Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City, Alabang, Muntinlupa City

CERTIFICATE OF PRODUCT REGISTRATION

Pursuant to the provisions of Republic Act (R.A.) No. 3720 as amended, known as the Foods, Drugs, Devices and Cosmetics Act, and consistent with R.A. No. 6675, known as the Generics Act of 1988, and R.A. No. 9711, otherwise known as the Food and Drug Administration Act of 2009, the product described hereunder has been found to conform with the requirements and standards for marketing authorization of pharmaceutical products per existing regulations in force as of date hereof.

Registration Number	:	**DR-XY39212**
Generic Name	:	Omeprazole
Brand Name	:	Inhibita
Dosage Strength & Form	:	40 mg Enteric Coated Capsule
Pharmacologic Category	:	Proton Pump Inhibitor
Classification	:	Prescription Drug (Rx)
Approved Shelf-life	:	24 months
Storage Condition	:	Store at temperatures not exceeding 30°C.
Packaging	:	Alu/Alu Blister Pack x 4's (Box of 20's and 100's)
Manufacturer	:	Delta Pharma Ltd. Tarakandi, Pakundia, Kishoreganj, Bangladesh
Importer/Distributor	:	Biomed Pharma, Inc. Unit 711 Marbella 2 Bldg., 2071 Roxas Blvd., Malate Manila, Metro Manila

The marketing authorization shall be valid until **23 March 2024** subject to the conditions listed on the reverse side. No change in the formulation, labelling and commercial presentation of this product shall be made at any time during the effectivity of this registration without prior written approval of this Office.

This marketing authorization is subject to suspension, cancellation or recall should any violation of R.A. No. 3720, R.A. No. 6675 and R.A. No. 9711 and/or regulations issued thereunder involving the product be committed.

Witness My Hand and Seal of this Office, this **22 April 2021**.

By Authority of the Director General
Per FDA Order No. 2016-005

JESUSA JOYCE N. CIRUNAY, RPh
Director IV
Center for Drug Regulation and Research

REG. STATUS : **Automatic Renewal (Correction)**
AMOUNT : **Php 10,100.00**
OR NUMBER : **1062595**
DATE : **30 Jan 2019**
BAR CODE
DOC TRACK : 2 0 1 9 0 1 2 5 1 2 5 8 5 7

Management System ISO 9001:2015
TÜVRheinland CERTIFIED
www.tuv.com ID 9105073396

FDA-0510363

Registration Number : DR-XY39212

SPECIAL CONDITION:

Provided that nothing in the registration of the product herein granted shall be interpreted or construed as an endorsement or representation by FDA, that Registrant has the right or privilege to the use of the name or brand so registered; Registrant hereby agrees and affirms to indemnify and/or hold FDA free and harmless against any and all third-party claims on infringement of patent, trademark or intellectual property right arising from the registration of the product.

	A	This is subject to batch notification.
	B	This is subject to lot release certification.
	C	This is subject to compliance with the requirements under FDA Circular No. 2013-004 for Monitored Release (MR) drug products.
x	**D**	Subject to post-marketing surveillance of the marketing authorization holder's strict compliance to the Generic Labeling Requirements following the applicable provisions of A.O No. 2016-0008 for drug products for human use and A.O. No. 105 s. 1991 for veterinary drug products.
	E	Submit a satisfactory Bioequivalence Study Report or Biowaiver (whichever is applicable) within the validity of this CPR in accordance with FDA Circular No. 2016-019.
	F	Dangerous Drug - To be prescribed by a PDEA S-2 licensed practitioner in a DOH (yellow) prescription form. It is a habit-forming drug.
	G	Dangerous Drug - To be prescribed by a PDEA S-2 licensed practitioner in a personalized ordinary prescription form. It is a habit-forming drug.
	H	Patient Information Leaflet - Appropriate information for the consumers shall be written in Filipino and/or local dialects, as appropriate.
	I	Submit a Certificate of Good Manufacturing Practice (GMP) Compliance of Foreign Drug Manufacturer(s) within the validity of this CPR in accordance with A. O. No. 2013-0022 and FDA Circular 2014-016.
	J	Review of the submitted Bioequivalence Study Report or Biowaiver, whichever is applicable, shall be completed by the FDA within the validity of this CPR; correspondingly, this CPR shall be revoked if product interchangeability has not been established.
	K	Subject to satisfactory compliance to the post-approval commitments detailed in the letter accompanying this CPR.

REMARKS:

This Certificate of Product Registration (CPR) is reconstructed to reflect correct (1) Generic Name from **Omperazole** to **Omeprazole**; and (2) Manufacturer's Address from **Pakundia, Kishoreganj, Bangladesh** to **Tarakandi, Pakundia, Kishoreganj, Bangladesh**. This cancels CPR control number FDA-0317392 valid until 23 March 2024, issued on 15 August 2019.

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

CERTIFICATION

This is to certify that the product with the following particulars:

Product Name	Registration Number	CPR Validity
Omeprazole 40 mg Enteric Coated Capsule [Inhibita]	DR-XY39212	23 March 2024

has been given approval for the following post-approval changes:

Previous	Proposed Change	Classification
Shelf-life: 24 months	Shelf-life: **36 months**	Extension of shelf-life of the drug product [MaV-15]

The Marketing Authorization Holder, **Biomed Pharma Inc.**, with business address at Unit 711 Marbella 2 Bldg., 2071 Roxas Blvd., Malate, Manila, shall attach this certification or copy of the certification to the Certificate of Product Registration.

Issued this **15th day of February 2022** at Alabang, Muntinlupa City, Philippines.

By Authority of the Director General
Per FDA Order No. 2016-005

JESUSA JOYCE N. CIRUNAY, RPh
Director IV
Center for Drug Regulation and Research

REG. STATUS : Automatic Renewal (Correction)(Variation)
AMOUNT : Php 1,010.00
OR NUMBER : Seq. # 110921355793
DATE : 9 November 2021
ATTACHMENT : Corrected labelling materials

20210728224627

Conditions:

[x] A maximum of twelve (12) months after the issuance of this Certification is hereby given to exhaust all existing inventory of the previous labeling materials (primary, secondary, and product information). No further extension will be granted.

[x] Subject to post-marketing surveillance of the marketing authorization holder's strict compliance to the Generic Labeling Requirements following the applicable provisions of A.O. No. 2016-0008 for drug products for human use and A.O. 105 s. 1991 for veterinary drug products.

[ ] Subject to post-marketing surveillance of the marketing authorization holder's strict compliance to the Generic Labeling Requirements following the applicable provisions of A.O. No. 2016-0008 upon renewal registration.

[x] The extended/reduced shelf-life of this product shall be applied only to batches manufactured after the completion of the submitted (3) batches **(008, 009 & 010)** of stability studies (June 2016, July 2016 & September 2017).

Carton Size :130 x 76 x 85 mm
Color Chart : 4 Color (CMYK)

Text of Inhibita 40 Capsule IC
Date : 09.01.19

Labeling materials should comply with the applicable provisions stated in A.O. No. 2016-0008.
>May refer to comparator/locally available product. However, proprietary matters should be considered. Update(s) in the package insert may correspond to a specific post-approval change(s).
-Package insert and immediate labeling should also comply with the applicable provisions stated in A.O. No. 2016-0008.

Inclusion of the Reference Monograph used in the formulation indicated after the API (if applicable). Also, note the format of presentation of data/information following the A.O. No. 2016-0008.

OMEPRAZOLE
℞ INHIBITA
40 mg Enteric-Coated Capsule
PROTON PUMP INHIBITOR
100 Capsules

100 Capsules

OMEPRAZOLE

℞ INHIBITA

40 mg Enteric-Coated Capsule
PROTON PUMP INHIBITOR

Manufactured by:
Delta Pharma Limited
Tarakandi, Pakundia
Kishoreganj, Bangladesh

Imported & Distributed by:
BioMed Pharma Inc.
Unit 711 Marbella 2 Bldg., 2071 Roxas Blvd., Malate Manila.

FORMULATION:
Each Enteric-Coated Capsule contains:
Omeprazole ..... 40 mg

INDICATION:
It is used to condition where inhibition of gastric acid secretion may be beneficial, including aspiration syndromes, dyspepsia, gastro-oesophageal reflux disease, peptic ulcer disease and the Zollinger-Ellison Syndrome.

DOSAGE AND ADMINISTRATION:
Benign and duodenal ulcers: 40 mg/day for 4 weeks.

Acid related dyspepsia: 40 mg/day for 2-4 weeks.

100 Capsules

OMEPRAZOLE

℞ INHIBITA

40 mg Enteric-Coated Capsule
PROTON PUMP INHIBITOR

Manufactured by:
Delta Pharma Limited
Tarakandi, Pakundia
Kishoreganj, Bangladesh

Imported & Distributed by:
BioMed Pharma Inc.
Unit 711 Marbella 2 Bldg., 2071 Roxas Blvd., Malate Manila.

STORAGE:
Store at temperatures not exceeding 30°C.
Keep out of the reach of children.

ADR REPORTING STATEMENT:
For suspected adverse drug reaction, report to the FDA: www.fda.gov.ph

CAUTION:
Foods, Drugs, Devices and Cosmetics Act prohibits dispensing without prescription.

SEE PACKAGE INSERT FOR MORE INFORMATION

DR-XY39212
Batch No. :
Mfg. Date :
Exp. Date :

Carton Size : 130 x 76 x 20 mm

Inhibita 40 Cap Carton

Inclusion of the Reference Monograph used in the formulation indicated after the API (if applicable). Also, note the format of presentation of data/information following the A.O. No. 2016-0008.

...ules

OMEPRAZOLE

℞ **INHIBITA**

40 mg Enteric-Coated Capsule
PROTON PUMP INHIBITOR

FORMULATION: Each Enteric-Coated Capsule contains: Omeprazole..... 40 mg

INDICATION: It is used to condition where inhibition of gastric acid secretion may be beneficial, including aspiration syndromes, dyspepsia, gastro-oesophageal reflux disease, peptic ulcer disease and the Zollinger-Ellison Syndrome.

DOSAGE AND ADMINISTRATION: Benign and duodenal ulcers: 40 mg/day for 4 weeks. Acid related dyspepsia: 40 mg/day for 2-4 weeks.

OMEPRAZOLE
INHIBITA
℞ 40 mg Enteric-Coated Capsule
PROTON PUMP INHIBITOR

Manufactured by:
Delta Pharma Limited
Tarakandi, Pakundia
Kishoreganj, Bangladesh

8 944161 210781

Imported & Distributed by:
BioMed Pharma Inc.
Unit 711 Marbella 2 Bldg., 2071 Roxas Blvd.,
Malate Manila.

Labeling materials should comply with the applicable provisions stated in A.O. No. 2016-0008.
>May refer to comparator/locally available product. However, proprietary matters should be considered. Update(s) in the package insert may correspond to a specific post-approval change(s).
-Package insert and immediate labeling should also comply with the applicable provisions stated in A.O. No. 2016-0008.

SEE PACKAGE INSERT
FOR MORE INFORMATION

ADR REPORTING STATEMENT:
For suspected adverse drug reaction, report to the FDA:
www.fda.gov.ph

Republic of the Philippines
Department of Health
Food and Drug Administration
Alabang, Muntinlupa

DOCUMENT TRACKING LOG

Tracking ID: *20190608094242*

20190608094242

Source: BIOMED PHARMA INC.

FDA JUN 18 2019 BY:

Subject:
Type: CPR
Center: CDRR
Company Name: BIOMED PHARMA INC.
Region: NCR
Activity: Importer
LTO: CDRR-NCR-DI-3191
Product/Brand Name: INHIBITA 40
Generic (if applicable) Name: OMEPRAZOLE
CPR: DR-XY39212
Description: 0
Application Details: Variation
Application Fee: 1000
LRF: 20
Surcharge: 0
Total: 1020

Contact Information:

EMail joy.biomedpharmainc@yahoo.com

Remarks:

Date	Details
6/8/2019 9:42:47 AM	Scheduled to appear on 18 June 2019 Remarks by: LJANuyda
6/8/2019 9:42:47 AM	Received by LJANuyda

RECEIVED JUN 18 2019

Department of Health
Food and Drug Administration

APPLICATION FORM

Document Tracking Number
20190608094242
Description (Optional):

APPLICATION FORM STATUS

GENERAL INFORMATION:	PROCEED
ESTABLISHMENT INFORMATION:	PROCEED
PRODUCT INFORMATION:	PROCEED
SUPPORTING INFORMATION:	PROCEED
SOURCES & CLIENTS:	PROCEED
APPLICANT INFORMATION:	PROCEED

ORDER OF PAYMENT

Amount Due:	Php	1,020.00
Fee :	Php	1,000.00
Legal Research Fee :	Php	20.00
Surcharge :	Php	-
OR Number :		
Date Paid:		
Computation Valid Until:		23 March, 2024

This form was last edited on 13 October 2016, 10:28 AM.

1 GENERAL INFORMATION — PROCEED

1.1 Product Center:	Drug
1.2 Authorization:	Product Registration
1.3 Type:	Variation
1.4 Primary Activity:	Importer
1.5 Current License Number:	CDRR-NCR-DI-3191
1.5.1 Expiry Date:	06-Apr-21
	Your License will expire in 659 days.
1.6 Current Registration Number:	DR-XY39212
1.6.1 Expiry Date:	23-Mar-24
	Your Registration will expire in 1741 days.
1.7.1 Type of Variation 1:	Minor - Prior Approval 1 to 20
1.7.1.1 Variation Code 1:	PA10
1.7.2 Type of Variation 2:	Minor - Prior Approval 21 to 35, PH01 to PH06
1.7.2.1 Variation Code 2:	PA30
1.7.3 Type of Variation 3:	Nothing Further

2 ESTABLISHMENT INFORMATION — PROCEED

2.1 Name of Establishment
BIOMED PHARMA INC.

2.3 Tax Identification Number: 007-484-508-000

2.4 Office Address — 2.5.1 Region: NCR
UNIT 711 MARBELLA 2 BLDG. 2071 ROXAS BLVD.
MALATE MANILA

2.5 Warehouse Address — 2.6.1 Region: NCR
UNIT 711 MARBELLA 2 BLDG. 2071 ROXAS BLVD.
MALATE MANILA

2.7.0 E-mail Address:	joy.biomedpharmainc@yahoo.co	
2.7.1 Contact Detail 1	Landline:	742-5681
2.7.2 Contact Detail 2	Landline:	425-9599
2.7.3 Contact Detail 3	Mobile:	0932-8484972

3 PRODUCT INFORMATION — PROCEED

3.1 Product Category: Human Drug, Branded

5

3.2 Product/Brand Name	3.2.1 *Generic Name*
INHIBITA 40	OMEPRAZOLE

3.2.2 EDL?	Yes	3.2.3 Samples?:	No
3.3.0 Drug Classification:	RX		
3.3.1 Dosage Strength:	40 MG		
3.3.2 Dosage Form:	ENTERIC COATED CAPSULE		
3.3.3 Pharma Category:	PROTON PUMP INHIBITOR		
3.4.0 Packaging:	ALU-ALU BLISTER PACK		
3.4.1 Presentation/GPIN/GTIN:	BOX OF 20'S & 100'S		
3.4.2 Storage Condition:	NOT EXCEEDING 30°C		
3.4.3 Shelf-life:	24 MONTHS		
3.4.4 Sugg. Retail Price	120 & 500 per BOX		

None
No

4 SUPPORTING INFORMATION — PROCEED

PROCEED
PROCEED
PROCEED

5 SOURCES & CLIENTS — PROCEED

1 None

6 APPLICANT INFORMATION — PROCEED

The undersigned attest to have provided true and complete information in this form, and to provide complete requirements at the time of submission. The undersigned agree to strict compliance with the rules and regulations of the Food and Drug Administration (FDA), including Good Manufacturing Practice (GMP), Good Distribution and Storage Practice (GDSP), Good Pharmacy Practice (GPP), and/or Good Laboratory Practice (GLP). Further, the undersigned agree to grant authority to the FDA to verify the truthfulness of the information provided with this application.

6.1 APPROVING AUTHORITY

Signature

6.1.1.0 Family Name:	HUSSAIN
6.1.1.1 First Name(s):	MD. TAREQUE
6.1.1.2 Middle Name:	B
6.1.2 Designation:	Owner/ General Manager/ President
6.1.3 Tax ID Number:	NONE
6.1.4.0 Type of Gov't ID:	Philippine Passport
6.1.4.1 ID Number:	BP0855563
6.1.4.2 Date Expiry:	NONE

6.1.5 Mailing Address
UNIT 1005 MARBELLA 2 BLDG. 2071 ROXAS BLVD. MALATE MANILA

6.1.6.0 E-mail Address:
[redacted]
6.1.6.1 Contact Detail 1 Landline: 742-5681
6.1.6.2 Contact Detail 2 Landline: 742-5681
6.1.6.3 Contact Detail 3 Mobile: 0998-1910911

6.2 APPLICANT

Signature

6.2.2.0 Family Name:	SANTOS
6.2.2.1 First Name(s):	JOY
6.2.2.2 Middle Name:	BARRETE
6.2.2 Designation:	Company Pharmacist
6.2.3 Tax ID Number:	203-839-807
6.2.4.0 Type of Gov't ID:	Professional Regulatory Commission
6.2.4.1 ID Number:	37741
6.2.4.2 Date Expiry:	19-Mar-22

6.2.5 Mailing Address
UNIT 711 MARBELLA 2 BLDG. 2071 ROXAS BLVD. MALATE MANILA

6.2.6.0 E-mail Address:
joy.biomedpharmainc@yahoo
6.2.6.1 Contact Detail 1 Landline: 742-5681
6.2.6.2 Contact Detail 2 Landline: 425-9599
6.2.6.3 Contact Detail 3 Mobile: 0998-1910911

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

Food and Drug Administration
PHILIPPINES

NOTIFICATION FOR MINOR VARIATION/S OF REGISTERED PHARMACEUTICAL PRODUCT

Date: 17 June 2019

NOTIFICATION NUMBER	
DTN:	
TO BE FILLED OUT BY FDA	
Received by:	
Signature	
Date	
PAYMENT DETAILS	
Amount Paid:	
OR No.:	
OR Date Issued:	

FOOD AND DRUG ADMINISTRATION
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City

Sir/Madam:

In accordance with Administrative Order No. 2013-0021 and related issuances, we wish to apply and notify FDA of our intention to make Minor Variation/s to our pharmaceutical product described below:

PRODUCT PARTICULARS

Generic Name: OMEPRAZOLE
Dosage Strength/Form: 40 mg ENTERIC COATED CAPSULE
Brand Name INHIBITA 40

Approved Shelf-life: 24 MONTHS
Storage Condition: STORE AT TEMPERATURE NOT EXCEEDING 30°C
Packaging/Presentation: ALU-ALU BLISTER PACK of 4'S (BOX OF 20'S & 100's)

FDA Registration No.: DR-XY39212 **Validity:** 23 MARCH 2019
Registration Status: RENEWAL

COMPANY PARTICULARS

Manufacturer: DELTA PHARMA LIMITED

Trader : N/A

Importer: BIOMED PHARMA INC.
UNIT 711 MARBELLA 2 BLDG., 2071 ROXAS BLVD., MALATE MANILA

Distributor: BIOMED PHARMA INC.
UNIT 711 MARBELLA 2 BLDG., 2071 ROXAS BLVD., MALATE MANILA

Packer / Repacker: N/A

NOTIFICATION NUMBER	
Received by:	

POST-APPROVAL CHANGES PARTICULARS

Table of Changes		
Current	**Proposed Changes**	**Specific Type of Minor Variation**
24 MONTHS	36 MONTHS	MiV-PA10
BLISTER PACK OF 4's	BLISTER PACK OF 10's	MiV-PA30

NOTIFICATION NUMBER	
Received by:	

DECLARATION

In support of our notification, I, the undersigned, hereby declare under oath that:

1. I am duly authorized to bind the establishment I represent pursuant to the authority attached to this Notification for Minor Variation Form (Board Resolution in case of corporation and Special Power of Attorney in all other cases both of which should be duly notarized);
2. In behalf of my company, the pharmaceutical product identified in the notification meets all the legal requirements, and conforms to existing standards and specification requirements applicable to the said product;
3. The particulars given in this notification are true and all data and information of relevance in relation to the notification have been supplied and that the documents enclosed are authentic or true copies;
4. I agree that the grant of acceptance shall be automatically revoked by FDA in the event that there is subsequent findings of misrepresentation in any of the data indicated in the required documents or any of the said documents is subsequently found to be falsified of fraudulently filed; and/or in case the samples of the identified pharmaceutical product collected through post marketing surveillance shall be found not to conform to the product's registered specifications or approved labeling.
5. The company I represent shall automatically cease and desist from further distributing the identified pharmaceutical product subject of revocation upon receipt of the notice of revocation and pending any administrative proceeding until further notice from FDA.
6. I, or my company undertake to:
   a) Ensure the identified pharmaceutical product's technical and safety information is made readily available to FDA anytime when requested, and to keep records of the distribution of the products for product recall purposes;
   b) Notify FDA of any adverse events consistent with the requirements of pharmacovigilance;
   c) Respond to and cooperate fully with Food-Drug Regulation Officers with regard to any subsequent post-marketing activity initiated by FDA.
   d) Exhaust the remaining stocks **of labeling materials and products** bearing the old product information up to a maximum of one (1) year from the date of receipt of the notification, at the manufacturing level.
   e) Submit a commercial sample of the first batch of manufacturing/importation/packaging/repackaging of the subject product, for all pack sizes, including the package insert or patient information leaflet (whichever is applicable) reflecting the notified change, as soon as available.
7. I understand that our company or establishment cannot place reliance on the acceptance of the notification by FDA in any legal proceedings concerning the above product, in the event that the identified product has failed to conform to any standards or specifications previously declared to FDA.

NOTIFICATION NUMBER	
Received by:	

COMPANY PHARMACIST

Signature: _____
Name: JOY B. SANTOS
Designation: Company Pharmacist
Date: June 17, 2019

SUBSCRIBED AND SWORN TO BEFORE ME this personally appeared the following:

Name	Residence Certificate	Date Issued	Place Issued
JOY B. SANTOS	**15415431**	**1/23/2019**	**Manila**

Known to me and to me known to be the same persons who executed the foregoing instrument and they acknowledged to me that the same is their free and voluntary act and deed.

WITNESS MY HAND AND SEAL on the date and place first above written.

Doc No. 56
Page No. 12
Book No. XXIII
Series of 2019

ATTY. CLIFF RICHARD E. GENESELA
NOTARY PUBLIC CITY OF MANILA / ROLL NO. 49005
Commission No. 2018-079 Issued on Feb 28, 2018 Until Dec. 31, 2019 / Manila
PTR No. 8011405 Issued on Dec. 28, 2018 Until Dec. 31, 2019 / Manila
IBP No. 058095 Issued on Dec. 28, 2018 Until Dec. 31, 2019
MCLE No. VI-0022302 Issued on April 4, 2019
Office Add: Rm 305, NPC Building Magallanes Drive, Intramuros, Manila

Letter of Request for Post-approval Change/s

DTN	20190608094242
Date	18 July 2019

Food and Drug Administration
Civic Drive, Filinvest Corporate City
Alabang, Muntinlupa City

Attention: Licensing and Registration Division
Center for Drug Regulation and Research

Sir/Madam,

We would like to submit our application for Post-approval Change/s, (*type of Post Approval Change as per AVG or Country-specific requirements*) for the following product/s:

Product Name/Strength and Form	CPR Validity/Drug Registration Number	Current	Proposed Change/s	Classification/ Specific Type of PAC/s
INIHIBITA 40 (40mg Enteric-Coated Capsule)	23 March 2019 / DR-XY39212	24 MONTHS	36 MONTHS	MiV-PA10
INIHIBITA 40 (40mg Enteric-Coated Capsule)	23 March 2019 / DR-XY39212	BLISTER PACK OF 4's	BLISTER PACK OF 10's	MiV-PA30

For your approval.

Very truly yours,

Joy B. Santos
Company Pharmacist
Company representative name and signature
Position