

Date: 11<sup>th</sup> May, 2022

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

Dear Sir/Madam,

**Sub: Alembic Pharmaceuticals receives USFDA Final Approval for Arformoterol Tartrate Inhalation Solution, 15 mcg (base)/2 mL Unit-dose Vial.**

With reference to the captioned subject, this is to inform the exchange that the Company has received US Food & Drug Administration (USFDA) Final Approval for Arformoterol Tartrate Inhalation Solution, 15 mcg (base)/2 mL Unit-dose Vial.

Please find enclosed herewith our press release.

We request you to kindly take the same on record.

Thanking you,

Yours faithfully,  
For Alembic Pharmaceuticals Limited



**Charandeep Singh Saluja**  
Company Secretary

Encl.: A/a.

**ALEMBIC PHARMACEUTICALS LIMITED**

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CIN : L24230GJ2010PLC061123



## PRESS RELEASE

11<sup>th</sup> May, 2022, Vadodara, India

### **Alembic Pharmaceuticals announces USFDA Final Approval for Arformoterol Tartrate Inhalation Solution, 15 mcg (base)/2 mL Unit-dose Vial.**

Alembic Pharmaceuticals Limited (Alembic) today announced that it has received final approval from the US Food & Drug Administration (USFDA) for its Abbreviated New Drug Application (ANDA) for Arformoterol Tartrate Inhalation Solution, 15 mcg (base)/2 mL Unit-dose Vial. The approved ANDA is therapeutically equivalent to the reference listed drug product (RLD), Brovana Inhalation Solution, 15 mcg/2 mL, of Sunovion Pharmaceuticals Inc. Arformoterol Tartrate Inhalation Solution is a long-acting beta2-adrenergic agonist (beta2-agonist) indicated for long-term, twice daily (morning and evening) administration in the maintenance treatment of bronchoconstriction in patients with chronic obstructive pulmonary disease (COPD), including chronic bronchitis and emphysema.

This ANDA has been co-developed in partnership with Orbicular Pharmaceutical Technologies Private Limited.

Arformoterol Tartrate Inhalation Solution, 15 mcg (base)/2 mL Unit-dose Vial, has an estimated market size of US\$ 251 million for twelve months ending Dec 2021 according to IQVIA.

Alembic has a cumulative total of 167 ANDA approvals (143 final approvals and 24 tentative approvals) from USFDA, including this second inhalational ANDA approval.

### **About Alembic Pharmaceuticals Limited**

Alembic Pharmaceuticals Limited, a vertically integrated research and development pharmaceutical company, has been at the forefront of healthcare since 1907. Headquartered in India, Alembic is a publicly listed company that manufactures and markets generic pharmaceutical products all over the world. Alembic's state of the art research and manufacturing facilities are approved by regulatory authorities of many developed countries including the USFDA. Alembic is one of the leaders in branded generics in India. Alembic's brands, marketed through a marketing team of over 5000 are well recognized by doctors and patients.

Information about Alembic can be found at <https://www.alembicpharmaceuticals.com/>; (Reuters: ALEM.NS) (Bloomberg: ALPM) (NSE: APLLTD) (BSE: 533573)

For more information contact:

Ajay Kumar Desai

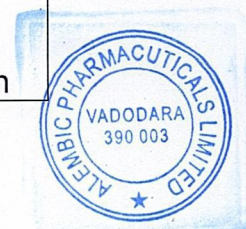
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