GOVERNMENT OF TELANGANA
DRUGS CONTROL ADMINISTRATION
Vengalarao Nagar, Hyderabad 500 038

CERTIFICATE OF PHARMACEUTICAL PRODUCT

This certificate conforms to the format recommended by the World Health Organization
(General Instructions and explanatory notes attached.)

No. of Certificate : **3826/A3/2021** Valid up to: **11.01.2023**

Exporting (certifying) country: **INDIA**

Importing (requesting) country: **MOLDOVA**

1. Name and dosage form of the product: **LEUPROLIDE ACETATE DEPOT FOR INJECTION 3.75 mg**
PROLEMAX 3.75 mg

1.1 Active Ingredient (S)[2] and amounts (S) per unit dose[3] :

Each Lyophilized vial contains

Leuprolide Acetate	USP	3.75 mg
Excipients		q.s
1 mL Ampoule of Solvent contains		
Each Sterile ampoule contains:		
Sodium Carboxymethyl Cellulose	USP	5 mg
Mannitol	USP	50 mg
Polysorbate 80	USP	1 mg
Water for Injection	USP	q.s.

1.2 Is this product licensed to be placed on the market for use in the exporting country? [5]
(Key in as appropriate)

Yes ☒ No ☐

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

Yes ☒ No ☐ Unknown ☐

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 2B6

SECTION 2A

2.A.1 Number of product Licence[7] and date of issue : **22/RR/TS/2015/F/R, Dated: 19.04.2018**

2.A.2 Product license holder (Name and address) : **GLS PHARMA LIMITED**
Plot.No. 10,IDA, Phase-I
Jeedimetla, R.R.Dist,
Hyderabad, Telangana, INDIA

2.A.3 Status of product – license holder[8] (Key is appropriate category as defined in note (8)

a) ☒ b) ☐ c) ☐

2A.3.1 For categories b and c the name and address of the Manufacturer producing the dosage form is [9] ?

Yes ☐ No ☐ Not applicable ☒

2.A.4 Is summary basis for approval appended [10] ? (enclosed at the time of product approval)

Yes ☒ No ☐ Not applicable ☐

2.A.5 Is the attached, officially approved product information complete and consonant with the license?[11]
(key as appropriate)

Yes ☒ No ☐ Not applicable ☐

2. A.6 Applicant for certificate, if different from license holder (Name & Address)[12]

Yes ☐ No ☒ Not applicable ☐

SECTION 2B IS TO BE OMITTED

2. B.1 Applicant for certificate (Name & address)

2. B.2 Status of applicant: (Key in the appropriate category as defined in note 8)

2. B.2.1 For categories b and c the name and address of the manufacturer producing the dosage from is[9] :

2. B.3 Why is marketing authorization lacking?
Not required / Not requested / under consideration / Refused (Key in as appropriate)

2. B.4 Remarks: [13]

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

Yes ☒ No ☐ Not applicable[14] ☐

If not or not applicable, proceed to question 4.

Periodicity of routine inspections (years) : ***NOT LESS THAN ONCE A YEAR***

Has the manufacturer of this type of dosage form been inspected Yes/No (Key in as appropriate)

Yes ☒ No ☐ Not applicable ☐

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

Yes ☒ No ☐ Not applicable ☐

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

Yes ☒ No ☐ Not applicable ☐

Address of certifying authority : **Office of the Deputy Director**
Drugs Control Administration, Vengalarao Nagar,
Hyderabad 500 038, Telangana, INDIA.

Telephone and Fax numbers : **TEL: +91 40 23814119 FAX: +91 40 23814360**

Name of Authorized Person :

Dr. Y. NAVEEN KUMAR.
JOINT DIRECTOR(FAC)
LICENSING & CONTROLING AUTHORITY

Signature :

Stamp and Date :

DRUG CONTROL ADMINISTRATION ★ GOVERNMENT OF TELANGANA ★
HYDERABAD
JD(FAC)

11/01/2021
Dr. Y. NAVEEN KUMAR
M.Pharm.,Ph.D
Joint Director (Enforcement)
Licensing & Controlling Authority (FAC)
Drugs Control Administration
Government of Telangana
Hyderabad-500 038, T.S.

ATTACHMENT TO COPP

Product Name : Leuprolide acetate for depot Injection USP 3.75 mg

Composition :

Each Lyophilized vial contains

Leuprolide acetate	USP	3.75mg
Excipients		q.s

2mL ampoule of solvent contains:

Sodium carboxy methyl cellulose	USP	5mg
Mannitol	USP	50mg
Polysorbate 80	USP	1 mg
Water for injection	USP	q.s

CERTIFICATE OF COMPOSITION

Ingredients	Qty/vial
Leuprolide acetate USP*	3.75 mg
PLGA(Polylacto Glycolic acid)	33.1 mg
Poly vinyl alcohol USP	60 mg
Gelatin USP	0.65 mg
Mannitol USP	6.60 mg
Methylene dichloride USP	0.825 mL
Water for Injection USP **	q.s

* Actual quantity of drug to be taken to get 100% assay on as is basis

** Loss in the process of Lyophilization

USP – United States Pharmacopeia

q.s – Quantity Sufficient

Deputy Director Drugs Control Administration Government Of Telangana HYDERABAD

GOVERNMENT OF TELANGANA
DRUGS CONTROL ADMINISTRATION
Vengalarao Nagar, Hyderabad 500 038

CERTIFICATE OF PHARMACEUTICAL PRODUCT

This certificate conforms to the format recommended by the World Health Organization
(General Instructions and explanatory notes attached.)

No. of Certificate : **3827/A3/2021** Valid up to: **11.01.2023**

Exporting (certifying) country: **INDIA**

Importing (requesting) country: **VENEZUELA**

1. Name and dosage form of the product: **LOMUSTINE CAPSULES 40 mg**
LOMCAP 40

1.1 Active Ingredient (S)[2] and amounts (S) per unit dose[3] :

Each capsule contain	
Lomustine	40 mg
Excipeints	q.s

1.2 Is this product licensed to be placed on the market for use in the exporting country? [5]
(Key in as appropriate)

Yes ☒ No ☐

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

Yes ☒ No ☐ Unknown ☐

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 2B6

SECTION 2A

2.A.1 Number of product Licence[7] and date of issue : **22/RR/TS/2015/F/G, Dated: 13.01.2015**

2.A.2 Product license holder (Name and address) : **GLS PHARMA LIMITED**
Plot.No. 10,IDA, Phase-I
Jeedimetla, R.R.Dist,
Hyderabad, Telangana, INDIA

2.A.3 Status of product – license holder[8] (Key is appropriate category as defined in note (8)

a) ☒ b) ☐ c) ☐

2A.3.1 For categories b and c the name and address of the Manufacturer producing the dosage form is [9] ?

Yes ☐ No ☐ Not applicable ☒

2.A.4 Is summary basis for approval appended [10] ? (enclosed at the time of product approval)

Yes ☒ No ☐ Not applicable ☐

2.A.5 Is the attached, officially approved product information complete and consonant with the license?[11]
(key as appropriate)

Yes ☒ No ☐ Not applicable ☐

2. A.6 Applicant for certificate, if different from license holder (Name & Address)[12]

Yes ☐ No ☒ Not applicable ☐

SECTION 2B IS TO BE OMITTED

2. B.1 Applicant for certificate (Name & address)

2. B.2 Status of applicant: (Key in the appropriate category as defined in note 8)

2. B.2.1 For categories b and c the name and address of the manufacturer producing the dosage from is[9] :

2. B.3 Why is marketing authorization lacking?
Not required / Not requested / under consideration / Refused (Key in as appropriate)

2. B.4 Remarks: [13]

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

Yes ☒ No ☐ Not applicable[14] ☐

If not or not applicable, proceed to question 4.

Periodicity of routine inspections (years) : ***NOT LESS THAN ONCE A YEAR***

Has the manufacturer of this type of dosage form been inspected Yes/No (Key in as appropriate)

Yes ☒ No ☐ Not applicable ☐

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

Yes ☒ No ☐ Not applicable ☐

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

Yes ☒ No ☐ Not applicable ☐

Address of certifying authority : **Office of the Deputy Director**
Drugs Control Administration, Vengalarao Nagar,
Hyderabad 500 038, Telangana, INDIA.

Telephone and Fax numbers : **TEL: +91 40 23814119 FAX: +91 40 23814360**

Name of Authorized Person :

Dr. Y. NAVEEN KUMAR.
JOINT DIRECTOR(FAC)
LICENSING & CONTROLING AUTHORITY

Signature :

Stamp and Date :

DRUG CONTROL ADMINISTRATION ★ GOVERNMENT OF TELANGANA ★
HYDERABAD
JD(FAC)

11/01/2021
Dr. Y. NAVEEN KUMAR
M.Pharm.,Ph.D
Joint Director (Enforcement)
Licensing & Controlling Authority (FAC)
Drugs Control Administration
Government of Telangana
Hyderabad-500 038, T.S.

GOVERNMENT OF TELANGANA
DRUGS CONTROL ADMINISTRATION
Vengalarao Nagar, Hyderabad 500 038

CERTIFICATE OF PHARMACEUTICAL PRODUCT

This certificate conforms to the format recommended by the World Health Organization
(General Instructions and explanatory notes attached.)

No. of Certificate : **3705/A3/2020** Valid up to: **14.02.2023**

Exporting (certifying) country: **INDIA**

Importing (requesting) country: **KENYA**

1. Name and dosage form of the product: **TEMOZOLOMIDE CAPSULES 20 mg**

1.1 Active Ingredient (S)[2] and amounts (S) per unit dose[3] :

Each Capsule contains:

Temozolomide	USP	20 mg
Excipients		q.s

Colour: Approved colours used in capsule shell

1.2 Is this product licensed to be placed on the market for use in the exporting country? [5]
(Key in as appropriate)

Yes ☒ No ☐

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

Yes ☒ No ☐ Unknown ☐

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 2B6

SECTION 2A

2.A.1 Number of product Licence[7] and date of issue : **22/RR/TS/2015/F/G, Dated: 13.01.2015**

2.A.2 Product license holder (Name and address) : **GLS PHARMA LIMITED**
Plot.No. 10,IDA, Phase-I
Jeedimetla, R.R.Dist,
Hyderabad, Telangana, INDIA

2.A.3 Status of product – license holder[8] (Key is appropriate category as defined in note (8)

a) ☒ b) ☐ c) ☐

2A.3.1 For categories b and c the name and address of the Manufacturer producing the dosage form is [9] ?

Yes ☐ No ☐ Not applicable ☒

2.A.4 Is summary basis for approval appended [10] ? (enclosed at the time of product approval)

Yes ☒ No ☐ Not applicable ☐

2.A.5 Is the attached, officially approved product information complete and consonant with the license?[11]
(key as appropriate)

Yes ☒ No ☐ Not applicable ☐

2. A.6 Applicant for certificate, if different from license holder (Name & Address)[12]

Yes ☐ No ☒ Not applicable ☐

SECTION 2B IS TO BE OMITTED

2. B.1 Applicant for certificate (Name & address)

2. B.2 Status of applicant: (Key in the appropriate category as defined in note 8)

2. B.2.1 For categories b and c the name and address of the manufacturer producing the dosage from is[9] :

2. B.3 Why is marketing authorization lacking?
Not required / Not requested / under consideration / Refused (Key in as appropriate)

2. B.4 Remarks: [13]

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

Yes ☒ No ☐ Not applicable[14] ☐

If not or not applicable, proceed to question 4.

Periodicity of routine inspections (years) : ***NOT LESS THAN ONCE A YEAR***

Has the manufacturer of this type of dosage form been inspected Yes/No (Key in as appropriate)

Yes ☒ No ☐ Not applicable ☐

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

Yes ☒ No ☐ Not applicable ☐

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

Yes ☒ No ☐ Not applicable ☐

Address of certifying authority : **Office of the Deputy Director**
Drugs Control Administration, Vengalarao Nagar,
Hyderabad 500 038, Telangana, INDIA.

Telephone and Fax numbers : **TEL: +91 40 23814119** **FAX: +91 40 23814360**

Name of Authorized Person :

Dr. Y. NAVEEN KUMAR.
JOINT DIRECTOR(FAC)
LICENSING & CONTROLING AUTHORITY

Signature :

Stamp and Date :

DRUG CONTROL ADMINISTRATION ★ GOVERNMENT OF TELANGANA ★
HYDERABAD
JD(FAC)

Dr. Y. NAVEEN KUMAR
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GOVERNMENT OF TELANGANA
DRUGS CONTROL ADMINISTRATION
Vengalarao Nagar, Hyderabad 500 038

CERTIFICATE OF PHARMACEUTICAL PRODUCT

This certificate conforms to the format recommended by the World Health Organization
(General Instructions and explanatory notes attached.)

No. of Certificate : **3706/A3/2020** Valid up to: **14.02.2023**

Exporting (certifying) country: **INDIA**

Importing (requesting) country: **KENYA**

1. Name and dosage form of the product: **TEMOZOLOMIDE CAPSULES 100 mg**
TEMOGET

1.1 Active Ingredient (S)[2] and amounts (S) per unit dose[3] :

Each Capsule contains:

Temozolomide	USP	100 mg
Excipients		q.s

Colour: Approved colours used in capsule shell

1.2 Is this product licensed to be placed on the market for use in the exporting country? [5]
(Key in as appropriate)

Yes ☒ No ☐

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

Yes ☒ No ☐ Unknown ☐

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 2B6

SECTION 2A

2.A.1 Number of product Licence[7] and date of issue : **22/RR/TS/2015/F/G, Dated: 13.01.2015**

2.A.2 Product license holder (Name and address) : **GLS PHARMA LIMITED**
Plot.No. 10,IDA, Phase-I
Jeedimetla, R.R.Dist,
Hyderabad, Telangana, INDIA

2.A.3 Status of product – license holder[8] (Key is appropriate category as defined in note (8)

a) ☒ b) ☐ c) ☐

2A.3.1 For categories b and c the name and address of the Manufacturer producing the dosage form is [9] ?

Yes ☐ No ☐ Not applicable ☒

2.A.4 Is summary basis for approval appended [10] ? (enclosed at the time of product approval)

Yes ☒ No ☐ Not applicable ☐

2.A.5 Is the attached, officially approved product information complete and consonant with the license?[11]
(key as appropriate)

Yes ☒ No ☐ Not applicable ☐

2. A.6 Applicant for certificate, if different from license holder (Name & Address)[12]

Yes ☐ No ☒ Not applicable ☐

SECTION 2B IS TO BE OMITTED

2. B.1 Applicant for certificate (Name & address)

2. B.2 Status of applicant: (Key in the appropriate category as defined in note 8)

2. B.2.1 For categories b and c the name and address of the manufacturer producing the dosage from is[9] :

2. B.3 Why is marketing authorization lacking?
Not required / Not requested / under consideration / Refused (Key in as appropriate)

2. B.4 Remarks: [13]

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

Yes ☒ No ☐ Not applicable[14] ☐

If not or not applicable, proceed to question 4.

Periodicity of routine inspections (years) : ***NOT LESS THAN ONCE A YEAR***

Has the manufacturer of this type of dosage form been inspected Yes/No (Key in as appropriate)

Yes ☒ No ☐ Not applicable ☐

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

Yes ☒ No ☐ Not applicable ☐

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

Yes ☒ No ☐ Not applicable ☐

Address of certifying authority : **Office of the Deputy Director**
Drugs Control Administration, Vengalarao Nagar,
Hyderabad 500 038, Telangana, INDIA.

Telephone and Fax numbers : **TEL: +91 40 23814119** **FAX: +91 40 23814360**

Name of Authorized Person :

Dr. Y. NAVEEN KUMAR.
JOINT DIRECTOR(FAC)
LICENSING & CONTROLING AUTHORITY

Signature :

Stamp and Date :

DRUG CONTROL ADMINISTRATION ★ GOVERNMENT OF TELANGANA ★
HYDERABAD
JD(FAC)

Dr. Y. NAVEEN KUMAR
M.Pharm.,Ph.D
Joint Director (Enforcement)
Licensing & Controlling Authority (FAC)
Drugs Control Administration
Government of Telangana
Hyderabad-500 038, T.S.

GOVERNMENT OF TELANGANA
DRUGS CONTROL ADMINISTRATION
Vengalarao Nagar, Hyderabad 500 038

CERTIFICATE OF PHARMACEUTICAL PRODUCT

This certificate conforms to the format recommended by the World Health Organization
(General Instructions and explanatory notes attached.)

No. of Certificate : **3707/A3/2020** Valid up to: **14.02.2023**

Exporting (certifying) country: **INDIA**

Importing (requesting) country: **KENYA**

1. Name and dosage form of the product: **TEMOZOLOMIDE CAPSULES 250 mg**
TEMOGET

1.1 Active Ingredient (S)[2] and amounts (S) per unit dose[3] :

Each Capsule contains:

Temozolomide	USP	250 mg
Excipients		q.s

Colour: Approved colours used in capsule shell

1.2 Is this product licensed to be placed on the market for use in the exporting country? [5]
(Key in as appropriate)

Yes ☒ No ☐

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

Yes ☒ No ☐ Unknown ☐

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 2B6

SECTION 2A

2.A.1 Number of product Licence[7] and date of issue : **22/RR/TS/2015/F/G, Dated: 13.01.2015**

2.A.2 Product license holder (Name and address) : **GLS PHARMA LIMITED**
Plot.No. 10,IDA, Phase-I
Jeedimetla, R.R.Dist,
Hyderabad, Telangana, INDIA

2.A.3 Status of product – license holder[8] (Key is appropriate category as defined in note (8)

a) ☒ b) ☐ c) ☐

2A.3.1 For categories b and c the name and address of the Manufacturer producing the dosage form is [9] ?

Yes ☐ No ☐ Not applicable ☒

2.A.4 Is summary basis for approval appended [10] ? (enclosed at the time of product approval)

Yes ☒ No ☐ Not applicable ☐

2.A.5 Is the attached, officially approved product information complete and consonant with the license?[11]
(key as appropriate)

Yes ☒ No ☐ Not applicable ☐

2. A.6 Applicant for certificate, if different from license holder (Name & Address)[12]

Yes ☐ No ☒ Not applicable ☐

SECTION 2B IS TO BE OMITTED

2. B.1 Applicant for certificate (Name & address)

2. B.2 Status of applicant: (Key in the appropriate category as defined in note 8)

2. B.2.1 For categories b and c the name and address of the manufacturer producing the dosage from is[9] :

2. B.3 Why is marketing authorization lacking?
Not required / Not requested / under consideration / Refused (Key in as appropriate)

2. B.4 Remarks: [13]

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

Yes ☒ No ☐ Not applicable[14] ☐

If not or not applicable, proceed to question 4.

Periodicity of routine inspections (years) : ***NOT LESS THAN ONCE A YEAR***

Has the manufacturer of this type of dosage form been inspected Yes/No (Key in as appropriate)

Yes ☒ No ☐ Not applicable ☐

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

Yes ☒ No ☐ Not applicable ☐

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

Yes ☒ No ☐ Not applicable ☐

Address of certifying authority : **Office of the Deputy Director**
Drugs Control Administration, Vengalarao Nagar,
Hyderabad 500 038, Telangana, INDIA.

Telephone and Fax numbers : **TEL: +91 40 23814119** **FAX: +91 40 23814360**

Name of Authorized Person :

Dr. Y. NAVEEN KUMAR.
JOINT DIRECTOR(FAC)
LICENSING & CONTROLING AUTHORITY

Signature :

Stamp and Date :

DRUG CONTROL ADMINISTRATION ★ GOVERNMENT OF TELANGANA ★
HYDERABAD
JD(FAC)

Dr. Y. NAVEEN KUMAR
M.Pharm.,Ph.D
Joint Director (Enforcement)
Licensing & Controlling Authority (FAC)
Drugs Control Administration
Government of Telangana
Hyderabad-500 038, T.S.