FDA-20194SRH7W32EB99OIYG1H1L

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

CERTIFICATE OF LISTING OF IDENTICAL DRUG PRODUCT

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-3835-06**
Generic Name	:	Hyoscine-N-Butylbromide
Brand Name	:	Ozin
Dosage Strength & Form	:	20 mg/mL Solution for Injection (IM/IV/SC)
Pharmacologic Category	:	Antispasmodic
Classification	:	Prescription Drug (Rx)
Approved Shelf-life	:	36 months
Storage Condition	:	Store at temperatures not exceeding 25°C.
Packaging	:	Type I Clear Colorless Glass Ampoule x 1 mL (Box of 10's)
Manufacturer	:	Huons Co., Ltd. 100 Bio Valley-ro, Jecheon-si Chungcheongbuk-do, Republic of Korea
Importer	:	H & B Pharma International Inc. Unit 603 Tycoon Centre Condominium Pearl Drive, Ortigas Center, San Antonio, District 1, Pasig City
Distributor	:	Starpharm, Inc. No. 28 Liamzon Street, Midtown III Subd., San Roque, Marikina, Metro Manila

The Certificate of Listing issued to the above Distributor shall be valid until **26 July 2025**, which covers the unexpired term of the Principal CPR, subject to the conditions listed on the reverse side. No change in the ownership, registrant's address/location, manufacturer, excipients, formulation, dosage form, strength, therapeutic indication, manufacturing process, labelling and commercial presentation, and packaging of the Principal product covered by the Principal CPR without prior approval of this Office.

This Certificate of Listing 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 **30 July 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 : **Php 8,080.00**
OR NUMBER : **1118091**
DATE : **30 April 2019**
CODE : **433-220**
BAR CODE / DOC TRACK : 2019040816284

FDA-0316848

Registration Number : DRP-3835-06

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: