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**GOVERNMENT OF PAKISTAN**
**Ministry of National Health Services, Regulations and Coordination**
**(Drug Regulatory Authority of Pakistan)**
*****

Islamabad, the 13th July, 2021.

## NOTIFICATION

**No. F.7-11/2012-B&A/DRAP.--** In exercise of the powers conferred by sub-section (1) of section 20 of the Drug Regulatory Authority of Pakistan Act, 2012 (XXI of 2012) read with clause (n) and clause (x) of section 7 and clause (d) of section 11 thereof, the Drug Regulatory Authority of Pakistan, with the approval of the Policy Board, is pleased to direct that the fee specified in column (4) of the Table below shall be levied in respect of functions specified in column (2) and (3) thereof, namely:-

TABLE

| Sr. | Regulatory functions | Sub-functions | Fee (Rs.) |
|---|---|---|---|
| (1) | (2) | (3) | (4) |
| 1. | Pre-registration variation | Variance to registration application i.e. changes in inactive raw materials, method of manufacture, testing methods or quality specifications, product specification, packing materials including change of labeling specification, etc. except those specified in the following entry (No. 2). | 7,500 / (in case of more than one variation, one fee will be charged) |
| 2. | | • Correction/ standardization of composition as per reference regulatory authority / innovator's product.<br>• Change of source.<br>• Change of manufacturer. | Full fee of registration |
| 3. | Grant / extension of contract manufacturing permission for export purpose | --- | 30,000/- per product |

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