RC-933759

Teka Pharmaceutical Company Limited

(A Member of the Teka Group)

...Ensuring Life to healthcare

Office: Teka House, Plot 6 Morgan Estate Phase II, Ojodu, Ikeja Lagos.
Tel: +234 (0) 07086666461. e-mail: tekapharma@yahoo.com info.tekagroup@gmail.com

8/2020

The Director.

Drug Registration and Regulatory Affairs.

National Agency for Food and Drug. Administration and Control

Isolo. Lagos

Attn.

Deputy Director,

Drug Registration Division.

APPLICATION FOR PACK SIZE EXTENSION

We hereby apply for the pack size extension of our registered products stated below:

S/No	Product name	Registered Pack size	Intended pack size
1.	Tekagra Jelly [Sildenafil Citrate Eq. to Sildenafil 100mg]	4 x 1 x 5g	7 x 1 x 5g
2.	Tokomol Tablets [Diclofenac Sodium and Paracetamol Tablets 50mg/325mg]	1 x 10's	10 x 1x 10's 20 x 1 x 10's

Find attached completed variation application form and CD containing soft copies of all the necessary documents.

Thank you for the usual co-operation.

Yours faithfully,

For Teka Pharmaceutical Company Ltd

Ugonna Orabuchi Henry

Managing Director

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL

Variation to a Registered Finished Pharmaceutical Product (FPP): Major, Minor or Immediate Notification

Please complete each section of this application form electronically as a Word document and as a scanned signed PDF file. Please ensure that the electronic and the printed versions of the completed form accompany your submission.

1. APPLICATION DETAILS

1.1 Variation type: (tick all applicable options)

☒ Immediate notification (IN) ☐ Minor variation (Vmin) ☐ Major variation (Vmaj)

1.2 Grouping of variations

☒ Single variation ☐ Grouped variations

1.3 Associated finished pharmaceutical product (FPP) name /NAFDAC Reg No:

TEKAGRA JELLY-B4-6967

1.4 Applicant details

Please note that the contact listed in the table below will be the local representative authorized by the FPP manufacturer (if different from the manufacturer) for communication for this specific application.

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL

Applicant	
Primary contact person responsible for this application	Title:Mr. First name: Henry Family name: Ugonna Orabuchi
Contact person's position	
Contact person's postal address	
Building/House No.	TEKA PHARMA LTD, TEKA HOUSE
Road/Street	NO.6 MORGAN ESTATE, PHASE II
Town/City	OJUDU
District/LGA	IKEJA
State	LAGOS STATE
Postal code	
Country	
Contact person's email address	tekapharma@yahoo.com
Contact person's phone number	+2348036857486

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL

If there are other contacts who should be routinely copied into correspondence for this application they should also be listed below.

Applicant	
Primary contact person responsible for this application	Title: First name: Family name:
Contact person's position	
Contact person's postal address	
Building/House No.	
Road/Street	
Town/City	
LGA	
State	
Postal code	
Country	
Contact person's email address	
Contact person's phone number	

NATIONAL AGENCY FOR FOOD AND DRUG ADMINISTRATION AND CONTROL

Applicant	
Primary contact person responsible for this application	Title: First name: Family name:
Contact person's position	
Contact person's postal address	
Building/House No.	
Road/Street	
Town/City	
LGA	
State	
Postal code	
Country	
Contact person's email address	
Contact person's phone number	

2. SUMMARY OF PROPOSED CHANGES

For multiple variations (grouped variations), reproduce this section and provide separate summaries for each proposed variation.

2.1 Variation title and number:

Immediate Notification # 40a:

Change in the package size involving: change in the number of units (e.g. tablets, ampoules, etc.) in a package

2.2 Summary of current and proposed details:

Current details	Proposed details
Pack size of 4 X 1 X 5G	Addition of pack sizes: 7 X 1 X 5G

2.3 Reason for change: To meet market demand and ensure rationale drug use. The change is in line with the approved poslogy of the product

2.4 Date of implementation (for Immediate Notifications only): Immediately (i.e once approval is obtained)

2.5 If relevant to the variation, list the supporting active pharmaceutical ingredient master file (APIMF) number: N/A

3. DOCUMENTATION CHECKLIST

The following documents have been submitted together with this application form:

Note: All documents must be provided for this application to be valid.	
Quality Information Summary (QIS) *For FPPs that have an agreed upon QIS, the QIS should be revised and submitted with any revised sections highlighted. A QIS should be completed in its entirety (irrespective of the proposed change). It should include information on all strengths, with any changes highlighted (e.g. in red type).*	☐ *Yes* ☒ *No agreed QIS* ☐ *No change to QIS*
Supporting documentation *All supporting documents as stipulated for the change in the Guidelines on Variation to a Registered Pharmaceutical Product are included in this submission*	☒ *Yes*

4. DECLARATION

Please check all declarations that apply.

I declare that:

☒ For each change all conditions as stipulated in the *Guidance on Variations to a Registered Pharmaceutical Product* for the change requested are fulfilled.

☒ There are no changes being made other than those applied for in this submission, except for possible editorial changes. Any other changes will be applied for separately.

☒ The information submitted is true and correct.

Name: Ugonna Orabuchi Henry

Signature: _____ Date: 6/07/2020

INDEX NO:

NAFDAC REG. NO:

B4-6967

CERT. NO: 00002770

PRODUCT PIN NO:

APPLICANT TIN NO:

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

Certificate of Registration

is hereby granted in respect of

TEKAGRA ORAL JELLY (ORANGE FLAVOUR)

Product

TEKA PHARMACEUTICALS CO. LTD

6, MORGAN ESTATE, PHASE 2, IKEJA, LAGOS STATE

Name & Address of Company/Applicant

NAVKETAN PHARMA PVT. LTD.

F-106, M.I.D.C, AREA WALUJ DIST; AURANGABAD-431136 (M.), INDIA

Name & Address of Manufacturer

Additional Manufacturing Sites

This certificate expires on 30TH MARCH, 2022

Dated this 31ST *Day of* MARCH, 2017

Director - General
(NAFDAC)

SCHEDULE TO CERTIFICATE OF REGISTRATION

NAFDAC REGISTRATION NO: **B4-6967**

1. Product Details

a)	Brand Name	TEKAGRA
b)	Generic Name	SILDENAFIL CITRATE
c)	Pharmacological Class	TYPE 5 PHOSPHODIEST ERASE INHIBITOR
d)	Approved Marketing Category	PRESCRIPTION ONLY MEDICINE
e)	Presentation	
f)	Dosage Form / Strength	ORAL GEL
g)	Approved Pack Sizes	4 X 1 X 5G
h)	Approved Indications	TREATMENT OF ERECTILE DYSFUNCTION
i)	Product HS Codes/Class No.	
j)	Safety Codes	

2. Active Ingredients / Excipients

SILDENAFIL CITRATE

navketan
PHARMA PVT. LTD.
WHO GMP CERTIFIED

FACTORY & ADMINI OFFICE :
F-106, M.I.D.C. WALUJ, DIST. AURANGABAD - 431 136 (M.S.) INDIA
Phone : +91-0240-2555432, 2553917. **Fax :** +91-0240-2554332
Email : navketanoper@gmail.com / akkarad@sancharnet.in
Website : www.navketanindustries.com

Date : 03rd/07/2020

The Director General
NAFDAC
LAGOS NIGERIA

UNDERTAKING

I, Vivek S. Ganore Mobile No.+91 917507266611 working as Director – Business & Development at M/s. Navketan Pharma Pvt. Ltd , having factory situated at F-106, MIDC, Waluj, Aurangabad -431136 (M.S.) India to hereby solemnly affirm as under :-

I say and declare that we will conduct the stability study of the following product :

TEKAGRA JELLY
Each 5 gm contains :
Sildenafil Citrate eq to
Sildenafil 100 mg
Excipients: q.s.
Colour :Sunset yellow
Flavour : Orange

(Pack Size : 7x1x5gm

I say and declare that we will conduct the stability study of the product and pack size mentioned at our own manufacturing premises M/s. Navketan Pharma Pvt. Ltd , having factory situated at F-106, MIDC, Waluj, Aurangabad -431136 (M.S.) India

The said stability studies will be conducted as per latest WHO GMP guidelines and all the data will be preserved with us. We will submit to you whenever asked for after completion of six months.

Whatever stated hereinabove is true and correct to the best of my knowledge and if found incorrect, I will be action under relevant laws.

Solemnly affirmed at: Aurangabad (M.S.)

(Seal of the firm)

Navketan Pharma Pvt. Ltd. F-106 MIDC WALUJ Aurangabad

Vivek S. Ganore
Director – Business & Development
M/s. Navketan Pharma Pvt.Ltd
F-106, MIDC, Waluj, Aurangabad – 431136
Date : 03/07/2020

75x20x55
08-08-2020

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

Access 7-840419

Treasury Book No. 6

000012458

TREASURY RECEIPT

Station: Lagos KOR (Ore)

Date: 29-7-2020

HEAD: NAFDAC

Sub-Head: } RRR No 3504-0890-6313

Received from: TEKA PHARMACEUTICAL CO. LTD

the sum of: Eighty four thousand [illegible] hundred fifty nine Naira

thirty [illegible] kobo being (description of payment)*

Retention [illegible]

(1) Tekagra jelly 7mg x 5 [illegible]

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

Michael

Name of Accounting Officer

Signature of Accounting Officer

Signature or Mark of Payer

Witness of Mark

84,459.35

N50