



Shilpa Medicare Limited

Corporate & Admin Office:

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Email: info@vbsilpa.com, Web: www.vbsilpa.com
CIN: L85110KA1987PLC008739

Dated: 1 Sept, 2023

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

National Stock Exchange of India Limited
Exchange Plaza, 5th 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

UK-MHRA Approval for Betahistine Dihydrochloride Orodispersible Films, 24 mg

This is to inform you that Shilpa Medicare Limited, headquartered at Raichur, Karnataka, India, has received Marketing Authorization from MHRA, UK, for Betahistine Dihydrochloride Orodispersible Films, 24 mg.

Shilpa is the first company to receive approval for the 24 mg strength as a Film formulation in UK. Shilpa's approval is a hybrid product application, which is bioequivalent to the reference product.

Betahistine is indicated for the treatment of vertigo, tinnitus, hearing loss and nausea associated with Meniere's syndrome and is available as tablets and oral liquid dosage forms in various strengths across UK, Europe. The Orally dispersible/dissolvable film formulation offers benefits with respect to patient compliance and ease of administration.

This approval has come from the Company's finished dosage form manufacturing facility, Shilpa Medicare Ltd, Unit VI, located at Dabaspeta, Bengaluru, Karnataka. The facility is approved by MHRA UK and this is the first approval for a prescription Oral Film product in regulated market from this facility. The facility is involved in manufacturing, packaging, labelling and testing of finished dosage forms (oral dispersible/dissolving Films and Transdermal Patches).

With Regards,

For **SHILPA MEDICARE LIMITED**

Ritu Tiwary
Company Secretary & Compliance Officer