



Date: 2nd October, 2023

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: APLLTD

Dear Sir/Madam,

Sub: Alembic Pharmaceuticals receives various US Food & Drug Administration (USFDA) product approvals during the quarter ended 30th September, 2023.

With reference the captioned subject, this is to inform the exchange that the Company has received various US Food & Drug Administration (USFDA) Product Approvals during the quarter ended 30th September, 2023.

The summary statement giving brief of all product approvals received during the quarter ended 30th September, 2023 is enclosed for your information and records.

Alembic has a cumulative total of 190 ANDA approvals (165 final approvals and 25 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 September, 2023.

| Product Name | Approval Final/Tentative | Innovator Name | Brand name | Indication* |
|--|---------------------------------|-------------------------------------|--|--|
| Chlorpromazine Hydrochloride Tablets USP, 10 mg, 25 mg, 50 mg, 100 mg, and 200 mg. | Final | Upsher-Smith Laboratories, LLC. | Chlorpromazine Hydrochloride Tablets USP | For the management of manifestations of psychotic disorders and treatment of schizophrenia. And other indications. |
| Brimonidine Tartrate Ophthalmic Solution, 0.1%. | Final | AbbVie, Inc. | Alphagan P Ophthalmic Solution | Brimonidine tartrate ophthalmic solution, 0.1% is an alpha adrenergic receptor agonist indicated for the reduction of elevated intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. |
| Guanfacine Extended-Release Tablets USP, 1 mg, 2 mg, 3 mg, and 4 mg. | Final | Takeda Pharmaceuticals U.S.A., Inc. | Intuniv Extended-Release Tablets | Guanfacine extended-release tablets are indicated for the treatment of Attention Deficit Hyperactivity Disorder (ADHD) as monotherapy and as adjunctive therapy to stimulant medications |
| Erythromycin Tablets USP, 250 mg and 500 mg. | Final | Azurity Pharmaceuticals, Inc. | Erythromycin Tablets USP | Erythromycin tablets are indicated in the treatment of infections caused by susceptible strains of the designated microorganisms. |

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| Product Name | Approval Final/Tentative | Innovator Name | Brand name | Indication* |
|---|--------------------------|------------------------|------------------------------|--|
| Brimonidine Tartrate and Timolol Maleate Ophthalmic Solution, 0.2%/0.5%. | Final | AbbVie, Inc. | Combigan Ophthalmic Solution | Brimonidine tartrate and timolol maleate ophthalmic solution 0.2% /0.5% is an alpha-adrenergic receptor agonist with a beta-adrenergic receptor inhibitor indicated for the reduction of elevated intraocular pressure (IOP) in patients with glaucoma or ocular hypertension who require adjunctive or replacement therapy due to inadequately controlled IOP. |
| Chlordiazepoxide Hydrochloride and Clidinium Bromide Capsules USP, 5 mg/2.5 mg. | Final | Bausch Health US, LLC. | Librax Capsules | Chlordiazepoxide hydrochloride and clidinium bromide capsules are indicated to control emotional and somatic factors in gastrointestinal disorders. Chlordiazepoxide hydrochloride and clidinium bromide capsules may also be used as adjunctive therapy in the treatment of peptic ulcer and in treatment of the irritable bowel syndrome (irritable colon, spastic colon, mucous colitis) and acute enterocolitis. |

*Refer label for full indication.

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