To be published in the extra ordinary Gazette of Pakistan, Part-II

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

NOTIFICATION

Islamabad, the 1st August, 2025.

S.R.O. 1399(I)/2025.– 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 sub-rule (3) of rule 4 of the Drug Regulatory Authority of Pakistan (Fee and Levy) Rules, 2022, and in partial modification of Notification No. S.R.O. 496(I)/2023 dated the 17th April, 2023, and in supersession of Notification No. S.R.O. 1324(I)/2024 dated the 30th August, 2024, 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 function	Description	Fee (Rs.)
(1)	(2)	(3)	(4)
Costing and Pricing			
1.	Hardship	- - -	38,700
2.	Additional Pack	- - -	9,400
3.	Consumer Price Index (CPI)	- - -	2,600
Controlled Drugs			
4.	Processing of application of quota allocation and issuance of import authorization (for routine and first time allocation) and NOC for combined Ground Check	- - -	26,100
5.	Processing of enhancement/ supplementary allocation of quota application by the firm	- - -	12,500
6.	Processing of application for destruction of controlled substances received from hospitals, pharmaceutical units, etc.	- - -	6,300
7.	Processing of application for export and issuance of export permit for medicine containing controlled substance and other miscellaneous function	- - -	5,200
8.	Processing of application of quota allocation and issuance of import authorization exclusively for tender supply to Government hospital institutions	- - -	26,100

9.	Processing of application of quota allocation of narcotic products for hospital use to private institution in Islamabad	- - -	4,200
Pharmacy Services			
10.	Grant of new license for Bio-equivalence / Bio-availability Studies center	- - -	386,600
11.	Grant of new license for Contract Research Organization	- - -	386,600
12.	Grant of new license for Bio-analytical Laboratory for Clinical Research	- - -	386,600
13.	Grant of new license for Clinical Trial Site	- - -	130,600
14.	Grant of renewal of license for Bio-equivalence / Bio-availability Studies Center, Contract Research Organization, Bio-analytical Laboratory for Clinical Research	If applied before expiry of validity of license	386,600
15.		If applied within 60 days of expiry of validity of license	517,200
16.	Grant of renewal of license for Clinical Trial Site	If applied before expiry of validity of license	130,600
17.		If applied within 60 days for expiry of validity of license	193,300
18.	Grant of approval and registration of Clinical Trials	- - -	256,000
19.	Grant of approval and registration of Bio-equivalence / Bio-availability Study	- - -	256,000
20.	Approval of amendment in already approved Clinical Trial or Bio-equivalence / Bio-availability Study	- - -	50% fee of relevant registration/approval
21.	Miscellaneous request related to clinical trials	- - -	32,400
22.	Approval of amendment in already approved License for Bio-equivalence / Bio-availability Studies Center, Contract Research Organization, Bio-analytical Laboratory for Clinical Research and Clinical Trial Site	- - -	50% fee of relevant license
23.	Per advertisement for print media	- - -	19,900
24.	Per advertisement for radio / audio	- - -	29,300
25.	Per advertisement for television / cinema	- - -	48,100
26.	Per advertisement for Display *(banner, flyers, billboards, product placement / dispensers etc.)*	- - -	48,100
Health and OTC Products			
27.	Processing fee for application of Site Verification for establishment of locally manufacturing facility	- - -	10,400
28.	Application for approval of layout plan / revised layout	- - -	3,100 per section
29.	Application for enlistment as local manufacturer	- - -	19,900

30.	Approval of change in qualified staff	- - -	3,100
31.	Approval/Enlistment of additional section	- - -	3,100
32.	Application for enlistment as importer	- - -	19,900
33.	Enlistment of imported product / new medicine	Alternative medicine (Herbal Unani)	3,100
34.		Health product	6,300
35.	Enlistment of locally manufactured homeopathic medicine	Mother tincture	3,100
36.		Dilutions and potencies	3,100
37.		Combination product and dosage form	6,300
38.	Enlistment of locally manufactured herbal / *Unani* product	- - -	3,100
39.	Enlistment of locally manufactured health product	- - -	6,300
40.	Firm / company enlistment for contract manufacturing or change in contract giver (manufacturer to manufacturer only)	- - -	19,900
41.	Product fee for contract manufacturing	For each category	6,300
42.		If contract manufacturing exceeds 10 products	12,500
43.	Variations allowed such as change of brand name and management	- - -	19,900
44.	Miscellaneous variation activities like additional pack, change in specifications, packing material, change in excipient and other activities	- - -	3,100
45.	Change in title of the firm / company or change in the ownership or management of the firm / company	- - -	19,900
46.	Addition or deletion of Director	- - -	3,100
47.	Change of product enlistment from import to local manufacturing	- - -	6,300
48.	Renewal	Manufacturing enlistment	Half of the initial fee
49.		Product enlistment	Half of the initial fee
Management Information Services			
50.	Processing fee for adjustment of online submitted challans	- - -	15,700
Quality Assurance and Laboratory Testing			
51.	Clearance of import requests for therapeutic goods	- - -	Rs.2,600 per consignment
52.	Issuance of GMP certificate for all therapeutic goods requiring panel inspection	- - -	26,100 per annum
53.	Issuance of a subsequent GMP certificate for any other country on the basis of already conducted inspection for GMP certificate	- - -	13,100

54.	Issuance of Free Sale Certificate for all therapeutic goods	- - -	7,800
55.	Issuance of CoPP of all therapeutic goods	- - -	7,800
Pharmaceutical Evaluations and Registration			
56.	Grant of registration	Any drug product for import including pellets, granules, bulk concentrate / ready to fill bulk	313,500
57.		Drugs for local manufacture	38,700
58.	Renewal of drugs registration (if the application for renewal is made before the expiry of the period of validity or registration)	Any drug for import	Half fee of registration
59.		Drug for local manufacture	Half fee of registration
60.	Renewal of drugs registration (if the application for renewal is made after the expiry of the period of validity but within 60 days after the expiry of the period of validity)	Any drug for import	Full fee of registration
61.		Drug for local manufacture	Full fee of registration
62.	Renewal of drugs registration (if the application for renewal is made after the expiry of the period of validity but within one year after the expiry of the period of validity under S.R.O. 1005(I)/2017)	Any drug for import	Applicable renewal fee as per S.R.O. 1005(I)/2017
63.		Drug for local manufacture	
64.	Grant/extension of contract manufacturing permission	For local manufacture	97,200 per product
65.		For export purpose only	31,300
66.	Pre-registration variation (Before issuance of registration certificate)	Variance to registration application except those specified in the below entry.	9,400 (in case of more than one variation, single fee will be charged)
67.		Change of source of drug substance	Half fee of registration (in case of more than one variation, single fee will be charged)
68.		Change of manufacturer	
69.		Change of MAH in case of import	
70.		Submission of afresh stability data of drug product	
71.	Post-registration variation (After issuance of registration certificate)	Any variation in registered drug except those specified in the following entry	12,500
72.		Change of brand name expect cases of resemblance	38,700
73.		Change of title/name of manufacturer/marketing authorization holder	38,700
74.		Change of source of pellets/substance	67,900

75.		Approval of additional source of pellets/ bulk drugs product/ substance	38,700
76.		Change of registration status from one manufacturer / marketing authorization holder to another manufacturer / marketing authorization holder	67,900
Drug Licensing			
77.	Grant of drug manufacturing License	By way of basic manufacturing	58,500
78.		By way of semi-basic manufacturing	58,500
79.		By way of formulation	193,300
80.		By way of repacking	114,900
81.	Renewal of drug manufacturing License (If the application for renewal is made before the expiry of the period of validity of license).	By way of basic manufacturing	29,300
82.		By way of semi-basic manufacturing	29,300
83.		By way of formulation	97,200
84.		By way of repacking	58,500
85.	Renewal of drug manufacturing license (If the application for renewal is made after the expiry of the period of validity of license but within sixty days of its expiry)	By way of basic manufacturing	9,400 per day surcharge, in addition to renewal fee
86.		By way of semi-basic manufacturing	
87.		By way of formulation	
88.		By way of repacking	
89.	Site verification and layout	Site inspection and verification	9,400 per section
90.		Approval of layout plan / Revision or extension of layout plan	9,400 per section
91.	Repacking of Drugs	- - -	9,400 per product
92.	Approval of technical person	- - -	9,400
93.	Attestation of DML	- - -	9,400
94.	Issuance of NOC for equipment	- - -	9,400
95.	Issuance of Inspection Book	- - -	9,400
96.	Grant of DML by way of Experimental Purpose	- - -	9,400
97.	Change of management/title of DML	By way of basic manufacturing.	29,300
98.		By way of semi-basic manufacturing	29,300
99.		By way of formulation.	97,200
100.		By way of repacking	58,500
101.	API enlistment	- - -	9,400
102.	Miscellaneous applications	Any other application having commercial significance	9,400

Medical Devices and Medicated Cosmetics			
103.	Enlistment / registration of medical devices and renewal of enlistment / registration thereof	Enlistment of Class A medical device for local manufacture or import and renewal thereof	6,300
104.		Registration of Class B, C & D medical device for local manufacture	26,100
105.		Renewal of registration of Class B, C & D medical device for local manufacture	12,500
106.		Registration of Class B medical device or accessory or component for import	32,400
107.		Renewal of registration of Class B medical for import	15,700
108.		Registration of Class C & D medical device or accessory or component for import	64,800
109.		Renewal of registration of Class C & D medical for import	32,400
110.		Enlistment or registration of accessory or component for local manufacture and renewal thereof	6,300
111.		Post enlistment or registration variation	6,300
112.		Any change in particulars of enlisted or registered medical device	Fifty percent of the registration / enlistment fee
113.	Establishment Licenses	Establishment license to manufacture medical devices	128,500
114.		Establishment license to import medical devices	26,100
115.		Renewal of establishment license to manufacture medical devices	64,800
116.		Renewal of establishment license to import medical devices	12,500
117.		Any change in particulars of licensed establishment	Fifty percent of the establishment license fee
118.	Import Permits	Import permit or its renewal for medical devices	6,300

119.	Miscellaneous	Any other application having commercial significance	9,400
120.	Outsourcing	Certificate to outsource manufacturing processes of medical devices for each contract acceptor	64,800
121.		Certificate to outsource analysis of medical devices for each contract acceptor	64,800
122.		Renewal of certificate to outsource manufacturing processes of medical devices for each contract acceptor	32,400
123.		Renewal of certificate to outsource analysis of medical devices for each contract acceptor	32,400
124.		Any change in particulars of certificate of outsourcing	Fifty percent of the initial fee of certificate
125.	Enlistment / registration of medical devices applying as an in-vitro cluster	Class A medical device for local manufacture or import	26,100 (for 20 articles / reagents) & 5,200 for each extra reagent / article incluster application
126.		Class B medical device for local manufacture or import	52,200 (for 20 articles / reagents) & 5,200 foreach extra reagent / article in cluster application
127.	Renewal of enlistment / registration of medical devices as in-vitro cluster	Class A & B medical device for local manufacture or import as an in-vitro cluster	Fifty percent of the registration / enlistment fee
128.	Enlistment / registration of medical devices as system / family having more than one medical device	Class A medical device for local manufacture or import	26,100 (for up to 20 medical devices / accessory / article) & 2,600 for each extra medical device / accessory / article
129.		Class B medical device for local manufacture or import	52,200 (for up to 20 medical devices / accessory / article) & 5,200 for each extra medical device / accessory / article
130.		Class C & D medical device for local manufacture or import	104,500 (for up to 20 medical devices / accessory / article) & 5,200 for eachextra medical device

131.	Renewal of enlistment / registration of medical devices as system / family having more than one medical device	Class A, B, C & D medical device for local manufacture or import as system / family having more than one medical device	Fifty percent of the registration / enlistment fee
Appellate Board			
132.	Application for appeal	- - -	64,800
Central Drugs Laboratory			
133.	Description (General)	- - -	1,000
134.	Identification (General)	- - -	1,500
135.	Identification (TLC)	Per molecule	5,000
136.	Identification (FTIR)	Per molecule	6,000
137.	Assay (Spectrophotometer)	Per molecule	8,000
138.	Assay (HPLC)	Per molecule	15,000
139.	Assay (Titration - Simple)	Per molecule	4,000
140.	Assay (Titration - Potentiometeric)	Per molecule	6,000
141.	Bio Assay	Per molecule	9,000
142.	Weight Variation/ Mass Variation	- - -	3,000
143.	Content Uniformity	Per molecule	30,000
144.	Dissolution Test (Spectrophotometric)	Per molecule	15,000
145.	Dissolution Test (HPLC)	Per molecule	21,000
146.	Disintegration Test (Uncoated/ Film Coated/ Sugar Coated Tablets and Capsules)	- - -	4,000
147.	Disintegration Test (Enteric Coted Tablets/capsules)	- - -	6,000
148.	Disintegration Test (Sustained Release Tablets and Capsules)	- - -	10,000
149.	pH Test	- - -	2,500
150.	Melting Point	- - -	3,000
151.	Loss on Drying	- - -	3,000
152.	Sulphated Ash	- - -	3,000
153.	Sterility Test (Direct)	- - -	10,000
154.	Sterility Test (Filter)	- - -	12,000
155.	Endotoxin (Gel Clot method)	- - -	12,000
156.	Endotoxin (Chromogenic Method)	- - -	16,000
157.	Gravimetric Assay	- - -	6,000
158.	Appearance of Solution (syringes)	- - -	1,500
159.	Acidity or Alkalinity	- - -	2,500
160.	Absorbance (Syringes)	- - -	3,000
161.	Reducing Substances	- - -	4,000
162.	Fibre Identification Test	- - -	2,000
163.	Absorbency (Cotton)	- - -	2,000
164.	Color of Aqueous Extract	- - -	4,000
165.	Flourescence Test	- - -	2,500
166.	Water Soluble Substance	- - -	6,000
167.	Warp Thread and Weft Thread Test (Bandage)	- - -	2,000
168.	Weight Per Unit Area (Bandage)	- - -	2,000

169.	Elasticity (Crepe Bandage)	- - -	3,000
170.	Clarity Test (Parenterals)	- - -	2,000
171.	Optical Rotation	- - -	8,000
172.	Specific Gravity	- - -	4,500
173.	Refractive Index	- - -	4,000
174.	Limit Test (Trace Elements) Titration	- - -	7,500
175.	Acid Value	- - -	6,000
176.	Iodine Value	- - -	6,000
177.	Sponification Value	- - -	6,000
178.	Acetyl Value	- - -	6,000
179.	Hydroxyl Value	- - -	6,000
180.	Viscosity Test	- - -	5,000
181.	Friability Test	- - -	4,500
182.	Alcohol Determination Test	- - -	9,000
183.	Others	- - -	10,000
184.	Mass Spectroscopy	- - -	80,000
185.	Gas Chromatography	- - -	45,000
186.	Dissolution Sustained Release/ Controlled Release by HPLC	- - -	30,000
187.	Dissolution Sustained Release/ Controlled Release by Spectrophotmeter	- - -	20,000
188.	Dissolution Sustained Release/ Controlled Release by Titration	- - -	17,000
189.	Elemental Assay by Atomic Absorption Spectroscopy (Per Element)	- - -	10,000
190.	TOC	- - -	10,000
191.	Visible Particulate Matter	- - -	4,000
192.	Sub Visible Particulate Matter	- - -	10,000
193.	Total Dissolve Organic Carbon	- - -	5,000

2. The fee deposited for any regulatory service shall in no case be refunded.

[No. F.11-2/2023-DD(LA)]

AAMAR LATIF,
Director (Legal Affairs).

The Manager,
Printing Corporation of Pakistan Press,
Islamabad.