MINISTRY OF HEALTH
NATIONAL AGENCY FOR MEDICINES
AND MEDICAL DEVICES OF ROMANIA
48, Av. Sănătescu St, Sector 1, 011478 Bucharest
Tel: +4021-317.11.00
Fax: +4021-316.34.97
www.anm.ro

CERTIFICATE OF A PHARMACEUTICAL PRODUCT[1]

This certificate conforms to the format recommended by the World Health Organization
(explanatory notes are attached)

No. of Certificate: **7804**

Exporting (certifying) country: **ROMANIA**

Importing (requesting) country: **MOLDOVA**

1. Name, dosage form and strength of the product:

Hepatect CP 50 UI/ml soluţie perfuzabilă - name for Romania
Hepatect CP 50 IU/ml solution for infusion - name for Moldova

1.1.Active ingredient(s)[2] and amount(s) per unit dose[3]:

Human plasma protein	***50 mg***	***50 mg***
of which		
Immunoglobulin G		***≥96 %***
HBs antibodies		***50 IU***

For complete composition including excipients, see attached [4].

1.2.Is this product licensed to be placed on the market for use in the exporting country?[5]

☑ ***Yes*** ☐ ***No***

1.3.Is this product actually on the market in the exporting country?

☑ ***Yes*** ☐ ***No***

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 2A and continue with section 2B[6].

2.A.1. Marketing Authorisation number[7]: **7349/2015/01-02-03-04**

Date of Marketing Authorisation: **30 Jnauary 2015**

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2.A.2. Product licence holder (name and address):

Name: **Biotest Pharma GmbH**
Address: **Landsteinerstrasse 5, 63303 Dreieich, Germany**

2. A.3. Status of product licence holder[8]:

a/b/c

Manufacturer involved in the manufacture, batch testing (except for pyrogen testing), filling, labeling, and packaging of the finished product
Name: **Biotest AG**
Address: **Landsteiner strasse 5, D-63303 Dreieich, Germany**

Manufacturers involved in pyrogen testing
Name: **Labor LS SE & Co. KG**
Address: **Mangelsfeld 4, 5, 6, D-97708 Bad Bocklet-Großenbrach, Germany**

Name: **Charles River Laboratories Ireland Limited**
Address: **Carrentrila, Ballina, Co. Mayo, Ireland**

Manufacturer involved in batch release of the finished product
Name: **Biotest Pharma GmbH**
Address: **Landsteiner strasse 5, D-63303 Dreieich, Germany**

A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form is[9]:

2. A.4. Is a summary basis for approval appended?[10]

☐ *Yes* ☑ *No*

2. A.5. Is the attached, officially approved product information complete and consonent with the licence?[11]

☐ *Yes* ☑ *Not Provided*

The applicant assumes the whole responsability for the accuracy of the translation of the text from Romanian into English.

2.A.6. Applicant for certificate, if different from licence holder (name and address)[12]: **Yes**

Name: **Prisum Heathcare SRL**
Address: **17 General Gheorghe Manu Street, Office No. 1, Sector 1, Postal Code 031216, Bucharest, Romania**

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3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced:

☐ *Yes* ☐ *No* ☐ ☑ *Not Applicable*

3.1. Periodicity of routine inspections (years): -

3.2. Has the manufacture of this type of dosage form been inspected?

☑ *Yes* ☐ *No*

3.3. Do the facilities and operations conform to GMP as recommended by the World Health Organization?[15]

☑ *Yes* ☐ *No* ☐ *Not Applicable*

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?[16]

☑ *Yes* ☐ *No*

Address of certifying authority:

48 Av. Sanatescu Street, sector 1, 011478 Bucharest - Romania

Telephone Number: + **0040-021-317 11 02**

Fax Number: + **0040-021-316 34 97**

E-mail: **www.anm.ro**

Name of authorized person: **Elena Valeria BRODEALĂ**

Signature:

Stamp and date: 23. SEP. 2025

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Complete composition:

One ml of solution for infusion contains:

Human plasma protein	***50 mg***
of which	
immunoglobulin G	***≥96 %***
HBs antibodies	***50 IU***
Glycine	*300 µmol*
Water for injections	*up to 1 ml*

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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 onproprietary 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.