

BUREAU OF CUSTOMS MAKABAGONG ADUANA, MATATAG NA EKONOMIYA



PROFESSIONALISM

INTEGRITY

ACCOUNTABILITY

AOCG Memo No. 409-2022

DUC-09-35828

MEMORANDUM

MASTER

TO

ALL DISTRICT COLLECTORS
ALL SUB-PORT COLLECTORS
ALL OTHERS CONCERNED

FROM

ATTY. EDWARD JAMES A. DY BUCO

Deputy Commissioner

Assessment and Operations Coordinating Group

SUBJECT

Food and Drug Administration (FDA) Recommendation for

The Release of Donated Pharmaceutical Products from Philippine Business for Social Progress (PBSP) to Department of Health – Disease Prevention and Control

Bureau (DOH-DPCB)

DATE

22 November 2022

Forwarding the herein attached letter dated 11 November 2022 addressed to Anthony B. Cu, MD, MPH-HSD, MPH-EOH, CESE, Director IV, Disease Prevention and Control Bureau, Department of Health (DPCB-DOH) from Jesusa Joyce N. Cirunay, Director IV, Center for Drug Regulation and Research, FDA recommending clearance for the release of donated pharmaceutical products from **PBSP** to the **DOH-DPCB** with the information that the release shall be subject to the following conditions:

- 1. the products shall have a shelf-life of not less than 12 months at the time of arrival;
- 2. the labels (primary, secondary, and product information) shall be in the English language; and
- 3. the clearance is without prejudice to tariff rules and customs regulations.

For information and appropriate action.



Republic of the Philippines Department of Health

FOOD AND DRUG ADMINISTRATION



CLEARANCE LETTER

11 November 2022



ANTHONY B. CU, MD, MPM-HSD, MPH-EOH, CESE

Director IV

BUREAU OF CUSTOMS
PORT OPERATIONS SEPULCE

CV

Disease Prevention Control Bureau

Department of Health, Bldg. 14, 3rd Floor

WInfectious Diseases Prevention and Control Division

\$an Lazaro Compound, Rizal Avenue

Sta. Cruz, Manila, 1003



Subject: Clearance of Foreign Drug Donations

Dear Sir/Madam:

Please be informed that this Office recommends clearance for the release of the following products as donation by Philippine Business for Social Progress – Unit 1 7th Floor, Citynet Central, Sultan Street Highway Hills, Mandaluyong, Philippines, to Department of Health (DOH)- Disease Prevention and Control Bureau (DPCB) located at the abovementioned address:

Pretomanid 200 mg Tablet [Dovprela] Packaging: White HDPE Bottle with Screw Cap x 26's (Box of 1's) Manufactured by: Mylan Laboratories Limited Plot No. H-12 & H-13, MIDC, Waluj, Aurangabad, 431136 Maharashtra State, India Storage conditions: Store at temperatures not exceeding 30°C. Pyrazinamide 500 mg Tablets Packaging: AluPVC Blister Pack x 28's (Box of 672's) Manufactured by: Macleods Pharmaceuticals Limited—304, Atlanta Arcade Marol Church Road Andheri (East) Mumbai — 400 059, India Storage conditions: Store at temperatures not exceeding 25°C. P-Aminosalicylate Sodium 5.52 g Powder for Oral Solution [PAS-Na] Packaging: Laminated Paper/PE/Alu Foil/PE Sachet x 5.52 g Manufactured by: Joint-Stock Company OLAINFARM Romanufactured by: Joint-Stock Company Storage conditions: Store at temperatures not exceeding 25°C. Levofloxacin (as hemihydrate) 500 mg Film Coated Tablet [Amesol] Packaging: Blister Pack x 10's (Box of 100's) Manufactured by: Macleods Pharmaceuticals Limited—304, Atlanta Arcade Marol Church Road Andheri (East) Mumbai — 400 059, India Storage conditions: 100322 31 March 2025 32 Alumpiactured by: Medochemie Ltd. 40122 31 March 2025 31 March 2025 31 March 2025 32 Alumpiactured by: Medochemie Ltd. 40122 31 March 2025 31 March 2025 32 Alumpiactured by: Medochemie Ltd. 40122 31 March 2025 32 Alumpiactured by: Medochemie Ltd. 40122 31 March 2025 31 March 2025 32 Alumpiactured by: Medochemie Ltd. 40122 31 March 2025 31 March 2025 31 March 2025 32 Alumpiactured by: Medochemie Ltd. 40122 31 March 2025 32 Alumpiactured by: Medochemie Ltd. 40122 31 March 2025 40122 40122 40122 40122 40122 40122 40122 40122 40122 40122 40122 40122 401	Product Description (Generic/Dosage Strength and Form/Brand)	Batch/Lot No.	Expiry Date	Total Quantity (Box)
Packaging: White HDPE Bottle with Screw Cap x 26's (Box of 1's) Manufactured by: Mylan Laboratories Limited Plot No. H-12 & H-13, MIDC, Waluj, Aurangabad, 431136 Maharashtra State, India Storage conditions: Store at temperatures not exceeding 30°C. Pyrazinamide 500 mg Tablets Packaging: AluPVC Blister Pack x 28's (Box of 672's) Manufactured by: Macleods Pharmaceuticals Limited—304, Atlanta Arcade Marol Church Road Andheri (East) Mumbai — 400 059, India Storage conditions: Store at temperatures not exceeding 25°C. p-Aminosalicylate Sodium 5.52 g Powder for Oral Solution [PAS-Na] Packaging: Laminated Paper/PE/Alu Foil/PE Sachet x 5.52 g Manufactured by: Joint-Stock Company OLAINFARM Rupnicu 5 Olaine, LV-2114, Latvia Storage conditions: Store at temperatures not exceeding 25°C. Levofloxacin (as hemihydrate) 500 mg Film Coated Tablet [Amesol] Packaging: Blister Pack x 10's (Box of 100's) Manufactured by: Medochemie Ltd. 1-10 Constantinoupoleos Street 3011 Limassol-Cyprus Storage conditions:				
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Store at temperatures not exceeding 25°C. p-Aminosalicylate Sodium 5.52 g Powder for Oral Solution [PAS-Na] Packaging: Laminated Paper/PE/Alu Foil/PE Sachet x 5.52 g Manufactured by: Joint-Stock Company OLAINFARM Rupnicu 5 Olaine, LV-2114, Latvia Rupnicu 5 Olaine, LV-2114, Latvia Store at temperatures not exceeding 25°C. Levofloxacin (as hemihydrate) 500 mg Film Coated Tablet [Amesol] Packaging: Blister Pack x 10's (Box of 100's) Manufactured by: Medochemie Ltd. 1-10 Constantinoupoleos Street 3011 Limassol-Cyprus Storage conditions:	Andheri (East) Mumbai – 400 059, India			94
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Cyprus Storage conditions:		202.00		
Storage conditions:	•	E0D104	20 February 2027	04,000 tablets
				100
	Store at temperatures not exceeding 25°C.	-		

Civic Drive, Filinvest City, Alabang 1781 Muntinlupa, Philippines Trunk Line +63 2 857 1900 Fax +63 2 807 0751

Website: www.fda.gov.ph

Email: info@fda.gov.ph





AOCG Memo No. 409-2022

MASTER COPY

Levofloxacin (as hemihydrate) 500 mg Film Coated Tablet Packaging: Blister Pack x 10's (Box of 100's) Manufactured by: Macleods Pharmaceuticals Ltd. Atlanta Arcade, Church Road, Near Leela Hotel, Andheri—Kurla Road, Andheri (East), Mumbai—400 059, India Storage conditions: Store at temperatures not exceeding 30°C.	BLB72115A	31 October 2025	480,000 tablets
	BLB72116A	31 October 2025	3,200 tablets
Pyridoxine (Vitamin B6) 50 mg Tablet [Teva] Packaging: Blister Pack x 10's (Box of 50's) Manufactured by: Teva Pharmaceuticals Polska Sp.z.o.o.— 53 Emilii Plater Str., 00-113 Warsaw, Poland Storage conditions: Store at temperatures not exceeding 30°C.	16113422	31 March 2025	1,223,400 tablets
Ethambutol 400 mg Tablet Packaging: Blister Pack x 10's (Box of 100's) Manufactured by: Cadila Pharmaceuticals Ltd.— Plot No. 1389, Trasad Road, Dholka-382 225, Dist. Ahmedabad Gujarat State, India Storage conditions: Store at temperatures not exceeding 30°C.	ET075E2002	31 December 2025	90,720 tablets
	ET075E2003	31 December 2025	16,128 tablets
	ET075E2004	31 December 2025	436,128 tablets
	ET075E2005	28 February 2026	973,056 tablets
	ET075E2006	28 February 2026	282,240 tablets
Bedaquiline 100 mg Tablet [Sirturo] Packaging: White HDPE Bottle with Screw Cap x 188's (Box of 1's) Manufactured by: Recipharm Pharmaservices Pvt. Ltd.— Khata No. 845/713 and 1108/970/1, 34th K.M. Tumkur Road, T-Begur, Nelamangala, Bangalore, 562 123, India Storage conditions: Store at temperatures not exceeding 30°C.	TMC21060	30 June 2024	6,204 tablets
	TMC21069	31 July 2024	114,116 tablets
Cycloserine 125 mg Capsule Packaging: Alu/Alu Blister Pack x 10's (Box of 100's) Manufactured by: Macleods Pharmaceuticals Ltd.—Phase II, Unit II, Plot No. 25-27, Survey No. 366, Premier Industrial Estate, Kachigam, Daman, 369 210 India Storage conditions: Store at temperatures not exceeding 30°C.	ECF722001A	31 January 2024	3,500 capsules
Cycloserine 250 mg Capsule Packaging: Alu/Alu Blister Pack x 10's (Box of 100's) Manufactured by: Dong-A ST Co., Ltd. 200-23, Baekseogongdan 1-ro, Seobuk-gu, Cheonan-si, Chungcheongnam-do, Republic of Korea Storage conditions: Store at temperatures not exceeding 30°C.	CSP21125194	13 December 2025	30,000 capsules
Levofloxacin (as Levofloxacin) [None] 100 mg Dispersible Tablet Packaging: Blister pack x 10's (Box of 100's) Manufactured by: Micro Labs Limited Unit-03 92, Sipcot Industrial Complex, Hosur-635 126, India Storage conditions: Store at temperatures not exceeding 30°C.	LFAH013	30 September 2024	2,800 tablets
	LFAH015	31 December 2024	16,200 tablets
	LFAH016	31 January 2025	3,800 tablets

--NOTHING FOLLOWS-----

AOCG Memo No. 409-2022



The release of said donated pharmaceutical products, intended for patients, is on the condition that the said products shall have:

1. a shelf-life of not less than 12 months at the time of arrival; and

2. Labels (primary, secondary, and product information) in English language.

This clearance is without prejudice to tariff rules and customs regulations.

Very truly yours,

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

Amt. Paid: Php 510.00 OR#: Seq#102822513598 Date: 28 October 2022 20221024074433

cc: Maria Soledad Q. Antonio, MD, PhD, MPH, DPAFP, CESE Director IV, Bureau of International Health Cooperation

Yogi Filemon L. Ruiz
Acting Commissioner, Bureau of Customs