GOVERNMENT OF HIMACHAL PRADESH
HEALTH AND FAMILY WELFARE DEPARTMENT
CERTIFICATE OF A PHARMACEUTICAL PRODUCT [1]

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

No. of Certificate : **HFW-H (Drugs) 995/14 (20/044)** Valid upto: **27.02.2022**

Exporting (Certifying) Country : **INDIA**

Importing (requesting) Country : **Afghanistan, Algeria, Argentina, Australia, Austria, Azerbaijan, Bahrain, Bangladesh, Belarus, Belgium, Bosnia, Brazil, Bulgaria, Burma (Myanmar), Cambodia, Canada, Caribbean, Central America, Chile, China, CIS Countries, Colombia, Costa Rica, Croatia, Cuba, Czechoslovakia, Denmark, Dominica, Egypt, Ethiopia, Fin'and, Fiji Islands, France, Geogia, Ghana, Germany, Great Britain, Greece, Hungary, Holland, Iceland, Ireland, Indonesia, Iran, Irae, Israel, Italy, Japan, Jordan, Kazakhstan, Kenya, Kyrgyzstan, Kuwait, Latin America, Laos Peopies Democratic Republic, Lebanon, Mauritius, Malaysia, Mexico, Middle East, Moldova, Morocco, Nepal, The Netherlands, New Zealand, Nigeria, Norway, Oman, Pakistan, Peru, Philippines, Portugal, Poland, Falestine, Republic of Romania, Russia, Singapore, Slovenia, South Africa, South Korea, Spain, Sri Lanka, Sweden, Switzerland, Syria, Saudi Arabia, Sudan, Tajikistan, Taiwan, Tanzania, Thailand, Tunisia, Turkey, Turkmenistan, U.K, U.S.A, Ukraine, United Arab Emirates, Uruguay, Uganda, Uzbekistan, Venezuela, Vietnam, Yemen, Yugoslavia, Zambia, Zimbabwe.**

1. Name and dosage form of product : **TEMOLOZ CAPSULES 250 mg**
(TEMOZOLOMIDE CAPSULES 250 mg)

1.1 Active Ingredient (s) [2] and amount(s) per unit dose [3] : **Each Hard Gelatin Capsule Contains:-**

Temozolomide : 250 mg.

Composition per Capsule

Temozolomide 250 mg,
Lactose Anhydrous USP 154 mg,
Sodium Starch Glycolate USP 23 mg,
Aerosil-200 USP 1 mg,
Tartaric Acid USP 9 mg,
Stearic Acid USP 13 mg
Approved colours used in Empty capsule shells

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 ☐ 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 continue section 2B [6]

2A

A.1 Number of product licence [7] and date of issue Permission No: **L/13/1339/MNB, Form No. 25A 12.03.2019**

A.2 Product license holder (Name and address): **M/s. Zuvius Lifesciences Pvt. Ltd. at 107A & 107B, EPIP, Phase-I, Jharmajri, Baddi, Distt. Solan, Himachal Pradesh**

A.3 Status of licence holder: [8] a ☒ b ☐ c ☐ d ☐

A.3.1. For categories b and c the name and address of the manufacturer producing the dosage form are [9] **N/A**

A.4 Is summary basis of approval appended? [10] Yes ☐ No ☒

A.5 Is the attached, officially approved product information complete and consonant with the license? [11] Yes ☐ No ☒ Not provided ☐

A.6 Application for certificate if different from licence holder [12]: **Not Applicable**

2B

B.1 Applicant for certificate (Name and address)

B.2 Status of application a ☐ b ☐ c ☐ d ☐

B.2.1 For categories b and c the name and address of the manufacturer producing the dosage forms are [9]

B.3 Why is marketing authorization lacking
☐ Not Required ☐ Not Requested ☐ Under Consideration ☐ Refused

B.4 Remark: [13]

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
Yes ☒ No ☐ Not Applicable [14] ☐ (If No or Not applicable proceed to question 4)

3.1 Periodicity of routine inspections (Years): **ONCE IN A YEAR**

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 ☐ If No Explain

09 SEP 2020

Name of the Authorized person:
Address of certifying authority:
O/o State Drugs Controller,
2nd floor, Himuda Complex, Phase-I,
Baddi, Distt. Solan -173 205, | HP | INDIA

Digitally signed by Chirtoacă Iurie
Date: 2021.12.15 11:46:00 EET
Reason: MoldSign Signature
Location: Moldova

Signature
Stamp and Date

(Dr. KAMLESH NAIK)
ASSISTANT DRUGS CONTROLLER
-cum-LICENSING AUTHORITY
O/o STATE DRUGS CONTROLLER
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