FDA-2019AJVAOLL4I6S8FPZK5SHK

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	:	**DRP-5307**
Generic Name	:	Losartan Potassium
Brand Name	:	Angel-50
Dosage Strength & Form	:	50mg Film-Coated Tablet
Pharmacologic Category	:	Angiotensin II Receptor Blocker
Classification	:	Prescription Drug (Rx)
Approved Shelf-life	:	36 months
Storage Condition	:	Store at temperatures not exceeding 30°C.
Packaging	:	Alu/Alu Blister Pack x 10's (Box of 30's and 100's)
Manufacturer	:	Healer's Lab Unit II Plot No. 33, HPSIDC, Extn. Baddi, Distt. Solan (HP), India
Importer	:	Pharmakon Biotec Inc. UG-01 Cityland 8, #98 Sen. Gil Puyat Ave., Makati City
Distributor	:	Pharmakon Biotec Inc. UG-01 Cityland 8, #98 Sen. Gil Puyat Ave., Makati City

The marketing authorization shall be valid until **26 May 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 **05 November 2019**.

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

ATTY. KATHERINE M. AUSTRIA-LOCK
Officer-in-Charge
Center for Drug Regulation and Research

REG. STATUS : Automatic Renewal
AMOUNT : Php10,100
OR NUMBER : 1122582
DATE : 14 May 2019
BAR CODE / DOC TRACK : 2019050309512 2

FDA-0445787

Registration Number : DRP-5307

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.
X	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 PDEA S-2 licensed practitioner in a DOH (yellow) prescription form. It is a habit-forming drug.
	G	Dangerous Drug - To be prescribed by PDEA S-2 licensed practitioner in a personalized ordinary prescription. 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 No. 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 granted following Department Circular 2011-0101: The Rules and Regulations Implementing Republic Act No. 9711 - The Food and Drug Administration Act of 2009.

Exhaustion of all existing inventory of the previous labelling materials is allowed only until **05 November 2020**. No further extension shall be granted.

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

NOTIFICATION FORM FOR MINOR VARIATION/S OF REGISTERED PHARMACEUTICAL PRODUCT

Date: 04 October 2021

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

DOCUMENT TRACKING NUMBER (DTN)	
20211011103356	
TO BE FILLED OUT BY FDA	
Received by:	FDAC
Signature:	FAPD
Date:	19 October 2021
PAYMENT DETAILS	
Amount Paid:	Php 510.00
OR No.:	Seq # 27000
OR Date Issued:	12 October 2021

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

Details should be consistent with the current CPR/CLIDP.

Generic Name	**LOSARTAN POTASSIUM**
Dosage Strength and Form	**50mg Film-Coated Tablet**
Brand Name	**ANGEL-50**
Approved Shelf-life	**36 months**
Storage Condition	**Store at temperatures not exceeding 30°C**
Packaging/Presentation	**Alu/Alu Blister pack x 10's (Box of 30's and 100's)**

FDA Registration No. **DRP - 5307**
Registration Status **Renewal (Amendment - PCPR)**

Validity **26 May 2024**
State the validity or the DTN of the renewal application, if the CPR/CLIDP has not yet been renewed

COMPANY PARTICULARS

Details should be consistent with the current CPR/CLIDP. Complete name/s and address/es of the involved establishment/s should be reflected.

Manufacturer	**HEALER'S LAB UNIT II** **Plot No. 33, HPSIDC, Extn. Baddi, Distt. Solan (HP), India**
Trader	**Not Applicable**
Importer	**Pharmakon Biotec Inc.** **UG-01 Cityland 8, #98 Senator Gil Puyat Avenue, Makati City**
Distributor	**Pharmakon Biotec Inc.** **UG-01 Cityland 8, #98 Senator Gil Puyat Avenue, Makati City**
Packer/Repacker	**Not Applicable**

DTN	
20211011103356	
Received by:	FDAC

POST-APPROVAL CHANGES PARTICULARS

Table of Changes		
Current	**Proposed Changes**	**Specific Type of Variation** *For MiV-PH-N7, indicate the original variation code applied for the PCPR, e.g. MiV-PH-N7 (MaV-15)*
UG-01 Cityland 8, #98 Senator Gil Puyat Avenue, Makati, Metro Manila	**New address of Pharmakon:** **Unit 10B 10/F Chatham House, 116 Valero cor. Herrera St., Bel-Air, Makati City, Metro Manila**	**MiV-N1**

***** NOTHING FOLLOWS *****

DTN	
20211011103356	
Received by:	FDAC

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 Form for Minor Variation/s of registered pharmaceutical product (Board Resolution in case of corporation and Special Power of Attorney in all other cases both of which should be duly notarized).
2. On behalf of my company, the pharmaceutical product identified in the notification form meets all the legal requirements, and conforms to existing standards and specification requirements applicable to the said product.
3. All conditions for the variations have been fulfilled and all required supporting documents are submitted.
4. 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.
5. I agree that the acknowledgement of this notification shall not preclude the Food and Drug Administration (FDA) in imposing appropriate regulatory actions in the event that there is/are outright negligence on the conditions for minor variation – notification and explicit misdeclaration of the applied changes as notification; lacking and deficient documentary requirements as stipulated in current Circulars on Post-Approval Changes; 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.
6. 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.
7. 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 (FDROs) 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.
8. 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.
9. There is/are no other change/s made to/proposed for the drug product aside from what is/are specified in the Post-Approval Changes Particulars of this Notification Form.

DTN	
20211011103356	
Received by:	FDAC

HEAD OF REGULATORY OFFICE		COMPANY PHARMACIST	
Signature:		**Signature:**	
Name:	**Rowena M. Dechimo**	**Name:**	**Rowena M. Dechimo**
Designation:	**Regulatory Affairs Pharmacist, Head**	**Designation:**	**Regulatory Affairs Pharmacist, Head**
Date:	04 October 2021	**Date:**	04 October 2021

SUBSCRIBED AND SWORN TO BEFORE ME this OCT 05 2021 personally appeared the following:

Name	Residence Certificate	Date Issued	Place Issued
Rowena M. Dechimo	**26664803**	**January 2021**	**Mandaluyong City**

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.

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Page No. 93
Book No. 212
Series of 2021

ATTY. JOHN DOMINGO A. PONCE, JR.
NOTARY PUBLIC
APPOINTMENT No. M-924 MAKATI CITY
UNTIL DECEMBER 31, 2021
(per Supreme Court En Banc Resolution
dated June 22, 2021)
PTR No. 8530267/01-04-2021/MAKATI CITY
IBP No. 142544/01-04-2021/RIZAL
MCLE COMPLIANCE No. VI-0027026/05-28-2019
ROLL NO. 36452/TIN No. 106-099-102-000
Unit G-14 Makati Executive Tower 3
Sen. Gil Puyat Avenue, Pio del Pilar,
Makati City, Metro Manila

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

NOTIFICATION FORM FOR MINOR VARIATION/S OF REGISTERED PHARMACEUTICAL PRODUCT

Date: 04 March 2021

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

DOCUMENT TRACKING NUMBER (DTN)	
20210324115355	
TO BE FILLED OUT BY FDA	
Received by:	FDAC
Signature:	SLSC
Date:	04 May 2021
PAYMENT DETAILS	
Amount Paid:	Php 510.00
OR No.:	SEQ NO. 29700
OR Date Issued:	04 May 2021

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

Details should be consistent with the current CPR/CLIDP.

Generic Name	**LOSARTAN POTASSIUM**
Dosage Strength and Form	**50mg Film-CoatedTablet**
Brand Name	**ANGEL-50**
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Packaging/Presentation	**Alu/Alu Blister Pack x 10's (Box of 30's and 100's)**

FDA Registration No. **DRP-5307** **Validity** **26 May 2024**
Registration Status **Renewal (Amendment-PCPR)**
State the validity or the DTN of the renewal application, if the CPR/CLIDP has not yet been renewed

COMPANY PARTICULARS

Details should be consistent with the current CPR/CLIDP. Complete name/s and address/es of the involved establishment/s should be reflected.

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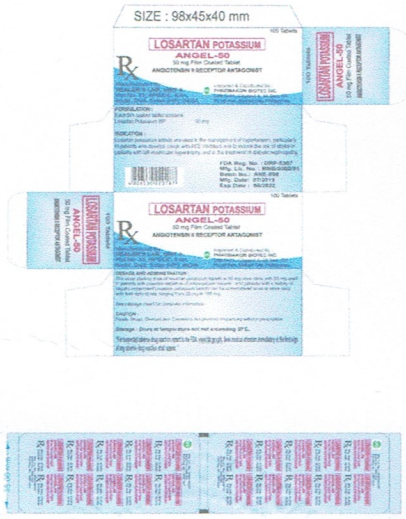
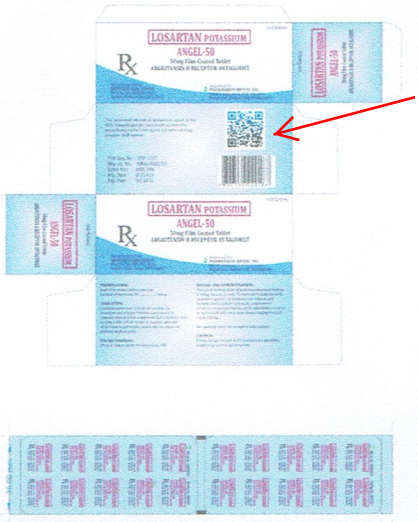
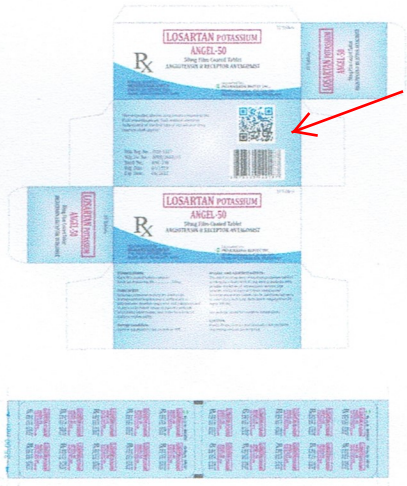
	Plot No. 33, HPSIDC, Extn. Baddi, Distt. Solan (HP), India
Trader	**Not Applicable**
Importer	**Pharmakon Biotec Inc.**
	UG-01 Cityland 8, #98 Senator Gil Puyat Avenue, Makati City
Distributor	**Pharmakon Biotec Inc.**
	UG-01 Cityland 8, #98 Senator Gil Puyat Avenue, Makati City
Packer/Repacker	**Not Applicable**

DTN	
20210324115355	
Received by:	FDAC

POST-APPROVAL CHANGES PARTICULARS

Table of Changes		
Current	**Proposed Changes**	**Specific Type of Variation** *For MiV-PH-N7, indicate the original variation code applied for the PCPR, e.g. MiV-PH-N7 (MaV-15)*
-Old Appoved Labeling Materials-	**-Proposed Labeling Materials-** Box of 100's	**MiV-PH-N1**
		
	Box of 30's	
		

*** NOTHING FOLLOWS ***

DTN	
20210324115355	
Received by:	FDAC

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 Form for Minor Variation/s of registered pharmaceutical product (Board Resolution in case of corporation and Special Power of Attorney in all other cases both of which should be duly notarized).
2. On behalf of my company, the pharmaceutical product identified in the notification form meets all the legal requirements, and conforms to existing standards and specification requirements applicable to the said product.
3. All conditions for the variations have been fulfilled and all required supporting documents are submitted.
4. 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.
5. I agree that the acknowledgement of this notification shall not preclude the Food and Drug Administration (FDA) in imposing appropriate regulatory actions in the event that there is/are outright negligence on the conditions for minor variation – notification and explicit misdeclaration of the applied changes as notification; lacking and deficient documentary requirements as stipulated in current Circulars on Post-Approval Changes; 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.
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   c) Respond to and cooperate fully with Food-Drug Regulation Officers (FDROs) with regard to any subsequent post-marketing activity initiated by FDA.
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   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.
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DTN	
20210324115355	
Received by:	FDAC

HEAD OF REGULATORY OFFICE		COMPANY PHARMACIST	
Signature:		Signature:	
Name:	Rowena M. Dechimo	Name:	Rowena M. Dechimo
Designation:	Regulatory Affairs Pharmacist, Head	Designation:	Regulatory Affairs Pharmacist, Head
Date:	04 March 2021	Date:	04 March 2021

SUBSCRIBED AND SWORN TO BEFORE ME this MAR 10 2021 personally appeared the following:

Name	Residence Certificate	Date Issued	Place Issued
Rowena M. Dechimo		**January 2021**	**Mandaluyong City**

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. 492
Page No. 100
Book No. 198
Series of 2021

ATTY. JOHN DOMINGO A. PONCE, JR.
NOTARY PUBLIC
APPOINTMENT No. M-92 / MAKATI CITY
UNTIL JUNE 30, 2021
(per Supreme Court En Banc Resolution dated December 1, 2020)
PTR No. 8530267 / 01-04-2021 /MAKATI CITY
IBP No. 142544 /01-04-2021/ RIZAL
MCLE COMPLIANCE No. VI-0027026 / 05-28-2019
ROLL NO. 36452 / TIN No. 106-099-102-000
Unit G-14 Makati Executive Tower 3
Sen. Gil Puyat Avenue, Plo del Pilar,
Makati City, Metro Manila