

No. of Certificate: 26/1/Drug/20/2019/8456

Date: 19/06/2020

Importing (Requesting) Country: Afghanistan, Africa, Algeria, Azerbaijan, Bahrain, Belarus, Bhutan, Bolivia, Brazil, Burkina Faso, Cambodia, Cameroon, Chad, Costa Rica, D.R. Congo Egypt, Equatorial Guinea, Guyana, Gabon, Ghana, Gorgia, Indonesia, Iran, Iraq, Israel, Ivory Coast, Jamaica, Jordan, Kazakhstan, Kenya, Korea, Kuwait, Kyrgystan, Madagascar, Malawi, Malaysia, Mangolia, Mozambique, Myanmar, Nepal, Nigeria, Oman, Panama, Peru, Philipines, Qatar, Republic of Congo, Republic of Guinea, Romania, Russia, Rwanda, Saudi Arabia, Senegal, Serbia, Singapore, South Africa, Srilanka, Sudan, Syria, Tajikistan, Tanzania, Thailand, Togo, Turkmenistan, UAE, Uganda, Ukraine, Uzbekistan, Venezuela, Vietnam, Yemen.

Exporting (Certifying) Country : INDIA

CERTIFICATE OF A PHARMACEUTICAL PRODUCT¹

1. Name & dosage form of product: **ZYTHRIMIX 500 CAPSULES (Azithromycin Capsules USP)**

1.1 Active ingredient (s)² and amount (s) per unit dose³ (complete qualitative composition including excipients, see attached)

Composition:

Each hard gelatin capsule contains:

Azithromycin USP.....500 mg

Excipients.....q.s.

Colour: Empty hard gelatin capsule shell contains approved colour

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

YES

If yes, complete box A, if no, complete box B:

1.3 Is this product actually on the market in the exporting country?⁵

YES

A	B
2A.1 Number of product licence ⁷ & date of issued: 65/UA/2016 & 65/UA/SC/P-2016 dt. 24/08/2016	2B.1 Applicant for certificate (name & address)
2A.2 Product licence holder: M/s SIGNATURE PHYTOCHEMICAL INDUSTRIES, 122, MI, SELAQUI INDUSTRIAL AREA, DEHRADUN	2B.2 Status of applicant: (a) <input type="checkbox"/> (b) <input type="checkbox"/> (c) <input type="checkbox"/> (d) <input type="checkbox"/>
2A.3 Status of product licence holder ⁸ : (a) <input checked="" type="checkbox"/> (b) <input type="checkbox"/> (c) <input type="checkbox"/>	2B.2.1 For categories b and c the names and address of the manufacturer producing the dosage form are ⁹ :
2A.3.1 For categories b and c the name and address of the manufacturer producing the dosage form are ⁹ : Not Applicable	2B.3 Why is marketing authorization lacking? Not Required <input type="checkbox"/> Not Requested <input type="checkbox"/> Under Consideration <input type="checkbox"/> Refused <input type="checkbox"/>
2A.4 Is summary basis of Approval appended ¹⁰ ? Yes <input type="checkbox"/> No <input checked="" type="checkbox"/>	2B.4 Remark: ¹³
2A.5 Is the attached, officially approved product information complete and consonant with the licence ¹¹ ? Yes <input type="checkbox"/> No <input type="checkbox"/> Not provided <input checked="" type="checkbox"/>	
2A.6 Applicant for certificate if different from licenced holder: Not Applicable ¹²	
3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced? Periodically of routine inspection (years): Once in a year	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> NA <input type="checkbox"/>
3.2 Has the manufacture of this type of dosage form been inspected	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
3.3 Do the facilities and operations conform to GMP as recommended by the World Health Organization? ¹⁵	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/>
4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product? ¹⁶	Yes <input checked="" type="checkbox"/> No <input type="checkbox"/> N <input checked="" type="checkbox"/>

WHO-GMP-CERT.NO. 26/1/Drug/20/2019/8456, Valid up to: 14/05/2023

Address of certifying authority:

Drug Licensing & Controlling Authority

Directorate General of Medical Health & Family Welfare,
Sahastradhara Road, Dehradun-248001 (Uttarakhand) (INDIA)

Directorate General of Medical Health & Family Welfare,
Sahastradhara Road, Dehradun-248001 (Uttarakhand) (INDIA)



Name of the authorized person:

Signature:

Stamp & Date

Stamp & Date

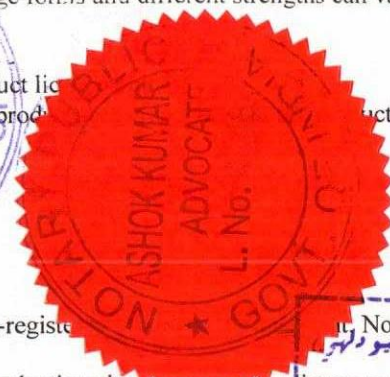


Attested

Sushmita
GUSHMITA
Secretary

Tajinder Singh
19/6/2020
Drug Controlling & Licensing Authority (Mfg.)
(Uttarakhand)

- The status of the pharmaceuticals produced shall be indicated by the following information for different dosage forms:
 International Nonproprietary Names, if applicable, shall be indicated on the certificate or be appended.
 The product shall conform to the agreement of the product specification for the distribution or administration of the product.
 The product shall not yet been approved.
 Market:



ce.

NOTARY PUBLIC
DELHI (INDIA)

6 JUN 2020

ii. Non completion of this section

EMBASSY OF THE REPUBLIC OF YEMEN (NEW DELHI)

has been licensed

cs (SPC).

d to the authority by the applicant: 0. 1.

مكتبة ابن سينا

المجلد ٥١

تاریخ: ۲۷/۷/۱۳۸۸

Fee received

333 11-1-1954

The Embassy is not responsible for the content of

Contents.

the thirty-second report of the Expenditure

SECRET

Standardization (WHP Technical Report)

10/10/2019

It is of particular importance when forel

with information to identify the contractor.

each of these parties

World Health Organization, 1971. Geneva.

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संस्कृत-विभाग

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GOVERNMENT OF INDIA
MINISTRY OF DEFENSE

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सं०
No.

लुण्णय मंडल में सहायक सचिव उप
हस्ताक्षर संस्थापित किए जाते हैं।

The Signature of Asstt. Secretary
Secretary/Secretary of Charge
Commercial Attestation

विदेश मंत्रालय इस दस्तावेज के विषय में
की जिम्मेदारी नहीं लेता।

Ministry of External Affairs
no responsibility for the contents of
document.