SUMMARY OF PRODUCT CHARACTERISTICS

ACCRETION PHARMACEUTICALS
29, Xcelon Industrial Park-1, Behind Intas Pharmaceuticals, Vasna-Chacharwadi,
Tal. Sanand, Dist. Ahmedabad, Gujarat-382213

BRAND NAME:	**KETOCOXEL**
GENERIC NAME:	**KETOCONAZOLE DUSTING POWDER 2 % W/W**

Product Characteristic Summary

Enclosed.

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1. Name of drug product

KETOCONAZOLE DUSTING POWDER 2 % W/W

1.1 (Trade) name of product

KETOCOXEL

1.2 Strength

Each Unit Contains:

Ketoconazole BP..... 2 % W/W

Excipients..... Q.S.

1.3 Pharmaceutical Dosage Form

Powder for topical application

BRAND NAME:	**KETOCOXEL**
GENERIC NAME:	**KETOCONAZOLE DUSTING POWDER 2 % W/W**

2. Qualitative & Quantitative Composition

2.1 Qualitative Declaration

Each Unit Contains:

Ketoconazole BP..... 2 % W/W

Excipients..... Q.S.

2.2 Quantitative Declaration

Batch Formula:

Batch Size:450 kg

Sr. No.	Ingredients	Grade	Rationale	Label Claim	Overages (%)	Quantity/ 100gm jar (in mg)	Quantity/ Batch(Kg)
1.	Ketoconazole	BP	Active	2 % w/w	--	2000.000	9.000
2	Starch	BP	Lubricant	--	--	3800.000	17.100
3	Jasmine Flavour	I H S	Fragrance	--	--	200.000	0.900
4.	Purified Talc base	BP	Moisturising agent	--	--	Q.S	Q.S

3. Pharmaceutical Dosage Form

Powder for topical application

4. Clinical Particulars

4.1 Therapeutic Indications

Ketoconazole which belongs to the group of medicines called antifungals. It is used to treat fungal and yeast infections of the skin in adults. This medicine works by binding to the fungal p450 enzymes and stops the cells making ergosterol of the cell wall which is necessary for them to grow.

4.2 Posology and Method of Administration

KETOCOXEL reduces infection by disrupting the production of ergosterol (an important component of fungal cell membranes), thus disrupting the cell membrane of infecting fungus.

Apply KETOCOXEL as advised by your physician. It is for external use only. Apply KETOCOXEL once daily to cover the affected and immediate surrounding area.

Use it only for the quantity and duration (preferably 2 weeks) specified by your doctor. Your physician will decide the correct dose and duration for you according to your age, body weight and disease condition.

4.3 Contraindications

It is contraindicated for patients who have shown hypersensitivity to Ketoconazole.

4.4 Special Warnings and Precautions for Use

General warnings

External use

KETOCOXEL is meant for external use only. Avoid contact with your eyes. In case of accidental contact with your eyes, rinse thoroughly with water. Seek immediate medical help in case of accidental ingestion.

Use only in confirmed infection

KETOCOXEL should not be used until the infection is diagnosed by a doctor. Other conditions may also show similar symptoms.

Diaper rash

KETOCOXEL is not recommended for diaper rash.

Asthma

KETOCOXEL should be used with caution if you have asthma (a lung condition leading to difficulty in breathing). Follow all the instructions given by your doctor.

Flammable Contents

KETOCOXEL can be inflammable (tendency to catch fire), hence you are advised to avoid smoking, fire, and flame during and immediately following application.

Other topical medicine

Inform your doctor if you are using any other topical medicine before starting the treatment with KETOCOXEL, as they can interact with each other. Your doctor may suggest alternatives for the safer use of the medicines.

Sulfite allergy

KETOCOXEL should be used with caution if you have a Sulfite allergy, as it can worsen your condition. Follow all the instructions given by your doctor.

4.5 Interaction with other medicinal products and other forms of interaction

A. Drug - Drug interactions:

Before applying KETOCOXEL, inform your doctor if you are using, have used, or might use any other medicine, including prescription, non-prescription or any herbal medicine.

4.6 Fertility, pregnancy and lactation

Pregnancy

There is no data available for use of KETOCOXEL in pregnancy. It should be used in pregnancy only if the potential benefit justifies the potential risk to the baby. Consult your doctor before applying it.

Breastfeeding

KETOCOXEL should be used with caution in breastfeeding women. If used during breastfeeding and the medicine is applied on the chest, take caution to avoid accidental ingestion of the medicine by your baby. Consult your doctor before applying it.

4.7 Effects on ability to drive and operate machine

KETOCOXEL is a topical preparation and may not affect the driving ability or ability to handle machinery.

4.8 Undesirable effects

RARE

Stop using KETOCOXEL and contact your doctor immediately if you experience any of the following side effects:

- Worsening of the condition
- Worsening of the irritation at the application site

4.9 Overdose

If you or anyone else accidentally use too much of KETOCOXEL, consult your doctor immediately or visit the nearby hospital.

5. Pharmacological properties

5.1 Pharmacodynamics property

Pharmacotherapeutic group: Antifungal agents,

ATC Code:D01AC08

Mechanism of Action

Ketoconazole blocks the synthesis of ergosterol, a key component of the fungal cell membrane, through the inhibition of cytochrome P-450 dependent enzyme lanosterol 14α-demethylase responsible for the conversion of lanosterol to ergosterol in the fungal cell membrane.

5.2 Pharmacokinetic properties

Absorption:

Ketoconazole is absorbed from the gastrointestinal tract; it is better absorbed from acidic aqueous solutions, so drugs that alter the pH of the stomach affect ketoconazole absorption. Therapeutic plasma concentrations are maintained for several hours following ketoconazole administration.

Metabolism:

Ketoconazole is mainly metabolized through CYP3A4. Other substances that either share this metabolic pathway or modify CYP3A4 activity may influence the pharmacokinetics of ketoconazole. Similarly, ketoconazole may modify the pharmacokinetics of other substances that share this metabolic pathway.

5.3 Preclinical safety data

There are no preclinical data of relevance to the prescriber which are additional to those already included in other sections of the Summary of Product Characteristics.

6. Pharmaceutical particulars

6.1 List of excipients

Purified Talc base

6.2 Incompatibilities

Not Applicable.

6.3 Shelf-Life

24 months from the date of manufacture.

6.4 Special Precautions for Storage

Store below 30°C. Protect from light

6.5 Nature and Contents of Container

White powder filled in white moulded round shaped HDPE bottle along with purple colour cap & swivel.

7. Marketing authorisation holder

ACCRETION PHARMACEUTICALS

CJ7+PG3, VasnaChacharavadi, Gujarat 382220

8. Marketing authorisation number(s)

9. Date of first authorisation/renewal of the authorisation

10. Date of revision of the text

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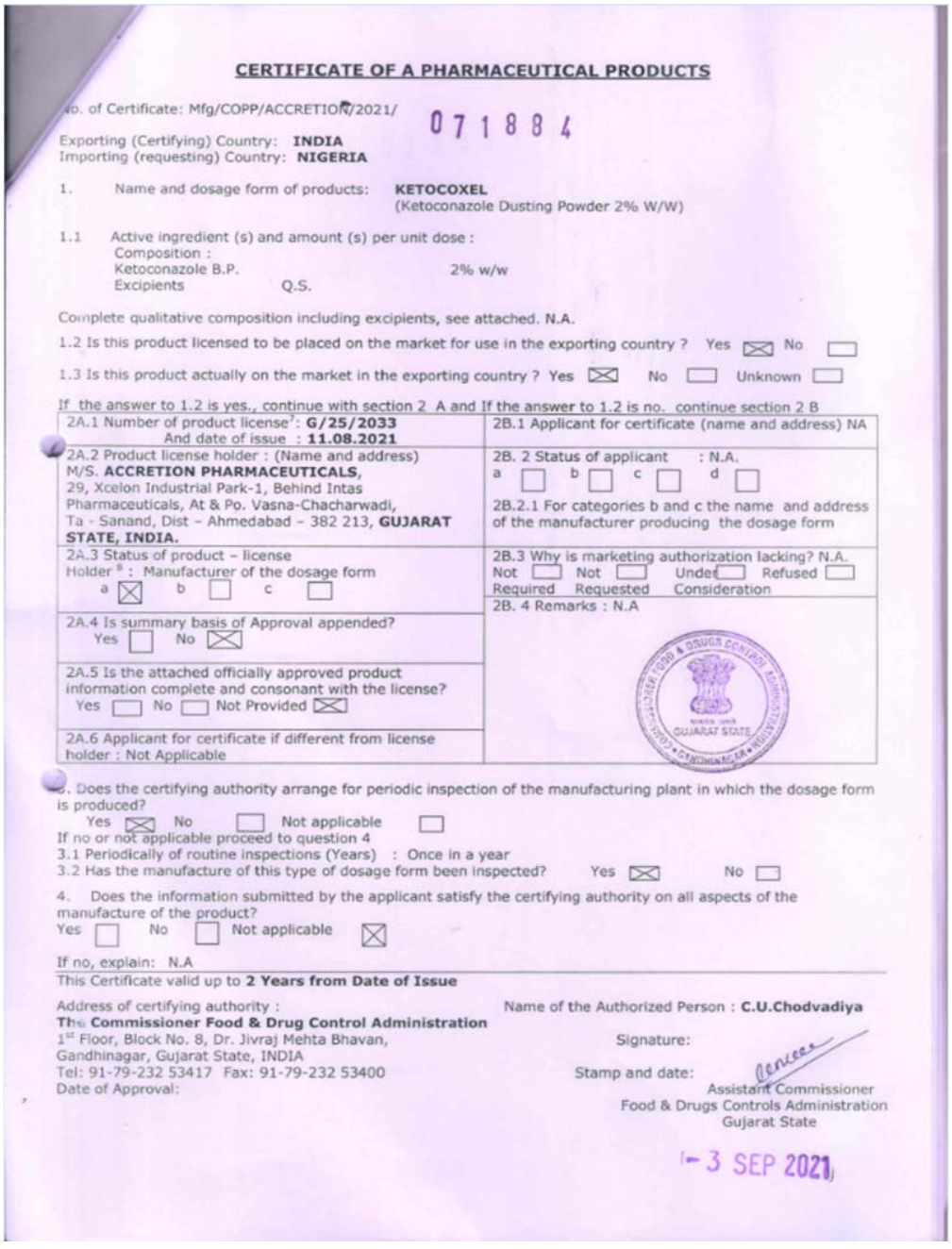
BRAND NAME:	**KETOCOXEL**
GENERIC NAME:	**KETOCONAZOLE DUSTING POWDER 2 % W/W**

CERTIFICATE OF A PHARMACEUTICAL PRODUCTS:



CERTIFICATE OF A PHARMACEUTICAL PRODUCTS

No. of Certificate: Mfg/COPP/ACCRETION/2021/ 071884

Exporting (Certifying) Country: **INDIA**
Importing (requesting) Country: **NIGERIA**

1. Name and dosage form of products: **KETOCOXEL**
(Ketoconazole Dusting Powder 2% W/W)

1.1 Active ingredient (s) and amount (s) per unit dose :
Composition :
Ketoconazole B.P. 2% w/w
Excipients Q.S.

Complete qualitative composition including excipients, see attached. N.A.

1.2 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 2 A and If the answer to 1.2 is no. continue section 2 B

2A.1 Number of product license[7]: **G/25/2033** And date of issue : **11.08.2021**	2B.1 Applicant for certificate (name and address) NA
2A.2 Product license holder : (Name and address) M/S. **ACCRETION PHARMACEUTICALS,** 29, Xcelon Industrial Park-1, Behind Intas Pharmaceuticals, At & Po. Vasna-Chacharwadi, Ta - Sanand, Dist – Ahmedabad – 382 213, **GUJARAT STATE, INDIA.**	2B. 2 Status of applicant : N.A. a ☐ b ☐ c ☐ d ☐ 2B.2.1 For categories b and c the name and address of the manufacturer producing the dosage form
2A.3 Status of product – license Holder [8] : Manufacturer of the dosage form a ☒ b ☐ c ☐	2B.3 Why is marketing authorization lacking? N.A. Not Required ☐ Not Requested ☐ Under Consideration ☐ Refused ☐
2A.4 Is summary basis of Approval appended? Yes ☐ No ☒	2B. 4 Remarks : N.A
2A.5 Is the attached officially approved product information complete and consonant with the license? Yes ☐ No ☐ Not Provided ☒	
2A.6 Applicant for certificate if different from license holder : Not Applicable	

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produced?
Yes ☒ No ☐ Not applicable ☐
If no or not applicable proceed to question 4
3.1 Periodically of routine inspections (Years) : Once in a year
3.2 Has the manufacture of this type of dosage form been inspected? Yes ☒ No ☐

4. Does the information submitted by the applicant satisfy the certifying authority on all aspects of the manufacture of the product?
Yes ☐ No ☐ Not applicable ☒

If no, explain: N.A

This Certificate valid up to **2 Years from Date of Issue**

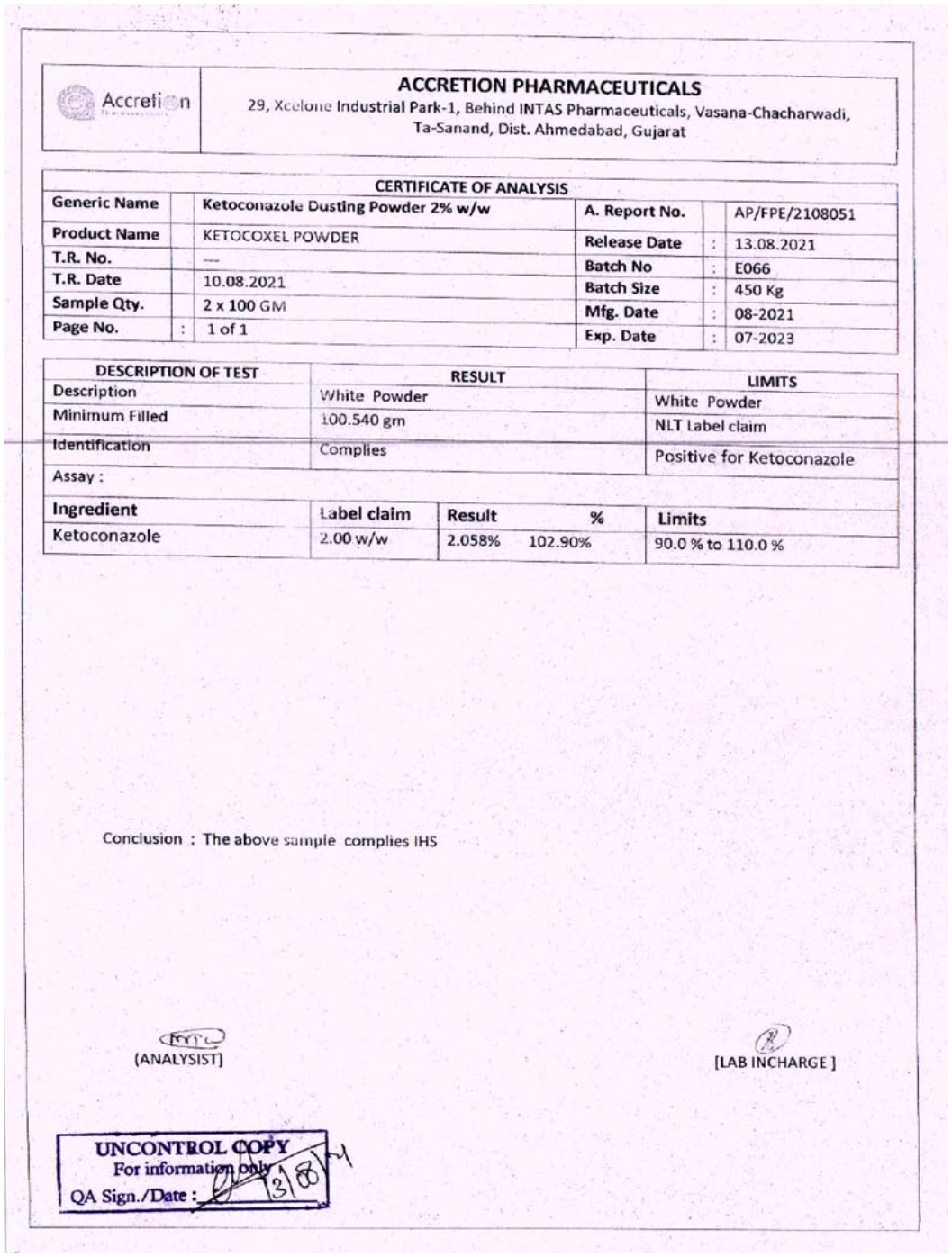
Address of certifying authority :
The Commissioner Food & Drug Control Administration
1st Floor, Block No. 8, Dr. Jivraj Mehta Bhavan,
Gandhinagar, Gujarat State, INDIA
Tel: 91-79-232 53417 Fax: 91-79-232 53400
Date of Approval:

Name of the Authorized Person : **C.U.Chodvadiya**
Signature:
Stamp and date:
Assistant Commissioner
Food & Drugs Controls Administration
Gujarat State

- 3 SEP 2021

Accretion Pharmaceuticals	**ACCRETION PHARMACEUTICALS** 29, Xcelon Industrial Park-1, Behind Intas Pharmaceuticals, Vasna-Chacharwadi, Tal. Sanand, Dist. Ahmedabad, Gujarat-382213
BRAND NAME:	**KETOCOXEL**
GENERIC NAME:	**KETOCONAZOLE DUSTING POWDER 2 % W/W**

CERTIFICATE OF ANALYSIS:



Accretion

ACCRETION PHARMACEUTICALS
29, Xcelone Industrial Park-1, Behind INTAS Pharmaceuticals, Vasana-Chacharwadi,
Ta-Sanand, Dist. Ahmedabad, Gujarat

CERTIFICATE OF ANALYSIS

Generic Name	Ketoconazole Dusting Powder 2% w/w		A. Report No.	:	AP/FPE/2108051
Product Name	KETOCOXEL POWDER		Release Date	:	13.08.2021
T.R. No.	---		Batch No	:	E066
T.R. Date	10.08.2021		Batch Size	:	450 Kg
Sample Qty.	2 x 100 GM		Mfg. Date	:	08-2021
Page No.	: 1 of 1		Exp. Date	:	07-2023

DESCRIPTION OF TEST	RESULT	LIMITS
Description	White Powder	White Powder
Minimum Filled	100.540 gm	NLT Label claim
Identification	Complies	Positive for Ketoconazole
Assay :		

Ingredient	Label claim	Result	%	Limits
Ketoconazole	2.00 w/w	2.058%	102.90%	90.0 % to 110.0 %

Conclusion : The above sample complies IHS

(ANALYSIST)

[LAB INCHARGE]

UNCONTROL COPY
For information only
QA Sign./Date : 3/8