Applications

Application form for registration of a medicine in Eritrea

1. Details of Applicant

1.1 Name and address of applicant

Name:

Azel Pharmacuetical Sh. Co.

Business Address:

175-11Str., No.51,

Postal Address:

6799

Country:

Eritrea

Phone number(+291):

121991

Fax:

400235

Institutional Email Website:

registration@azelpharma.com

Contact person Information

Name:

Yohannes Ukubagabir

Position:

QA and RA Manager

Country:

Eritrea

City:

Asmara

Address line one:

175-11Str., No.51

Address line two:

Phone number(+291):

400233

Institutional Email:

qualityassurance@azelpharma.com

1.2 Name and address of the local agent

Name:

Yohannes Ukubagabir

City:

Asmara

Address:

175-11Str., No.51,

Postal Address:

12

Country:

Eritrea

Phone number(+291):

121991

Web Site url:

www.azelpharma.com

Fax:

400235

Institutional Email Website:

registration@azelpharma.com

Local Agent Contact person Information

Name:

Yohannes Ukubagabir

Position:

QA and RA Manager

Country:

Eritrea

City:

QA and RA Manager

Address line one:

175-11Str., No.51

Address line two:

Position

Phone number(+291):

400233

Institutional Email:

qualityassurance@azelpharma.com

2. Type of Application

- [x] New Application
- [ ] Applications for renewal
- [ ] Request fast track
- ( ) WHO PQP
- ( ) SRA product
- ( ) MoH Tender

3. Details of the Product

3.1 Product Name and Description

Generic/Approved/International Non-proprietary Name(s):

Metformin HCl Tab, 500mg

Proprietary/Trade name of the product::

GLOCOBAN 500 Tablet

Dosage form:

TABLET

Route of Administraion:

Oral

Pharmacotherapeutic Classification (Anatomic-Therapeutic Classification system):

Anti-diabetic Agents, Blood glucose lowering drugs, Biguanides

Storage conditions:

Store at a temperature between 15- 30 degree celsius, protected from light.

Proposed shelf life:

36

Proposed shelf life (after reconstitution or dilution):

N/A

Shelf Life (in months)

36

Visual Description:

White circular shallow biconvex, film coated tablet with “GLOCOBAN” embossed on one side & “500” on the other side

Commercial presentation of the product:

Blister of 2 x 5 parallel

Container, closure and administration devices:

Blistered using PVC with the printed Aluminum sheets; Hospital packs of different pack sizes, other overprinting information ava

Packaging and pack size:

Boxes of 30 blistered film-coated tablets of GLOCOBAN 500 Tablets. Boxes of 500 blistered film-coated tablets of GLOCOBAN 50

Category of use:

- [x] **POM (Prescription only medicine**
- [ ] **P (Pharmacy Medicine)**
- [ ] **OTC (Over The Counter medicine)**
- [ ] **Controlled Substances**
- [ ] **Hosiptal/Health Facilities Only Medicines**

3.2 Product Composition

Indicate per unit dosage form (Tablet, Capsule, 2ml) the Complete qualitative and quantitative composition of the product

Name (INN)	Quantity	Reason for inclusion	Reference standards	Type
Metformin Hydochloride	105 kg	Active ingredients	United States Pharmacopeia (USP)	API

3.3 Product Manufacturer(s)

3.3.1 Name(s) and complete address(es) of the manufacturer(s) of the finished pharmaceutical product (FPP), including the final product release if different from the manufacturer.

Manufactures Name	City	State	Address	Postal Address	Telephone	Activity	Block	Unit
AZEL PHARMACEUTICAL SH. CO	Keren		175-11Str., No.51	89 Keren, Eritrea	400234	Manufacturing, Packaging and Labelling	-	-

3.3.2 Name(s) and complete address(es) of the manufacturer(s) of the API(s)

API Product Manufatures	API Name	City	State	Address	Postal Address	Telephone	Block	Unit
IPCA LABORATORIES LIMITED	Metformin Hydrochloride	Mumbai	Maharashtra	48, Kandivli Industrial Estate, Kandivli (West), India-400 067	2564113	62105005	431	136

4. Declaration

I, the undersigned certify that all the information in this form and all accompanying documentation submitted to Eritrea for the registration of (Metformin HCl Tab, 500mg, TABLET) manufactured at (AZEL PHARMACEUTICAL SH. CO , 175-11Str., No.51) is true and correct. I further certify that I have examined the following statements and I attest to their correctness:-

1. The current edition of the WHO Guidelines on good manufacturing Practices (GMP) for pharmaceuticals products or equivalent guideline is applied in full in all premises involved in the manufacture of this medicine.
2. The formulation per dosage form correlates with the master formula and with the batch manufacturing record.
3. The manufacturing procedure is exactly as specified in the master formula and batch manufacturing record.
4. Each batch of all starting materials is either tested or certified (in accompanying certificate of analysis for that batch) against the full specifications in the accompanying documentation and must comply fully with those specifications before it is released for manufacturing purposes.
5. All batches of the active pharmaceutical ingredient(s) are obtained from the source(s) specified in the accompanying documentation.
6. No batch of active pharmaceutical ingredient(s) will be used unless a copy of the batch certificate established by the manufacturer is available.
7. Each batch of the container/closure system is tested or certified against the full specifications in the accompanying documentation and complies fully with those specifications before released for the manufacturing purposes.
8. Each batch of the finished product is either tested, or certified (in an accompanying certificate of analysis for that batch), against the full specifications in the accompanying documentation and complies fully with release specifications before released for sale.
9. The person releasing the product is an authorized person as defined by the WHO Guidelines on good manufacturing Practices (GMP) for pharmaceuticals products
10. The procedures for control of the finished product have been validated. The assay method has been validated for accuracy, precision, specificity and linearity.
11. All the documentation referred to in this application is available for review during GMP inspection.
12. Clinical trials (where applicable) were conducted in accordance with ICH, WHO or equivalent guidelines for Good Clinical Practice,
I also agree that:
13. As a holder of marketing authorization/registration of the product I will adhere to Eritrean National Pharmacovigilance Policy requirements for handling adverse reactions.
14. As holder of registration I will adhere to Eritrean requirements for handling batch recalls of the products.

I agree ☑

Declaration Name :

Yohannes Ukubagabir

Qualification :

Pharmacist

Position :

QA & RA Manager

Date :

09/03/2022