



Innovating for  
affordable healthcare

# Shilpa Medicare Limited

**Manufacturers and Exporters of Bulk Drugs**

# 12-6-214/A1, Hyderabad Road,  
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CIN No. L85110KA1987PLC008739

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Dated: 31 Jan, 2020

Corporate Relationship Department,  
BSE Limited  
Phiroze Jeejeebhoy Towers,  
Dalal Street, Fort,  
**Mumbai-400 001**

National Stock Exchange of India  
Limited  
Exchange Plaza, 5<sup>th</sup> Floor,  
Plot No.C/1, G Block  
Bandra Kurla Complex, Bandra (E)  
**MUMBAI-400 051**

Dear Sir/Madam,

**Sub: Intimation U/R 30 of the SEBI(LODR) Regulations- Reg.**

**Ref: Stock Code: NSE: SHILPAMED/BSE-530549**

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This is to inform you that the Company has received U.S Food and Drug Administration tentative approval for its ANDA, Pirfenidone Tablets, 267 mg and 801 mg on 30 Jan 2020. The ANDA is filed as 'First to File' submission on NCE -1 date.

Pirfenidone Tablets, 267 mg and 801 mg is a generic equivalent of reference listed drug (RLD) Esbriet Tablets, 267 mg and 801 mg, of Hoffmann La Roche Inc. used in the treatment of idiopathic pulmonary fibrosis as recommended in the label approved by FDA.

According to IQVIA MAT Q2 2019 data, the overall US market for Pirfenidone, 267 mg and 801 mg, strengths is approximately US\$ 716.3 Million.

This is for your information and doing the needful.

With Regards,

For **SHILPA MEDICARE LIMITED**

  


**V V KRISHNA CHAITANYA**  
**COMPANY SECRETARY**