No. F. 3-10/2017 Reg-II (M-273)
Government of Pakistan
Ministry of National Health Services, Regulation & Coordination
Drugs Regulatory Authority of Pakistan
****

Islamabad, the 28th February, 2018

"SAY NO TO CORRUPTION"

M/s Getz Pharma (Pvt) Limited,
29-30/27, Korangi Industrial Area,
Karachi.

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	[redacted]	Approved Shelf Life
1	086970	Velpaget 400mg/100mg Tablet Each film coated tablet contains: Sofosbuvir .....400 mg Velpatasvir .....100 mg (As per *Innovator's Specification)	28's	[redacted]	Two Years

CONDITIONS:-

(i) The Manufacturer shall place first three production batches on real time stability studies throughout the proposed shelf life and on accelerated stability studies for six monthes.

(ii) The manufacturer will perform pharmaceutical product development and stability studies, validation of manufacturing process and method of analysis before sale of drug.

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

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

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

(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 or have already been registered.

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(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 & Research Division, National Institute of Health, Islamabad.
- Director, Central Drug Laboratory, Building No.4 (WFP), SMCHS, Block-D, Karachi-74400.
- Director, Drugs Testing Laboratory, 1-Birdwood Road, Lahore.
- Director, Drugs Testing Laboratory, Sindh, Karachi.
- Director, Drugs Testing Laboratory, K.P.K, Peshawar.
- Director, Drugs Testing Laboratory, Balochistan, Brewery Road, Quetta.

(x) One copy of the master formula (of all registered drug) containing the names of active and inactive materials (s) along with the quantities shall be furnished to the Assistant Drugs Controller 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 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.

(xiv) WHO specification shall be followed for biological products, vaccines or other drugs where such products are not included in 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 adhere to.

Abdul Mughees Muddassir Assistant Director (Reg-II)	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 & Chief Commissioner, Islamabad.
2. Additional Director (PE&R), DRAP, Islamabad.
3. Additional Director (E&M), DRAP, Karachi.
4. D.D (Pricing), DRAP, Islamabad.
5. D.D (RRR), DRAP, Islamabad.
6. Master file.