No.F.1-3/2019.PR-PE&R-DRAP(M.24-PRVC)
Government of Pakistan
Drugs Regulatory Authority of Pakistan
Ministry of National Health Services Regulation and Coordination
TF Complex, Sector G-9/4, Islamabad
****

"SAY NO TO CORRUPTION"

Islamabad, the 26th February, 2019.

M/s Davis Pharmaceuticals Laboratories,
Plot #. 121,Industrial Triangle area,
Islamabad.

Digitally signed by Chitic Vlad
Date: 2022.06.02 20:58:26 EEST
Reason: MoldSign Signature
Location: Moldova

Subject:- **REGISTRATION OF DRUGS UNDER SECTION 7 OF THE DRUGS ACT, 1976 AND RULES 30 OF THE DRUGS (LICENSING, REGISTERING AND ADVERTISING) RULES, 1976 (EXCLUSIVELY FOR EXPORT PURPOSE).**

The drug(s) as per details given below has/have been registered subject to the conditions appearing hereinafter.

Sr.	Reg. No.	Name of Drug(s) & Composition	Pack size & Specifications
1.	007761-Ex	**Tenomid Tablet** Each film coated tablet contains: Tenofovir alafenamide fumarate equivalent to tenofovir alafenamide……..…..25mg	As per requirement of importing country.
2.	007762-Ex	**Bayzobram 5mg tablet** Each film coated tablet contains: Escitalopram oxalate equivalent to escitalopram……..…..5mg	As per requirement of importing country
3.	007763-Ex	**Dasobuvir Tablet** Each film coated tablet contains: Sofosbuvir……..…..400mg	As per requirement of importing country
4.	007764-Ex	**Virenta Tablet** Each film coated tablet contains: Entecavir……..……..1mg	As per requirement of importing country
5.	007765-Ex	**Tenovir B Tablet** Each film coated tablet contains: Tenofovir disoproxil Fumarate…....300mg	As per requirement of importing country
6.	007766-Ex	**Sofovel-C Tablet** Each film coated Tablet contains: Sofosbuvir……..…..400mg Velpatasvir……100mg	As per requirement of importing country
7.	007767-Ex	**Apobram 10mg Tablet** Each film coated tablet contains: Escitalopram oxalate equivalent to escitalopram……..……10mg	As per requirement of importing country
8.	007768-Ex	**Virenta Tablet** Each film coated tablet contains; Entecavir……0.5mg	As per requirement of importing country

(Contd... P/2)

9.	007769-Ex	**Daclovir Tablet** Each film coated Tablet contains: Declatasvir Dihydrochloride equivalent to declatasvir.....60mg	As per requirement of importing country

CONDITIONS:-

i. **Manufacturer will export the product after complying with all the requirements as required under Drug Act, 1976 and relevant rules including No Objection Certificate from concerned DRAP office.**

ii. **Manufacturer will also furnish export documents endorsed from custom authorities (if required for any query) in order to ensure the export of the product.**

iii. Manufacturer will perform pharmaceutical development, stability studies, validation of manufacturing process and method of analysis as per undertaking submitted in registration dossier.

iv. The Registration Number, Maximum Retail Price and other particulars shall be provided as per Drugs (Labeling & Packing) Rules, 1986.

v. One of the complete method of testing of the finished drug (s) (containing full details of all minor and major steps and protocols along with specification) (lower and upper limits) shall be submitted to the following institutions within a period of one month:-

- Chief Drugs Control & Traditional Medicine Division, National Institute of Health, Islamabad.
- Director, Central Drug Laboratory, 4th B SMCH Sharah-e-Faisal,
- 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, Quetta.

vi. One copy of the master formula (of all registered drugs) containing the names of active and inactive material (s) alongwith 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.

vii. The import of raw materials 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 above mentioned drugs are registered under the permission that these drugs shall not be sold in the local market and incase of any violation this permission/registration would render invalid.

x. **These drugs are registered exclusively for export purpose only & this approval shall not be meant for marketing above product in local market.**

(Hafiz Muhammad Jawad Ali)
Assistant Director (PE&R)
Export Facilitation Desk

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

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

Copy forwarded to:-

1. Provincial Health Secretary of K.P.K, Punjab, Sindh, Balochistan, GilgitBaltistan, Azad Jamu Kashmir & Chief Commissioner, Islamabad.
2. Additional Director (PE &R), DRAP, Islamabad.
3. Additional Director DRAP, Islamabad.
4. Deputy Director (RRR), DRAP, Islamabad.
5. Area FID, DRAP Islamabad.
6. Concerned Registration Section.
7. Master File.

No.F.41-PRVC/2020 (PR-I)
Government of Pakistan
(Drug Regulatory Authority of Pakistan)
Ministry of National Health Services, Regulation and Coordination
(PE & R Division)
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"SAY NO TO CORRUPTION"

Islamabad, the 20th May, 2020

M/s Davis Pharmaceuticals Laboratories,
Plot No.121, Industrial Triangle, Kahuta Road,
Islamabad

Subject: **APPROVAL FOR CHANGE OF BRAND NAME OF REGISTERED DRUG(S) FOR EXPORT PURPOSE ONLY.**

Please refer to your application on the subject cited above. Chairman, Registration Board, in 41st meeting of PRVC, has approved your request for the change of brand name of your following registered drug exclusively for export purpose only, on the same terms and conditions as already approved.

Sr. No.	Reg. No.	Previous Brand Name(s) with Composition	Approved Brand Name(s)
1.	007768-EX	Virenta Tablets Eah film coated tablet contains: Entecavir.....0.5mg	Hepentar Tablets

2. This approval is post registration variation and shall not be considered as renewal of registered drug.

20/05/2020

(SANA KANWAL)
Assistant Director (PR-I)

Copy to:-

1. Additional Director (PE&R), DRAP, Islamabad.
2. Additional Director (E&M), DRAP, Islamabad.
3. Deputy Director (RRR), DRAP, Islamabad.
4. Area FID, DRAP, Islamabad.
5. Master File.