

## CERTIFICATE OF A PHARMACEUTICAL PRODUCT

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

CERTIFICATE NO.: NO. HFW-H-(DRUGS) 217/09/2022/60

VALID UPTO: 22.02.2025

Exporting (certifying) country : **INDIA**  
Importing (requesting) country : **Annexure Attached**  
1. Name and dosage form of product : **EUROLIDE DEPOT (Leuprolide Acetate for Injection) (Lyophilized)**

1.1 Active ingredient (s) and : Each vial contains  
Amount (s) per unit dose : Leuprolide Acetate 3.75mg  
Excipients q.s

1.2 For complete qualitative composition including Excipients: N.A.  
Is this product licensed to be placed on the market for use in the exporting country?

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 2B.

2A.  
A.1 No of product license : MB/09/791 in Form No. 28  
And date of issue 27.01.2017  
A.2 Product License holder : M/s Samarth Life Sciences Pvt. Ltd.  
Plot No. 2, Industrial Area, Vill.  
Lodhimajara, Baddi, Distt. Solan  
H.P. 173205 India  
A.3 Status of Product-license Holder :  
a ☒ b ☐ c ☐  
A.3.1 For categories b and c, The name and address of the  
Manufacturer producing the dosage form are  
Not Applicable  
A.4 Is summary Basis of Approval appended ? :  
Yes ☐ No ☒  
A.5 Is the attached, officially approved product information  
Complete and consonant with the License ? :  
Yes ☐ No ☐ Not provided ☒  
A.6 Applicant for certificate if different from License holder :  
Not Applicable

2B  
B. 1 Applicant for certificate  
(name and address) :  
B. 2 Status of applicant:  
a ☐ b ☐ c ☐  
B.2.1 For categories b and c the name  
and address of the Manufacturer  
producing the dosage form are  
B. 3 Why is marketing authorization  
lacking ?  
Not ☐ Not ☐ Under ☐  
Required Requested consideration  
Refused ☐  
B. 4 Remark :

3. Does the certifying authority arrange for periodic inspection of the  
manufacturing plant in which the dosage form is produced  
if no or not applicable, proceed to question 4  
3.1 Periodicity of routine inspection (years)  
3.2 Has the manufacture of this type of dosage form been inspected?  
3.3 Do the facilities and operations conform to GMP as recommended  
by the World Health Organization ?  
4. Does the information submitted by the applicant satisfy the certifying  
authority on all aspects of the manufacture of the product ?  
If no, explain:

: Yes  
: Once in a year  
: Yes  
: Yes  
: Yes

### Address of Certifying Authority:

State Drug Controller  
Controlling Cum Licensing Authority  
Baddi Distt. Solan (H.P) -173205  
01795-244228, sdc4hp@gmail.com



Name of the Authorized Person : Navneet Marwaha  
Designation : State Drug Controller  
Signature : (NAVNEET MARWAHA)

Stamp and Date : State Drugs Controller  
Baddi, Distt. Solan (H.P) -173205  
01795-244288, sdc4hp@gmail.com

# Annexure to Certificate of a Pharmaceutical Product1

Certificate No. HWF-H-(Drugs)217/09/2022/60

Valid up to 22-02-2025 granted to

M/S SAMARTH LIFE SCIENCES PVT LTD. UNIT-II

For EUROLIDE DEPOT (Leuprolide Acetate for Injection 3.75 mg) (Lyophilized) for the following Countries:

1.	Albania	42.	Costa Rica	83.	Iraq	124.	Nepal	165.	St. Kitts & Nevis
2.	Afghanistan	43.	Croatia	84.	Ireland	125.	Netherlands Antilles	166.	St. Lucia
3.	Algeria	44.	Cuba	85.	Italy	126.	New-Zealand	167.	St. Vincent
4.	Angola	45.	Cyprus	86.	Ivory Coast	127.	Nicaragua	168.	Sudan
5.	Anguilla	46.	Czechoslovakia	87.	Jamaica	128.	Niger	169.	Sultanate of Oman
6.	Antigua	47.	Dem. Rep. Of Congo	88.	Japan	129.	Nigeria	170.	Suriname
7.	Argentina	48.	Denmark	89.	Jordan	130.	North Korea	171.	Swaziland
8.	Armenia	49.	Djibouti	90.	Kazakhstan	131.	Norway	172.	Sweden
9.	Australia	50.	Dominica	91.	Kenya	132.	PAHO	173.	Switzerland
10.	Austria	51.	Dominican Rep.	92.	Kiribati	133.	Pakistan	174.	Syria
11.	Azerbaijan	52.	East Timor	93.	Kosovo	134.	Palestine	175.	Taiwan
12.	Bahamas	53.	Ecuador	94.	Kuwait	135.	Panama	176.	Tajikistan
13.	Bahrain	54.	Egypt	95.	Kyrgyzstan	136.	Papua New Guinea	177.	Tanzania
14.	Bangladesh	55.	El Salvador	96.	Laos	137.	Paraguay	178.	Thailand
15.	Barbados	56.	England	97.	Latvia	138.	Peru	179.	The Netherlands
16.	Belarus	57.	Equatorial Guinea	98.	Lebanon	139.	Philippines	180.	Togo
17.	Belgium	58.	Eritrea	99.	Lesotho	140.	Poland	181.	Tonga
18.	Belize	59.	Estonia	100.	Liberia	141.	Portugal	182.	Trinidad & Tobago
19.	Benin	60.	Ethiopia	101.	Libya	142.	Puerto Rico	183.	Tunisia
20.	Bermuda	61.	Fiji Islands	102.	Lithuania	143.	Qatar	184.	Turkey
21.	Bhutan	62.	Finland	103.	Luxembourg	144.	Rep. of South Africa	185.	Turkmenistan
22.	Bolivia	63.	France	104.	Macau	145.	Rep. of Yemen	186.	Turk & Caicos
23.	Bosnia Herzegovina	64.	Gabon	105.	Macedonia	146.	Romania	187.	Uganda
24.	Botswana	65.	Gambia	106.	Madagascar	147.	Russian Federation	188.	Ukraine
25.	Brazil	66.	Georgia	107.	Malawi	148.	Rwanda	189.	UNHCR
26.	British Virgin islands	67.	Germany	108.	Malaysia	149.	Samoa	190.	UNICEF
27.	Brunei	68.	Ghana	109.	Maldives	150.	Sao Tome & Principe	191.	United Arab Emirates
28.	Bulgaria	69.	Grand Cayman	110.	Mali	151.	Saudi Arabia	192.	United kingdom
29.	Burkina Faso	70.	Greece	111.	Malta	152.	Senegal	193.	Uruguay
30.	Burundi	71.	Grenada	112.	Marshall islands	153.	Serbia & Montenegro	194.	Uzbekistan
31.	Cambodia	72.	Guatemala	113.	Mauritania	154.	Seychelles	195.	Vanuatu
32.	Cameroon	73.	Guinea	114.	Mauritius	155.	Sierra Leone	196.	Vatican City
33.	Cape Verde	74.	Guinea Bissau	115.	Mexico	156.	Singapore	197.	Venezuela
34.	Cayman Islands (E)	75.	Guyana	116.	Moldova	157.	Slovakia	198.	Vietnam
35.	Central African Rep.	76.	Haiti	117.	Mongolia	158.	Slovenia	199.	Western Samoa
36.	Chad	77.	Holland	118.	Montserrat	159.	Solomon islands	200.	WHO
37.	Chile	78.	Honduras	119.	Morocco	160.	Somalia	201.	Yugoslavia
38.	China	79.	Hong Kong	120.	Mozambique	161.	South Korea	202.	Zambia
39.	Colombia	80.	Hungary	121.	Myanmar	162.	Spain	203.	Zimbabwe
40.	Comoros	81.	Indonesia	122.	Namibia	163.	Sri-Lanka		
41.	Congo	82.	Iran	123.	Nauru	164.	St. Kitts		

## ADDRESS OF CERTIFYING AUTHORITY:

State Drug Controller  
Controlling cum licensing Authority,  
Baddi Distt. Solan (H.P.)- 173205  
01795-244228, sdc4hp@gmail.com



## Name of authorized person:

NAVNEET MARWAHA  
Designation: State Drug Controller  
Signature: [Signature]  
Stamp and date: [Stamp]  
01795-244228, sdc4hp@gmail.com

14.3.22