



No. F. 3-1/2023-I&V-II/Human Import (M-324)
Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
Drug Regulatory Authority of Pakistan

FORM-6

Islamabad, the th30 August, 2023.

M/s Highsea Pharmaceuticals,
2nd Floor, 39 Commercial Cavalry Ground,
Lahore.
Godown: 189-G4 (Lower Portion) Johar Town, Lahore.

SUBJECT: - REGISTRATION OF DRUGS UNDER SECTION 7 OF THE DRUGS ACT, 1976 AND RULES 27, 28, 29 AND 30 OF THE DRUGS (LICENSING, REGISTERING AND ADVERTISING) RULES, 1976.

The drug(s) as per details given below has/have been registered in your name subject to the conditions appearing hereinafter:-

Reg. No.	Name of Drug(s) & Composition	Packing	Maximum Retail Price	Approved Shelf Life
114286	Alslar Inhalation Solution Each 100ml contains: Isoflurane.....100% v/v (USP Specifications)	1's (100ml)	Rs.2,110/- ✓	24 Months ✓

Product License Holder & Manufacturer:- M/s Fujian Highsea United Pharmaceutical Co., Ltd, No. 15, Zone D, Mingxi Economic Development Zone, Mingxi Country, Fujian Province, 365200 China.

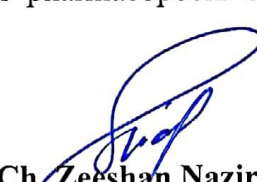
CONDITIONS:-

- The drug(s) shall be imported in compliance to the provision of Drugs Act, 1976 and rules framed thereunder.
- Every drug shall be imported in sufficient quantity so as to ensure its regular and adequate supply in the market.
- The import of any drug shall not, without the prior approval of the Registration Board, be discontinued for a period, which may result in its shortage.
- Colour scheme of the labels/cartons and packaging material should not resemble with any of the drug(s) which has or have already been registered.
- One copy of the complete method of testing of the finished drug(s) (containing full details of all minor and major steps and protocols along with specifications, (lower and upper limits) shall be submitted to the following institutions within a period of one month: -
 - Chief, Drugs Control & Research Division, National Institute of Health, Islamabad.
 - Director, Central Drug Laboratory, Building NO.4 (WFP) SMCHS, Block -B, Karachi
 - Director, Drugs Testing Laboratory, Lahore, Faisalabad, Bahawalpur, Multan & Rawalpindi.

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- Director, Drugs Testing Laboratory, Mirpur Azad Jammu Kashmir.
 - Director, Drugs Testing Laboratory, Gilgit Baltistan.
 - Director, Drugs Testing Laboratory, Sindh, Karachi.
 - Director, Drugs Testing Laboratory, Khyber Pakhtunkhwa, Peshawar.
 - Director, Drugs Testing Laboratory, Balochistan, Brewery Road, Quetta.
- (vi) One copy of the master formula (of all registered drug), containing the names of active and inactive material(s)/excipients alongwith the quantities shall be furnished to the Assistant Director (I&E) concerned within a period of one month for which a receipt shall also be obtained.
- (vii) The import will be made at competitive rates in accordance with the Import Trade Control Order.
- (viii) The name shall be changed in case it has resemblance with already registered drugs.
- (ix) The registered drugs shall conform to the specifications of pharmacopoeial reference as provided in the Rules. In case, if the drug is not yet included in any of the pharmacopoeia, it shall conform to the *innovator's company specifications as approved by the regulatory authority of any reference countries specified by the Registration Board subject to compliance of Drug (Specifications) Rules, 1978. The innovator's specifications, however, are valid only till inclusion of the product in the official pharmacopoeia of reference countries as specified by the Registration Board.
- (x) WHO Specifications shall be followed for Drug products, where such products are not included in the official pharmacopoeia of reference countries as specified by the Registration Board.


(Muhammad Sarfraz Nawaz)
Assistant Director (I&V-II)


(Ch. Zeeshan Nazir Bajar)
Additional Director (PE&R)/
Secretary, Registration Board


(Dr. Muhammad Fakhruddin Aamir)
Director (PE&R)/
Chairman, Registration Board