

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

Islamabad, the 13th July, 2021.

NOTIFICATION

No. F.8-4/2018-H&OTC/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.	Services to be Provided	Category of application	Fee (Rs.)
(1)	(2)	(3)	(4)
1.	Application for approval of layout plan/revised layout	---	2,500 / whole facility.
2.	Application for Enlistment as local manufacturer	---	15,000/-
3.	Approval of change in qualified staff.	---	2,500/-
4.	Approval of additional section	---	2,500/-
5.	Application for Enlistment as Importer	---	15,000/-
6.	Application for Enlistment of imported product/ new medicine	Alternative medicine	2,500/-
7.		Health product	5,000/-
8.	Enlistment of locally manufactured homeopathic medicine	Mother tincture	2,500/-
9.		Dilutions and potencies	2,500/-
10.		Combination product and dosage form	5,000/-
11.	Enlistment of locally manufactured herbal / <i>unani</i> product	---	2,500/-
12.	Enlistment of locally manufactured health product	---	5,000/-
13.	GMP Inspection	---	25,000/- annum
14.	Firm/Company Enlistment for contract manufacturing or change in contract giver. (Manufacturer to Manufacturer only)	---	15,000/-
15.	Product Fee for contract manufacturing	For each category	5,000
16.		If contract manufacturing exceeds 10 products	10,000 per product
17.	Enlistment for referral laboratories	---	50,000/-

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18.	Variations allowed such as change of brand name & management change.	---	15,000/-
19.	Miscellaneous variation activities like additional pack, change in specifications, packing material/ change in excipient and other activities.	---	2,500/-
20.	Change in title of the firm/ company or change in the ownership/ management of the firm/ company.	---	15,000/-
21.		Addition or deletion of Director.	2,500/- per case
22.	Transfer of product enlistment from import to local manufacturing	---	5,000/-
23.	Renewal	Manufacturing enlistment after 02 years	Half of initial fee
24.		Product enlistment after 02 years	Half of initial fee
25.	Free Sale Certificate	---	2,500/-
26.	CoPP of alternative medicine & health product	---	2,500/-
27.	Fee for grant of approval of product testing from the referral laboratory (not for routine testing).	---	2,500/-
28.	Advertisement and clinical trials.	---	Same fee as applicable for other therapeutic goods.
29.	Import license fee	---	Same fee as applicable for other therapeutic goods.

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