U.T. ADMINISTRATION OF DNH, DAMAN & DIU
DRUGS LICENSING AUTHORITY
DRUGS CONTROL DEPARTMENT
PRIMARY HEALTH CENTRE
MOTI DAMAN-396220

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No. DCD/D&D/LA/2021-2022/ 5641 Dated: 4 /05/2021

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LICENCE VALIDITY CERTIFICATE
(See rule 72 and 84 C)

Ref: No. MPLD/FDA/GU7/15/2021 dated 07/04/2021.

1) A Licence No. DD/654 & DD/655 granted on 25/04/2011 to **M/S. MACLEODS PHARMACEUTICALS LIMITED. (UNIT-VII),** situated at Survey No. 363/1 (8-9), Plot No. 8 & 9, Ganesh Industrial Estate, Kachigam, Daman -396 210, INDIA, in Form 25 and Form 28 shall remain perpetually valid upto **24/04/2026** as the licencee has deposited a licence retention fee vide Challan No. 4 dated 07/04/2021 as per the Drugs & Cosmetics Rules, 1945.
2) Names of drugs: As per list attached.
3) Names of approved competent technical staff: As per list attached.
4) Firm shall comply to the Drugs & Cosmetics Act, 1940 & Rules 1945 thereunder.

Dated:

LICENSING AUTHORITY
लाइसन्सिंग प्राधिकारी
सत्यमेव जयते
दमण/Daman
U.T. OF DAMAN & DIU

(Dr. V. K. DAS)
Director,
Medical & Health Services,
Drugs Licensing Authority
UT of DNH, Daman & Diu
Daman.

Note:

1) In Form 25 for paragraph 3, the following paragraph shall respectively be substituted, 3. "The Licence unless sooner suspended or cancelled shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs & Cosmetics Act, 1940 (23 of 1940) and Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach".

2) In Form 28 for paragraph 4, the following paragraph shall respectively be substituted, "The licence, unless sooner suspended or cancelled, shall remain valid perpetually. However, the compliance with the conditions of licence and the provisions of the Drugs & Cosmetics Act, 1940n (23 of 1940) and the Drugs and Cosmetics Rules, 1945 shall be assessed not less than once in three years or as needed as per risk based approach".

MACLEODS

This list of products to be manufactured by M/**s. Macleods Pharmaceuticals Ltd.**, situated at Survey No. 363/1 (8 - 9), Plot No. 8 - 9, Ganesh Industrial Estate, Kachigam, Daman - 396210 under License No.**DD/655** granted on **25/04/2011** valid up to **24/04/2026**.

LIST OF PRODUCTS UNDER SCHEDULE C & C1 (for Export)

Sr. No.	Product Nomenclature	Composition
1	**Budetrol 200** (Formoterol Fumarate and Budesonide Powder for Inhalation)	Each hard gelatin capsule contains: Formoterol Fumarate Dihydrate BP/Ph. Eur equivalent to Formoterol Fumarate... 6 mcg Budesonide BP/Ph. Eur ..... 200 mcg
2	**Budetrol 400** (Formoterol Fumarate and Budesonide Powder for Inhalation)	Each hard gelatin capsule contains: Formoterol Fumarate Dihydrate BP/Ph. Eur equivalent to Formoterol Fumarate..... 6 mcg Budesonide BP/Ph. Eur ..... 400 mcg
3	**Macgris 250** (Griseofulvin Tablets BP 250 mg)	Each uncoated tablet contains: Griseofulvin BP ..... 250 mg
4	Pyridoxine Tablets BP 25 mg	Each uncoated tablet contains: Pyridoxine Hydrochloride BP ..... 25 mg

UNDERTAKING

1) The above are the only Drugs approved for manufacture at present and we present undertake that any addition thereto or any deletion there from will not be carried out with out any prior permission of the Licensing Authority.
2) We undertake to comply with all the provisions of the law in force and the direction issue from the time to time by Licensing Authority and not to manufacture any drug same belonging to another manufacturer.
3) We undertake not to manufacture or sale or distribute any drug even if it approved list of products but by or any competent Authority if it is or as and when it will be banned by the Drugs Controller (India) or Govt. of India.
4) The brand names, artwork and designs of the products submitted for approval in this application are not copied from others. It is further declared that these or similar brand names, artworks and designs are not used by any other manufacturer to the best of our belief. If the brand names, artworks or designs of our products are found to be imitation of or resemble in a manner likely to deceive, another drugs manufactured by another company prior to ours, we undertakes to stop to sell, or distribute of our products and we understand that we shall be liable for legal action in such eventuality.
5) We herewith undertake that the thermo labile products, which will be manufactured by us, will be subjected to the stability for the period of at least one year with periodic testing at least for three batches of every product and the reports thereof will be submitted to the Licensing Authority.
6) The vehicle, excipients, additives and pharmaceutical aids used in the formulation and under the conditions in which are formulations for administration and use are recommended are safe.

For, Macleods Pharmaceuticals Ltd.

(Authorised Signatory)
(Kailash Modi)

DRUGS LICENSING AUTHORITY
औषधी लाईसेंस प्राधिकारी
DRUGS CONTROL DEPARTMENT
औषधी नियंत्रण विभाग
UT OF DAMAN & DIU, DAMAN
संघ प्रदेश दमण एवं दीव, दमण

MACLEODS PHARMACEUTICALS LIMITED

Regd. Office :
Atlanta Arcade, Church Road,
Near Leela Hotel, Andheri-Kurla Road,
Andheri (East), Mumbai-400 059, India.

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Fax : 91 - 22 - 2925 6599
Email : customercare@macleodspharma.com
Website : www.macleodspharma.com
CIN : U24239MH1989PLC052049

Works :
Survey No. 363/1 (8-9),
Ganesh Industrial Estate,
Kachigam, (Unit - VII),
Daman, PIN - 396 210