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- 10748**
Generic Name	:	Atorvastatin (as calcium)
Brand Name	:	Trovipri
Dosage Strength & Form	:	40 mg Film-Coated Tablet
Pharmacologic Category	:	Lipid Modifying Agent (HMG CoA Reductase Inhibitor)
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)
Manufacturer	:	Stallion Laboratories Pvt. Ltd. C1B, 305/2, 3, 4 & 5 G.I.D.C. Kerala, Bavla-382 220, Dist: Ahmedabad, Gujarat, India
Importer	:	Ambica International Corporation No.9 Amsterdam Extension, Merville Park Subd., Parañaque City
Distributor	:	Ambica International Corporation No.9 Amsterdam Extension, Merville Park Subd., Parañaque City

The marketing authorization shall be valid until **15 November 2026** 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 **15 November 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 : **Initial**
AMOUNT : **Php 15,660.00**
OR NUMBER : **1215569**
DATE : **20-November-2019**
BAR CODE
DOC TRACK : 2 0 1 9 0 9 1 2 1 5 3 3 0 0

FDA-0563771

Registration Number : DRP-10748

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 bioavailability/bioequivalence study report or biowaiver evidence (whichever is applicable) within the validity 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.
X	**I**	Submit a Certificate of Good Manufacturing Practice (GMP) Compliance of Foreign Drug Manufacturer(s) within the validity 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 this Center within the validity, provided, the CPR shall be revoked if interchangeability is not established.
X	**K**	Subject to satisfactory compliance to the post-approval commitments detailed in the letter accompanying this CPR.

REMARKS:

NOTARIZED ANNEX C

Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

NOTIFICATION FORM FOR MINOR VARIATION/S OF REGISTERED PHARMACEUTICAL PRODUCT

Date: January 18, 2022

DOCUMENT TRACKING NUMBER (DTN)	
20220224085653	
TO BE FILLED OUT BY FDA	
Received by:	FDAC
Signature:	FAPD
Date:	09 March 2022
PAYMENT DETAILS	
Amount Paid:	1020
OR No.:	Seq # 68200
OR Date Issued:	03 March 2022

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

Details should be consistent with the current CPR/CLIDP.

Generic Name	**Atorvastatin (as calcium)**
Dosage Strength and Form	**40 mg Film-Coated Tablet**
Brand Name	**Trovipri**
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)**

FDA Registration No. **DRP-10748**
Registration Status **Initial**

Validity **15 November 2026**
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	**Stallion Laboratories Pvt. Ltd.**
	C 1B, 305/2, 3,4, & 5 G.I.D.C. Kerala, Bavla-382 220, Dist: Ahmedabad, Gujarat, India
Trader	**N/A**
Importer	**Ambica International Corporation**
	No.9 Amsterdam Extension, Merville Park Subd., Parañaque City
Distributor	**Ambica International Corporation**
	No. 9 Amsterdam Extension, Merville Park Subd., Parañaque City
Packer/Repacker	**N/A**

DTN	
20220224085653	
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)*
Current Pack Size **Box of 30's**	**Proposed Pack Size** **Box of 30's and Box of 100's**	**MiV-PH-N7** **(Addition of pack size for non-sterile drug product)**
Current Artwork Design	**Proposed Artwork Design**	**MiV-PH-N1** **(Change in Packaging Design)**

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

DTN	
20220224085653	
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	
20220224085653	
Received by:	FDAC

HEAD OF REGULATORY OFFICE		COMPANY PHARMACIST	
Signature:		**Signature:**	
Name:	**Zarah Obanan-Santos**	**Name:**	**Katherine Anne C. Acuin**
Designation:	**Corporate Pharmacist/Regulatory Affairs Head**	**Designation:**	**Company Pharmacist/Senior Regulatory Manager**
Date:	**January 18, 2022**	**Date:**	**January 18, 2022**

JAN 19 2022

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

Name	Residence Certificate	Date Issued	Place Issued
Zarah Obanan-Santos	**PRC License No.: 056694**	**Valid Until: October 20, 2024**	**Manila**
Katherine Anne C. Acuin	**PRC License No.: 60463**	**Valid Until: 16 March 2024**	**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. 266
Page No. 54
Book No. 15
Series of 2022

GEORGE V. DE JOYA
Notary Public
Pasig San Juan Pateros
Until Dec. 31, 2022
Appt No. 23 (2021-2022)
Roll 34154/06-02-86
MCLE Compliance No. VI-0015247/11-28-18
PTR No. 8145602 BCE/01-07-22/Pasig City
IBP Lifetime No. 06817 (Pasig Chapter)
No. 32 G. Raymundo St., Malinao, Pasig Ci