No.F.8-1/2019-Reg-III (M-286)
Government of Pakistan
Ministry of National Health Services, Regulation & Coordination
Drugs Regulatory Authority of Pakistan
****

"Say No to Corruption"

Islamabad, the 17th January, 2019

M/s Bio-Lab, Pvt. Ltd.
Plot No. 145, Industrial Triangle,
Kahuta Road, Islamabad.

SUBJECT: - **REGISTRATION OF DRUGS UNDER SECTION 7 OF THE DRUGS ACT, 1976 AND RULES 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 subject to the conditions appearing hereinafter.

S. No.	Reg. No.	Name of Drug(s) & Composition	Packing	MRP	Approved Shelf Life
1.	094344	Bio-Tasvir Tablets 30mg Each film coated tablet contains: Daclatasvir (as dihydrochloride) .....30mg (As per *innovator's specifications)	28's	Rs.2782/-	Two years
2.	094345	Bio-Tasvir Tablets 60mg Each film coated tablet contains: Daclatasvir (as dihydrochloride) .....60mg (As per *innovator's specifications)	28's	Rs.4552/-	Two years
3.	094346	Lesof 400mg tablet Each film coated tablet contains: Sofosbuvir.....400mg (As per *innovator's specifications)	28's	Rs.5868/-	Two years
4.	094347	Lesof Plus tablet 400mg/90mg Each film coated tablet contains: Sofosbuvir.....400mg Ledipasvir.....90mg (As per *innovator's specifications)	28's	Rs.29,400/-	Two years
For above products, the firm shall mention USFDA approved black box warning on the label.					

CONDITIONS:-

i. Manufacturer will place first three production batches on long term stability studies throughout proposed shelf life and on accelaerated studies for six monthes.

ii. The manufacturer shall perform Pharmaceutical product development and stability studies, validation of manufacturing process and method of analysis before sale of the drug.

iii. The drug(s) shall be manufactured in compliance to the provision of Drugs Act, 1976 and Rules framed there under.

iv. Every drug shall be produced in sufficient quantity so as to ensure its regular and adequate supply in the market.

v. The manufacturing of any drug shall not, without the prior approval of the Registration Board, be discontinued for a period which may result in its shortage.

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vi. The manufacturer shall follow information in label/patient information leaflet and medical literature regarding clinical use, route of administration, dosage, storage conditions of finished products and type of container closure system/packaging material in line with the innovator brand or reference regulatory authorities or as approved by Registration Board.

vii. The manufacturer shall not use any of banned excipient moreover all excipients will be of pharmaceutical grade and within safe limits as defined by reference regulatory authorities.

viii. Colour Scheme of the labels / cartons & packaging material should not resemble with any of the Drug (s) which has / have already been registered.

ix. One of the complete method of testing of the finished drug(s) (containing full details of 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 & Traditional Medicine Division, N.I.H, Islamabad.
- Director, Central Drug Laboratory, 4-B, SMCHS, Karachi.
- Director, Drugs Testing Laboratory, 1-Birdwood Road, Lahore.
- Director, Drugs Testing Laboratory, Karachi. Sindh
- Director, Drugs Testing Laboratory, Peshawar K.P.K
- Director, Drugs Testing Laboratory, Quetta Balochistan

x. One copy of the master formula (of all registered drugs) containing the names of active and inactive materials (s) along with the quantities shall be furnished to the Assistant Director concerned within a period of one month for which a receipt shall also be obtained.

xi. The import of raw materials will be made at competitive rates in accordance with the Import Trade Control Order.

xii. The name shall be changed in case it has resemblance with already registered drugs.

xiii. The registered drugs shall conform to the specifications of official pharmacopoeial reference as provided in the Rules. In case, if the drugs is not yet included in any of the pharmacopeia, 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 the compliance of Drug (Specifications) Rules, 1978. The innovator's specifications, however, are valid only till inclusion of the product in the official pharmacopeia of reference as specified by the Registration Board.

xiv. WHO specification shall be followed for biological products, vaccines or other drugs where such products are not included in the official pharmacopeia of reference countries as specified by the Registration Board.

xv. Other conditions as contained under the Drugs Act, 1976 and Rules framed there under including stability studies shall be strictly adhered to.

(Urooj Fatima)
Assistant Director
(Reg-III)

(Abdullah)
Additional Director (PE & R)/
Secretary Registration Board

(Dr. Obaidullah)
Director (PE & R)/
Chairman Registration Board

Copy for information to:-

1. Provincial Health Secretaries of K.P.K., Punjab, Sindh, Balochistan, Gilgit Baltistan, Azad Jamu Kashmir & Chief Commissioner, Islamabad.
2. Addl. Director (PE & R), DRAP, Islamabad, Peshawar, Lahore Karachi & Balochistan.
3. Deputy Director (Pricing), DRAP, Islamabad.
4. Deputy Director (IRR), DRAP, Islamabad.