☒)* [14] **3.3.** Da li proizvodni pogoni i procesi proizvodnje odgovaraju GMP standardima propisanim od strane Svetske zdravstvene organizacije? [15] *(Označiti odgovarajući odgovor ☒)* [14]	☒**yes** ☒**da**	☐**no** ☐**ne**	☐**not applicable** ☐**nije primenljivo**
4.Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? [16] *(Key in as appropriate ☒)* **4.** Da li podaci podneti od strane podnosioca prijave zadovoljavaju zahteve nadležnog organa po svim pitanjima proizvodnje? [16] *(Označiti odgovarajući odgovor ☒)*	☒**yes** *If no explain:* ☒**da** *Ukoliko je odgovor ne, objasniti:*	☐**no** ☐**ne**	

Address of certifying authority: Adresa davaoca ovlašćenja:	**Medicines and Medical devices Agency of Serbia** **458 Vojvode Stepe Str., Belgrade 11152, Republic of Serbia** **Agencija za lekove i medicinska sredstva Srbije** **Vojvode Stepe br. 458, 11152 Beograd, Republika Srbija**
Telephone: Telefon:	+ 381 11 3951 139, +381 11 3951 107 + 381 11 3951 139, +381 11 3951 107
Fax No: Br. faksa:	+ 381 11 3951 131 + 381 11 3951 131

Name of authorized person:
Saša Jaćović, MD sp., Managing Director
Ime ovlašćene osobe:
Spec. dr med. Saša Jaćović, Direktor

Signature / Potpis:

Stamp and date:
Pečат i datum:

Explanatory notes

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.
3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.
4. Details of quantitative composition are preferred but their provision is subject to the agreement of the product-licence holder.
5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product licence.
6. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the licence is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market:
    a. manufactures the dosage form;
    b. packages and/or labels a dosage form manufactured by an independent company; or
    c. is involved in none of the above.
9. This information can only be provided with the consent of the product-licence holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product licence. If the production site is changed, the licence has to be updated or it is no longer valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC)
12. In this circumstance, permission for issuing the certificate is required from the product-licence holder. This permission has to be provided to the authority by the applicant.
13. Please indicate the reason that the applicant has provided for not requesting registration.
    a. the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of export;
    b. the product has been reformulated with a view to improving its stability under tropical conditions;
    c. the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
    d. the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
    e. any other reason, please specify.
14. Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
15. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).
16. This section is to be completed when the product-licence holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.