

Date: 3rd July, 2024

To,
The Manager,
Department of Corporate Services,
BSE Limited
P. J. Towers, Dalal Street,
Fort, Mumbai – 400 001
BSE Scrip Code: 533573

To,
The Manager,
Listing Department,
National Stock Exchange of India Ltd.
'Exchange Plaza', Bandra Kurla Complex,
Bandra (E), Mumbai – 400 051
NSE Symbol: APL LTD

Dear Sir/Madam,

Sub: Alembic Pharmaceuticals receives US Food & Drug Administration (USFDA) product approvals (Final & Tentative) during the quarter ended 30th June, 2024.

With reference to the captioned subject, we are pleased to inform the exchanges that the Company has received 11 US Food & Drug Administration (USFDA) Product Approvals (Final & Tentative) during the quarter ended 30th June, 2024.

The summary statement giving brief of the product approvals received during the quarter ended 30th June, 2024 is enclosed for your information and records.

Alembic has a cumulative total of 206 ANDA approvals (179 final approvals and 27 tentative approvals) from USFDA.

We request you to kindly take the above on record.

Thanking you,

Yours faithfully,
For Alembic Pharmaceuticals Limited

Manisha Saraf
Company Secretary

Encl: A/a.

ALEMBIC PHARMACEUTICALS LIMITED

REGD. OFFICE: ALEMBIC ROAD, VADODARA - 390 003. • TEL: (0265) 2280550, 2280880 • FAX: (0265) 2281229
Website : www.alembicpharmaceuticals.com • E-mail : alembic@alembic.co.in • CIN : L24230GJ2010PLC061123

Annexure

Summarised Product Approval received during the quarter ended 30th June, 2024.

Product Name	Approval Final/Tentative	Reference Listed Drug or Reference Standard Holder	Brand name	Indication*
Clindamycin Phosphate Topical Gel USP 1%	Final	Pharmacia & Upjohn	Cleocin T	Clindamycin phosphate gel is indicated in the treatment of acne vulgaris.
Diazepam Injection USP, 10mg/2mL (5 mg/mL), Single-Dose Prefilled Syringe	Final	Hoffmann LA Roche Inc.	Valium® (Diazepam) Injection	Diazepam Injection USP Diazepam is indicated for the management of anxiety disorders or for the short-term relief of the symptoms of anxiety.
Selexipag Tablets 1,000mcg and 1,200mcg.	Tentative	Actelion Pharmaceutica ls Inc.	Uptravi	Selexipag tablets are indicated for the treatment of pulmonary arterial hypertension (PAH, WHO Group I) to delay disease progression and reduce the risk of hospitalization for PAH.
Binimetinib Tablets 15mg	Tentative	Array Biopharm	Mektovi	Binimetinib tablet is a kinase inhibitor indicated, in combination with encorafenib, for the treatment of patients with unresectable or metastatic melanoma with a BRAF V600E or V600K mutation.
Tretinoin Cream USP, 0.1%,	Final	Bausch Health US, LLC., USA	Retin-A	Tretinoin Cream is indicated for topical application in the treatment of acne vulgaris.
Sacubitril and Valsartan Tablets, 24mg/26mg, 49mg/51mg, and 97mg/103 mg.	Final	Novartis Pharmaceutica ls Corporation	Entresto	Sacubitril and Valsartan Tablets are indicated to reduce the risk of cardiovascular death and hospitalization for heart failure in adult patients with chronic heart failure. It is also indicated for the treatment of symptomatic heart failure with systemic left ventricular systolic

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Product Name	Approval Final/Tentative	Reference Listed Drug or Reference Standard Holder	Brand name	Indication*
				dysfunction in paediatric patients aged one year and older.
Methotrexate Tablets USP, 2.5mg	Final	Strides Pharma Global Pte. Limited	Rheumatrex	Methotrexate Tablets are indicated for the treatment of neoplastic diseases, rheumatoid arthritis, polyarticular juvenile idiopathic arthritis and psoriasis.
Venlafaxine Hydrochloride Extended-Release Capsules USP, 37.5mg, 75mg, and 150mg.	Final	Upjohn US 2 LLC	Effexor XR	Venlafaxine Hydrochloride Extended-Release Capsules are indicated for the treatment of major depressive disorder, generalized anxiety disorder, social anxiety disorder and panic disorder.
Icatibant Injection, 30mg/3 mL (10 mg/mL)	Final	Takeda Pharmaceutica ls U.S.A	Firazyr	Icatibant injection is indicated for the treatment of acute attacks of hereditary angioedema (HAE) in adults 18 years of age and older.
Dabigatran EteXilate Capsules, 75mg and 150mg	Final	Boehringer Ingelheim Pharmaceutica ls, Inc.	Pradaxa	Dabigatran EteXilate Capsules are indicated for reduction of risk of stroke and systemic embolism in non-valvular atrial fibrillation in adult patients; treatment and reduction in the risk of recurrence of deep venous thrombosis and pulmonary embolism in adult patients.
Dabigatran EteXilate Capsules, 110mg	Tentative	Boehringer Ingelheim Pharmaceutica ls, Inc.	Pradaxa	Dabigatran EteXilate Capsules are indicated for reduction of risk of stroke and systemic embolism in non-valvular atrial fibrillation in adult patients; treatment and reduction in the risk of recurrence of deep venous

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Product Name	Approval Final/Tentative	Reference Listed Drug or Reference Standard Holder	Brand name	Indication*
				thrombosis and pulmonary embolism in adult patients.
Doxycycline Capsules, 40mg.	Final	Galderma Laboratories, L.P.	Oracea	Doxycycline capsules are indicated for the treatment of only inflammatory lesions (papules and pustules) of rosacea in adult patients.
Bosutinib Tablets, 100mg and 500mg	Tentative	PF Prism C.V.	Bosulif	Bosutinib tablets are indicated for the treatment of adult patients with a certain type of leukemia called Philadelphia chromosome-positive chronic myelogenous leukemia.

*Please refer label for full indication

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