NAFDAC REG. NO. : A4-0107

1 x 10 Oral Capsules

Loperamide Hydrochloride Capsules USP 2mg

Maydon Diadon®

48 mm

65 mm

Maydon

Diadon®

Loperamide Hydrochloride Capsules USP 2mg

1 x 10 Oral Capsules

NAFDAC REG. NO. : A4-0107

107 mm

Diadon®

Loperamide Hydrochloride Capsules USP 2mg

Composition: Each capsule contains:
Loperamide Hydrochloride USP.......2 mg
Excipients....................................q.s.
Capsule shells contains approved colours
Dosage: As directed by a physician.
Storage: Store below 30°C, in a dry place, protect from light.
Keep all medicines out of reach of children.
Indication and dosage: See enclosed package insert.

Composition: Chaque gélule contient:
Chlorhydrate de Lopéramide USP.........2 mg
Excipients...q.s.
Les coques des gélules contiennent des couleurs approuvées
Dosage: Selon les directives d'un médecin.
Indication et posologie: voir la notice jointe.
Gardez tous les médicaments hors de la portée des enfants.
Stockage: Conserver en dessous de 30°C, dans un endroit sec, à l'abri de la lumière.

Marketed By:
Maydon Pharmaceuticals Ltd
15, Wilmer Street, Off Town Planning way,
Ilupeju, Lagos -Nigeria

48 mm

Lock bottom

Maydon

Diadon®

Gélules de Chlorhydrate de Lopéramide USP 2 mg

1 x 10 Gélules Orales

NAFDAC REG. NO. : A4-0107

Diadon®

Loperamide Hydrochloride Capsules USP 2mg

Mfg. Lic. No.	: G/25/1839
Batch No.	:
Mfg. Date	:
Exp. Date	:

8 904185 709821

MAXHEAL Laboratories Pvt Ltd

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL
OFFICE OF THE DIRECTOR
DRUG EVALUATION AND RESEARCH DIRECTORATE
Plot 1, Isolo Industrial Scheme, Oshodi-Apapa Expressway, Isolo, Lagos
Director's E-mail: ijeoma.nwankwo@nafdac.gov.ng Office E-mail: der.headquarters@nafdac.gov.ng

REF NO: NAF/DER/HQ/OFF/200/VOL 1 Date:22/2/2021

The Managing Director,
Maydon Pharmaceuticals Limited.
15, Wimer Street, Opposite Town Planning Way,
Ilupeju, Lagos State.

Dear Sir,

CLEARANCE IN LIEU OF ONSITE INSPECTION

Following your application for Good Manufacturing Practice (GMP) inspection of your foreign manufacturer's site at **MAXHEAL PHARM INDIA LTD. J-7, M.I.D.C, TARAPUR INDUSTRIAL AREA, BOISAR, DIST: PALGHAR MAHARASHTRA 401506.**; I wish to inform you that a provisional clearance in lieu of on-site GMP inspection of your foreign manufacturer's site has been granted you. This is to enable further processing of your application for the registration of the following product;

NAME OF DRUG/STRENGTH/PACKSIZE

1. HALAR CREAM (CLOTRIMAZOLE USP 1.% W/W, BETHAMETHASONE USP 0.05% W/W, NEOMYCIN SULPHATE 0.05% W/W)
2. FAMTER ORAL SUSPENSION (ARTEMETHER 240MG, LUMEFANTRINE 1440MG)
3. WORMTAC SUSPENSION (ALBENDAZOLE ORAL SUSPENSION
4. WORMTAC TABLETS (ALBENDAZOLE 400MG)
5. ESPEN SUSPENSION (IBUPROFEN ORAL SUSPENSION BP)
6. ESPEN 200MG TABLETS (IBRUPROFEN BP 200MG)
7. ESPEN 400MG TABLETS (IBRUPROFEN BP 400MG)
8. ERYFAST SUSPENSION 125MG (ERTHROMYCIN ESTOLATE FOR ORAL SUSPENSION)
9. ERYFAST SUSPENSION 250MG (ERTHROMYCIN ESTOLATE FOR ORAL SUSPENSION)
10. SISKIN CREAM (KETOCONAZOLE+CLOBESTASOL+NEOMYCIN)
11. P-PRED TABLETS (PREDNISOLE TABLETS BP 5MG)
12. XANAP GEL (LINSEED OIL 3. 00% W/W, DICLOFENAC SODIUM 1.00% W/W, MENTHOL BP 5.00% W/W, PRESERVATIVE BENYL ALCOHOLIC 1.00% W/W)
13. MALAMOX TABLETS (SULFADOXINE USP 500MG, PYRIMETHAMINE USP 25MG)

Please note that the inspection of the site will be carried out at a later date after the COVID -19 pandemic and that any failure to meet minimum NAFDAC GMP requirements at the time will invalidate this approval. Also, in view of the above you are required to give your commitment to provide a seamless involvement in processing of staff visas when the time comes, otherwise the approval shall be reversed.

You may reach out to Director Drug Registration and Regulatory Affairs Directorate for further processing of your application.

Thank you,

Mrs. Ijeoma U. Nwankwo
Director (DER)
For: Director General (NAFDAC)

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL (NAFDAC)

ZENITH
7000747 Treasury Book No. 6

TREASURY RECEIPT

000034043

Station: LAGOS / DER

Date: 19 - 02 - 2021

HEAD: NAFDAC

Sub-Head: INSP FEE & VAT } RRR No. 2404-5757-9133

Received from: MARDUM PHARM LTD

the sum of: Two million, forty two thousand, Naira five hundred only kobo being (description of payment)*

Foreign GMP Inspection Fee for Maxheal Pharm India Ltd I-7, M.I.D.C, Tarapur Ind. Area, Boisar Dist. Palghar Maharashtra

ORIGINAL

*If space is insufficient further particulars must be entered on back of Receipt

401506 Shodipo

Name of Accounting Officer

Signature or Mark of Payer

2,042,500

Signature of Accounting Officer

Witness of Mark

NIGERIA N50

BRAND NAME:	**DIADON**
GENERIC NAME:	**LOPERAMIDE HYDROCHLORIDE CAPSULES USP 2 MG**

1.3 PRODUCT INFORMATION

1.3.1 SUMMARY OF PRODUCT CHARACTERISTICS (SMPC)

Enclosed

BRAND NAME:	**DIADON**
GENERIC NAME:	**LOPERAMIDE HYDROCHLORIDE CAPSULES USP 2 MG**

1. Name of drug product

DIADON

1.1 (Trade) name of product

DIADON

(Loperamide Hydrochloride Capsule USP 2 mg)

1.2 Strength

Loperamide Hydrochloride 2 mg

1.3 Pharmaceutical Dosage Form

Oral dosage form **(**Capsules)

2. QUALITATIVE & QUANTITATIVE COMPOSITION

2.1 Qualitative Declaration

Each Capsule Contains:

Loperamide Hydrochloride USP……..2 mg

Excipients …… q.s.

Capsule Shell contains approved color

MAXHEAL
For Maximum Healing

BRAND NAME:	**DIADON**
GENERIC NAME:	**LOPERAMIDE HYDROCHLORIDE CAPSULES USP 2 MG**

Batch Formula:

Batch Size: 15, 50,000 Capsules

Sr. No.	Ingredients	Function	Spec.	Unit Formula (mg)	Batch Formula (kg)
Active Material					
1.	Loperamide Hydrochloride USP	API	USP	2.060	3.193*
Dry Mixing					
2.	Maize Starch	Diluent	BP	24.94	42.523***
3.	Lactose	Diluent	IH	77.500	120.125**
4.	Dicalcium Phosphate anhydrous	Diluent	BP	25.000	38.750
Lubricants					
5.	Sodium Laural Sulphate	Disintegrant	BP	1.000	1.550
6.	Colloidal Silicon Dioxide (Aerosil)	Disintegrant	BP	1.500	2.325
7.	Sodium Starch Glycollate	Disintegrant	BP	2.000	3.100
8.	Magnesium Stearate	Lubricant	BP	1.000	1.550
Total Fill Weight of Capsule				**135.000**	**209.250**
9.	E. H.G. Capsules size “4” empty hard gelatin capsule with “Green” colored cap & “Gray” colored body.	Capsule Shell	IH	40.000	15,81,000# Nos.
Total Weight of Filled Capsules				**175.000**	**271.250**

*3.0% Overages added in formula of Loperamide Hydrochloride USP and quantity of Loperamide Hydrochloride USP will change after calculation based on assay.
**Lactose quantity changes according to change in quantity of Loperamide hydrochloride.
***10% Extra Maize Starch added to compensate process loss during drying.
2.0% extra empty capsules to be issue for compensates the loss during filling.

3. PHARMACEUTICAL DOSAGE FORM

Solid Oral Dosage (Capsules).

4. CLINICAL PARTICULARS

4.1 Therapeutic Indications:

For symptomatic treatment of acute diarrhoea in adults and children aged 12 years and over.

4.1 Posology and Method of Administration

Posology

Adults and children over 12 years of age:

Two capsules to be taken initially, followed by one capsule after each loose motion, up to a maximum of six capsules in any 24 hours.

Children under 12 years of age:

Not recommended

Use in Elderly

No dose adjustment is required for the elderly.

Renal impairment

No dose adjustment is required for patients with renal impairment.

Hepatic impairment

Although no pharmacokinetic data are available in patients with hepatic impairment Loperamide should be used with caution in such patients because of reduced first pass metabolism (see section 4.4 Special warnings and precautions for use).

Method of administration

Oral use.

4.2 Contraindication

Hypersensitivity to the active substance or to any of the excipient listed in section 6.1.

When inhibition of peristalsis is to be avoided due to the possible risk of significant sequelae including ileus, megacolon, toxic megacolon and certain poisonings in particular:

• Children less than 12 years of age.

• When ileus or constipation are present or when abdominal distension develops

• In patients with acute ulcerative colitis.

• In patients with bacterial enterocolitis caused by invasive organisms including Salmonella, Shigella, and Campylobacter.

• In patients with pseudomembranous colitis associated with the use of broad- spectrum antibiotics.

Loperamide hydrochloride should not be used alone in acute dysentery, which is characterised by blood in stools and elevated body temperatures.

4.3 Special warnings and special precautions for use

Treatment of diarrhoea with loperamide is only symptomatic. Whenever an underlying etiology can be determined, specific treatment should be given when appropriate.

The priority in acute diarrhoea is the prevention or reversal of fluid and electrolyte depletion. This is particularly important in young children and in frail and elderly patients with acute diarrhoea. Use of loperamide hydrochloride does not preclude the administration of appropriate fluid and electrolyte replacement therapy.

Since persistent diarrhoea can be an indicator of potentially more serious conditions, loperamide hydrochloride should not be used for prolonged periods until the underlying cause of the diarrhoea has been investigated.

Loperamide hydrochloride must be used with caution when the hepatic function necessary for the drug's metabolism is defective (eg in cases of severe hepatic disturbance), as this might result in a relative overdose leading to CNS toxicity

Patients with AIDS treated with loperamide hydrochloride for diarrhoea should have therapy stopped at the earliest signs of abdominal distension. There have been isolated reports of toxic megacolon in AIDS patients with infectious colitis from both viral and bacterial pathogens treated with loperamide hydrochloride.

When no clinical change is observed in the acute diarrhoea within 48 hours, the administration of loperamide must be interrupted and the patient must be advised to consult his doctor.

Treatment with Loperamide must be interrupted immediately when obstipation, abdomnial distension or subileus develops

Cardiac events including QT interval and QRS complex prolongation and torsades de pointes have been reported in association with overdose. Some cases had a fatal outcome (see section 4.9). Overdose can unmask existing Brugada syndrome. Patients should not exceed the recommended dose and/or the recommended duration of treatment.

Patients with rare hereditary problems of galactose intolerance, the Lapp lactase deficiency or glucose-galactose malabsorption should not take this medicine because it contains lactose.

4.4 Interaction with other medicinal products and other forms of interaction

Non-clinical data have shown that loperamide is a P-glycoprotein substrate. Furthermore, loperamide is mainly metabolised by CYP3A4 and CYP2C8.Concomitant administration of loperamide (16 mg single dose) with quinidine, or ritonavir, which are both P-glycoprotein inhibitors, resulted in a 2 to 3-fold increase in loperamide plasma levels.

The results of one published pharmacokinetic study suggested that the concomitant administration of loperamide with oral desmopressin may result in a 3-fold increase of desmopressin plasma concentrations although no clinical effects were reported.

Possible interactions may occur with drugs that delay intestinal peristalsis (for instance anti-cholinergic drugs) because the effects of loperamide could be enhanced.

Administration of itraconazole with loperamide (4 mg single dose) increased loperamide plasma levels 3- to 4-fold. In addition, gemfibrozil, a CYP2C8 inhibitor, increased the AUC of loperamide 2-fold. Concomitant use of itraconazole and gemfibrozil with loperamide raised the mean Cmax and AUC of loperamide about 2- and 13-fold, respectively. This increase did not lead to measurable CNS effects.

The concomitant administration of loperamide (16mg single dose) and ketoconazole, an inhibitor of CYP3A4 and p-glycoprotein, resulted in a 5-fold increase in loperamide plasma concentrations. This increase was not associated with increased pharmacodynamic effects as measured by pupillometry.

The clinical relevance of these pharmacokinetic interactions, when loperamide is given at recommended dosages (2 mg, up to 12 mg maximum daily dose), is unknown.

4.5 Pregnancy and lactation

Pregnancy

A limited amount of data from the use of loperamide in pregnant women is available. In one of two epidemiological studies the use of loperamide during early pregnancy suggested a possible moderate increased risk for hypospadia, however, an increased risk for major malformations could not be identified. Animal studies do not indicate direct or indirect harmful effects with respect to reproductive toxicity (see section 5.3). Safety in human pregnancy has not been established, although from animal studies there are no indications that loperamide HCl possesses any teratogenic or embryotoxic properties.

If possible the use of loperamide should be avoided during the first trimester of pregnancy, however, it may be used during the second and third trimester of pregnancy

Breast-feeding

Small amounts of loperamide may appear in human breast milk. Therefore, this medicine is not recommended during breast-feeding. Women who are pregnant or breast feeding infants should therefore be advised to consult their doctor for appropriate treatment.

Fertility

Only high doses of loperamide hydrochloride affected female fertility in non-clinical studies (see section 5.3).

4.6 Effects on ability to drive and use machines

Loperamide hydrochloride has moderate influence on the ability to drive and use machines. Loss of consciousness, depressed level of consciousness, tiredness, dizziness or drowsiness may occur when diarrhoea is treated with loperamide hydrochloride.

Therefore, it is advisable to use caution when driving or operating machinery..

4.7 Undesirable effects

Adults and children aged ≥ 12 years

The safety of loperamide hydrochloride was evaluated in 2755 adults and children aged ≥ 12 years who participated in 26 controlled and uncontrolled clinical trials of loperamide hydrochloride used for the treatment of acute diarrhoea.

The most commonly reported (i.e. ≥1% incidence) adverse drug reactions (ADRs) in clinical trials with loperamide hydrochloride in acute diarrhoea were: constipation (2.7%), flatulence (1.7%), headache (1.2%) and nausea (1.1%).

Table 1 displays ADRs that have been reported with the use of loperamide hydrochloride from either clinical trial (acute diarrhoea) or post-marketing experience.

The frequency categories use the following convention: very common (≥1/10); common (≥1/100 to <1/10); uncommon (≥1/1,000 to <1/100); rare (≥1/10,000 to <1/1,000); and very rare (<1/10,000) and not known (cannot be estimated from the available data).

Table 1 Adverse Drug reactions

System Organ Class	Indication			
	Common	Uncommon	Rare	Not known
Immune System Disorders			Hypersensitivity reaction[a] Anaphylactic reaction (including Anaphylactic shock)[a]	

			Anaphylactoid reaction[a]	
Nervous System Disorders	Headache Dizziness	Somnolence[a]	Loss of consciousness[a] Stupor[a] Depressed level of consciousness[a] Hypertonia[a] Coordination abnormality[a]	
Eye Disorders			Miosis[a]	
Gastrointestinal Disorders	Constipation Nausea Flatulence	Abdominal pain Abdominal discomfort Dry mouth Abdominal pain upper Vomiting Dyspepsia[a]	Ileus[a] (including paralytic ileus) Megacolon[a] (including toxic megacolon[b]) Glossodynia[a] Abdominal distension	Acute pancreatitis
Skin and Subcutaneous Tissue Disorders		Rash	Bullous eruption[a] (including Stevens-Johnson syndrome, toxic epidermal necrolysis and erythema multiforme) Angioedema[a] Urticaria[a] Pruritus[a]	
Renal and Urinary Disorders			Urinary retention[a]	
General Disorders and Administration Site Conditions			Fatigue[a]	

a: Inclusion of this term is based on post-marketing reports for loperamide hydrochloride. As the process for determining post marketing ADRs did not differentiate between chronic and acute

indications or adults and children, the frequency is estimated from all clinical trials with loperamide hydrochloride (acute and chronic), including trials in children ≤ 12 years (N=3683).

b: See section 4.4 Special Warnings and Special Precautions for use.

4.8 Overdose

Symptoms

In case of overdose (including relative overdose due to hepatic dysfunction), CNS depression (stupor, coordination abnormality, somnolence, miosis, muscular hypertonia, and respiratory depression), urinary retention and ileus may occur. Children may be more sensitive to CNS effects than adults.

In individuals who have ingested overdoses of loperamide HCl, cardiac events such as QT interval prolongation, torsades de pointes, other serious ventricular arrhythmias, cardiac arrest and syncope have been observed. Fatal cases have also been reported. Overdose can unmask existing Brugada syndrome.

Treatment

If symptoms of overdose occur, naloxone can be given as an antidote. Since the duration of action of loperamide is longer than that of naloxone (1 to 3 hours), repeated treatment with naloxone might be indicated. Therefore, the patient should be monitored closely for at least 48 hours in order to detect possible CNS depression.

5 Pharmacological properties

5.1 Pharmacodynamics properties

Pharmacotherapeutic Group: Antipropulsives;

ATC code: A07DA03

Loperamide hydrochloride is a synthetic opioid which inhibits gut motility by binding to opiate receptors in the gut wall and may also reduce gastrointestinal secretions, resulting in improvement in diarrhoea symptoms.

Loperamide also increases the tone of the anal sphincter. Onset of antidiarrhoeal effect occurred as soon as one hour after intake of a 4 mg dose of loperamide.

In a double blind randomised clinical trial in 56 patients with acute diarrhoea receiving loperamide, onset of anti-diarrhoeal action was observed within one hour following a single 4 mg dose. Clinical comparisons with other antidiarrhoeal drugs confirmed this exceptionally rapid onset of action of loperamide.

5.2 Pharmacokinetic Properties

Absorption: Most ingested loperamide is absorbed from the gut, but as a result of significant first pass metabolism, systemic bioavailability is only approximately 0.3%.

Distribution: Studies on distribution in rats show a high affinity for the gut wall with a preference for binding to receptors of the longitudinal muscle layer. The plasma protein binding of loperamide is 95%, mainly to albumin. Non-clinical data have shown that loperamide is a P-glycoprotein substrate.

Biotransformation: Loperamide is almost completely extracted by the liver, where it is predominantly metabolised, conjugated and excreted via the bile. Oxidative N-demethylation is the main metabolic pathway for loperamide, and is mediated mainly through CYP3A4 and CYP2C8. Due to this very high first pass effect, plasma concentrations of unchanged drug remain extremely low.

Elimination: The half-life of loperamide in man is about 11 hours with a range of 9-14 hours. Excretion of the unchanged loperamide and the metabolites mainly occurs through the faeces.

Paediatric Population: No pharmacokinetic studies were performed in the paediatric population. It is expected that pharmacokinetic behaviour of loperamide and drug-drug interactions with loperamide will be similar to those in adults.

5.3 Preclinical safety data

Non-clinical data reveal no special hazard for humans based on conventional studies of safety pharmacology, repeated dose toxicity, genotoxicity, carcinogenic potential, toxicity to reproduction and development.

Acute and chronic studies on loperamide showed no specific toxicity.

Loperamide had no effect on fertility in male rats when administered orally prior to mating at doses up to approximately 40 mg/kg. No pregnancy occurred in females dosed with approximately 40 mg/kg. Lower doses (approximately 10 and 2.5mg/kg) did not affect female fertility. In rabbits no differences in pregnancy rate were observed when females were administered orally up to 40mg/kg.

No malformations of offspring were noted in rats and rabbits dosed up to 40 mg/kg. Loperamide did no show genotoxic potential.

In an 18-month carcinogenicity study in rats, with doses up to 100 times the maximum human dose no evidence of carcinogenesis was found.

Non-clinical in vitro and in vivo evaluation of loperamide indicates no significant cardiac electrophysiological effects within its therapeutically relevant concentration range and at significant multiples of this range (up to 47-fold. However, at extremely high concentrations associated with overdoses (see section 4.4), loperamide has cardiac electrophysiological actions consisting of inhibition of potassium (hERG) and sodium currents, and arrhythmias.

BRAND NAME:	**DIADON**
GENERIC NAME:	**LOPERAMIDE HYDROCHLORIDE CAPSULES USP 2 MG**

6 PHARMACEUTICAL PARTICULARS

6.1 List of excipients

Maize Starch
Lactose
Dicalcium Phosphate anhydrous
Sodium Laural Sulphate
Colloidal Silicon Dioxide (Aerosil)
Sodium Starch Glycollate
Magnesium Stearate

6.2 Incompatibilities

Not Known

6.3 Shelf life

36 Month.

6.4 Special precautions for storage

Store below 30°C, in a dry place, protect from light.

6.5 Nature and contents of container

1 X 10 Alu/PVC Blister Pack.

6.6 Special precautions for disposal

No special requirements.

7.0 Manufacturer

MAXHEAL LABORATORIES PVT. LTD.
Plot No.2-7/80-85 SURSEZ, Sachin,
Dist. Surat (Gujarat) 394 230.

8. Marketing authorization number

Not Applicable

9. Date of first authorization

Not Applicable

10. Date of Version

Not Applicable

75.00 mm

Diadon®

Loperamide Hydrochloride Capsules USP 2mg

Composition:
Each capsule contains:
Loperamide Hydrochloride USP 2 mg.
Excipients q.s.
Capsule shells contains approved colours

Description:
Loperamide belongs to a group of medicines called "antidiarrhoeals" which are used to treat diarrhoea. It is used to treat sudden acute cases of diarrhoea in adults and in children over 12 years of age by slowing down an overactive bowel. It also helps the body to absorb more water and salts from the bowel.

Indications:
Symptomatic relief of acute and chronic diarrhoea.

Contra-Indications:
Allergic reactions which can produce swelling of the face, eyes, tongue or lips, difficulty in breathing and/or swallowing or itching. Severe skin rashes including blistering of skin, mouth, eyes and genitals. Megacolon including toxic mega colon (abnormal enlargement of the intestines). Toxic epidermal necrolysis (serious illness with blistering of the skin). Stevens-Johnson Syndrome (serious illness with blistering of the skin, mouth, eyes and genitals).

Special Precautions:

Do not take this medicine while driving or operating machinery because it causes drowsiness and sleepiness.

Do not take this medicine during pregnancy or breast feeding.

Drug Interactions:
"Loperamide may interact with other medicines. You should inform your doctor or pharmacist if you are taking any of the following:
- Co-trimoxazole, an antibiotic used in the treatment of bacterial infections such as chronic bronchitis.
- Quinidine, used in the treatment of abnormal heart beats.
- Ritonavir, used in the treatment of HIV infection and AIDS."

53.00 mm

Dosage and Administration:

Acute diarrhoea:

Adults: Take 2 capsules after the initial episode of diarrhoea and then 1 capsule after each episode of diarrhoea for up to 5 days.

Children: 9-12 yrs: Give 1 capsule 3 times daily for up to 5 days. 8 yrs and below: As directed by a physician.

Chronic diarrhoea:

Adults: Initial dose of 2 capsules once followed by 1 capsule after each episode of diarrhoea, not to exceed 8 capsules in any 24-hour period.

Storage: Store below 30°C, in a dry place, protect from light.

Dosage : As directed by a physician.

Keep all medicines out of reach of children.

Presentation:
A carton of 10 blisters of 10 capsules each.

NOT FOR PAEDIATRIC USE

SPI 0288-00

NAFDAC REG. NO.: A4-0107

Mfg. Lic. No.: G/25/1839

MAXHEAL
For Maximum Healing

Manufactured in India by:
MAXHEAL Laboratories Pvt. Ltd.
H.O.: 401, Maxheal House, Bangur Nagar, Goregaon (W), Mumbai - 090.
Factory: 2-7/80-85, SURSEZ, Sachin, Dist-Surat, Gujarat - 394230.
info@maxheal.in / www.maxheal.in

Maydon

Marketed By:
Maydon Pharmaceuticals Ltd
15, Wilmer Street, Off Town Planning way,
Ilupeju, Lagos -Nigeria

MAYDON PHARMACEUTICALS LTD.
15, Wilmer Street,
Off Town Planning Way,
Ilupeju Lagos.
Phone: 08074150577,
09037655687
e mail: maydonpharma@yahoo.com

6th December, 2023

The Deputy Director
Drug R&R
NAFDAC
Isolo,
Lagos.

Dear sir/ma,

SUBMISSION OF LAB SAMPLES

We hereby submit the samples of our products below for laboratory analysis.

- **CLONEX A CREAM**
- **DIADON CAPSULES**
- **WORMTAC**
- **DIFLAZON 50MG**
- **FANMET CAPSULES**
- **TENZELTOL 200MG TABLET**

Please find attached all the necessary supporting documents for your perusal

Yours faithfully

Pharm Ayobambo f
Managing Director