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Government of Pakistan
Ministry of National Health Services, Regulations and Coordination
Drug Regulatory Authority of Pakistan
❦❦❦❦❦❦

Islamabad, the 29th September, 2026.

NOTIFICATION

S.R.O. 1660(I)/2026.— 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 supersession of Notification No. S.R.O. 1399(I)/2025 dated the 1st August, 2025, 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)
Division of Costing and Pricing			
1.	Hardship Application	---	41,400
2.	Additional Pack	---	10,100
3.	Consumer Price Index	Paragraph 7 of DPP 2018	2,800
4.	Consumer Price Index	Paragraph 8 of DPP 2018	2,800
Division of Controlled Drugs			
5.	Processing of application of quota allocation and issuance of import authorization and NOC for combined Ground Check	(for routine and first-time allocation)	27,900
6.	Processing of enhancement/ supplementary allocation of quota application by the firm	---	13,400
7.	Processing of application for destruction of controlled substances received from hospitals, pharmaceutical units, etc.	---	6,700
8.	Processing of application for export and issuance of export permit for medicine containing controlled substance and other miscellaneous function	---	5,600
9.	Processing of application of quota allocation and issuance of import authorization exclusively for tender supply to Government hospital institutions	---	27,900

Sr.	Regulatory function	Description	Fee (Rs.)
10.	Processing of application of quota allocation of narcotic products for hospital use to private institution in Islamabad	---	4,500
11.	Extension in validity of Permit: Import/Procurement/Export Permit	---	10,000
12.	Change of source in Import / Procurement Permit	---	10,000
13.	Extension in validity of Import / Procurement Permit along with Change of source in Import / Procurement Permit	---	20,000
14.	Any other miscellaneous application	---	10,000
Division of Pharmacy Services			
15.	Clinical Research	Grant of new license for Bio-equivalence / Bio-availability Studies Center	413,900
16.		Grant of new license for Contract Research Organization / Service Provider	413,900
17.		Grant of new license for Bio-analytical Laboratory for Clinical Research	413,900
18.		Grant of new license for Clinical Trial Site	139,800
19.		Grant of new license for Investigational Product Storage & Management Services (IPSMS)	413,900
20.		Grant of renewal of license for Bio-equivalence / Bio-availability Studies Center (Before expiry of the licence)	413,900
21.		Grant of renewal of license for Contract Research Organization / Service Provider (Before expiry of the licence)	413,900
22.		Grant of renewal of license for Bio-analytical Laboratory for Clinical Research (Before expiry of the licence)	413,900
23.		Grant of renewal of license for Clinical Trial Site (Before expiry of the licence)	139,800

Sr.	Regulatory function	Description	Fee (Rs.)
24.	Grant of Renewal of License for BA/BE studies centre, Contract Research Organization, Bio-analytical laboratory for Clinical Research (after Expiry of validity of license)	If applied within 60 days of expiry of validity of license	Full prescribed fee applicable to the respective licence category, as mentioned above, shall be payable as a penalty for each month after expiry of the licence until its renewal
25.	Grant of Renewal of License for Clinical Trial Site (after Expiry of validity of license)	If applied within 60 days of expiry of validity of license	Full prescribed fee applicable to the respective licence category, as mentioned above, shall be payable as a penalty for each month after expiry of the licence until its renewal
26.	Post License Variations/Amendments	License for Bio-equivalence / Bio-availability Studies Center	207,000
27.		License for Contract Research Organization / Service Provider	207,000
28.		License for Bio-analytical Laboratory for Clinical Research	207,000
29.		License for Clinical Trial Site	69,900
30.	Registration	Grant of approval and registration of Clinical Trials	274,000
31.		Grant of approval and registration of Bio-equivalence / Bio-availability Study	274,000
32.		Approval of amendment in already approved Clinical Trial or Bioequivalence / Bio-availability Study	137,000
33.	Miscellaneous	Miscellaneous request related to Clinical Research	34,700
34.	Advertisement	Internet / digital media (including all the digital/ social media platforms e.g. Meta (Facebook, Instagram, WhatsApp), Google (YouTube), LinkedIn, TikTok, X or any	100,000

Sr.	Regulatory function	Description	Fee (Rs.)
		other website for audio and visual ads)	
35.		Print media (newspapers, journals, magazines, etc.) (per product per advertisement)	21,300
36.		Electronic media (Radio/Audio) (per product per advertisement)	31,400
37.		Electronic media (T.V / Cinema) (per product per advertisement)	51,500
38.		Display media (banners, flyers, billboards, product placement/dispensers, etc.) (per product per advertisement)	51,500
Division of Health and OTC Products			
39.	Enlistment of Firm / Company	Application for Enlistment as local manufacturer	21,300
40.		Application for Enlistment as Importer	21,300
41.		Firm/Company Enlistment for contract manufacturing or change in contract giver. (Manufacturer to Manufacturer only)	21,300
42.		Application for approval of layout plan/revised layout (Per Section)	3,300
43.		Processing fee for application of site verification for establishment of local manufacturing facility	11,100
44.		Change in qualified staff	3,300
45.	Enlistment of Therapeutic Goods	Product Fee for contract manufacturing (For each category)	6,700
46.		Application for Enlistment of imported product/ new medicine (Alternative medicine)	3,300
47.		Application for Enlistment of imported product/ new medicine (Health product)	6,700
48.		Enlistment of locally manufactured homeopathic medicine (Mother tincture)	3,300

Sr.	Regulatory function	Description	Fee (Rs.)
49.		Enlistment of locally manufactured homeopathic medicine (Dilutions and potencies)	3,300
50.		Enlistment of locally manufactured homeopathic medicine (Combination product and dosage form)	6,700
51.		Enlistment of locally manufactured herbal / <i>unani</i> product	3,300
52.		Enlistment of locally manufactured health product	6,700
53.	Post Product Enlistment Variation	Change of brand name of enlisted product	21,300
54.		Change in title of the firm/ company or change in the ownership/ management of the firm/ company.	21,300
55.		Miscellaneous variation activities like additional pack, change in specifications, packing material/ change in excipient	3,300
56.	Miscellaneous (Please Specify) Per document	Attestation of enlistment certificates	10,000
57.		Duplicate issuance of enlistment certificates	10,000
Division of Management Information Services			
58.	Processing fee for adjustment of online submitted challans	Adjustment of Online Challans	16,800
59.	Miscellaneous (Please Specify)	Rectification of Electronic Record in Company Profile	8,300
Division of Quality Assurance and Laboratory Testing			
60.	Drug Import License	Form 5	8,000
61.	Drug Import License	Form 6	8,000
62.	GMP Certificate	Issuance of GMP certificate for all therapeutics goods requiring panel inspection (per annum)	27,900
63.	GMP Certificate	Subsequent GMP Certificate for any other country on the basis of already conducted inspection for GMP Certificate (per anum)	14,000

Sr.	Regulatory function	Description	Fee (Rs.)
64.	Consignment Clearance	Clearance of import request for all therapeutic goods (API, excipients, intermediates, finished products etc.) Per consignment	2,800
65.	Consignment Clearance	(Hospitals Only) clearance of import request for all therapeutic goods (API, excipients, intermediates, finished products etc.) Per consignment	2,800
66.	Inspection fee for Consumption verification of controlled drugs	---	20,000
67.	Attestation of GMP Certificate / inspection report	---	10,000
68.	Miscellaneous (Please Specify)	Issuance of Free Sale Certificate for all therapeutic goods	8,300
69.		Issuance of CoPP of all therapeutics goods	8,300
70.	Miscellaneous (Please Specify)	Any Other Application Having commercial significance	8,000
71.		Application Fee for Issuance of Export NOC/Permit	8,000
72.		Application Fee for Issuance of NOC for Import of Unregistered/Not Available Therapeutic Goods	8,000
73.		Application Fee for Import of Short Shelf-Life Therapeutic Goods per Batch	8,000
Division of Pharmaceutical Evaluation and Registration / Division of Biological Evaluation and Research			
74.	Grant of registration	Any drug product for import including pellets, granules, bulk concentrate / ready to fill bulk	335,600
75.		Drugs for local manufacture	41,400
76.		Drug for Export Purpose.	41,400
77.		Exemption of inspection of manufacturer abroad for grant of registration.	10,100
78.	Renewal of drugs registration	Any drug for import	167,800

Sr.	Regulatory function	Description	Fee (Rs.)
79.	(Within due date)	Drug for local manufacture / export	20,700
80.	Renewal of drugs registration (Within sixty days after due date)	Any drug for import	335,600
81.		Drug for local manufacture / export	41,400
82.	Renewal of drugs registration (Within one year after due date)	Any drug for import	Applicable renewal fee as per S.R.O. 1005(I)/2017
83.		Drug for local manufacture / export	Applicable renewal fee as per S.R.O. 1005(I)/2017
84.	Grant/ renewal of registration on contract manufacturing basis	For local manufacture	104,100 per product
85.		For export purpose only	33,500
86.	Pre-registration variation (Before issuance of registration certificate)	Variance to registration application except those specified in the below entries.	10,100
87.		Approval of source of drug substance	20,700
88.		Change of manufacturer	20,700
89.		Change of MAH in case of import	167,800
90.		Submission of Additional product related data (stability data, CDP, etc.) product (locally manufactured)	20,700
91.		Submission of Additional product related data (stability data, CDP, etc.) product (Import)	167,800
92.	Post-registration variation (After issuance of registration certificate)	Any variation in registered drug except those specified in the following entry	13,400
93.		Change of brand name except cases of resemblance	41,400
94.		Approval/Change / additional source of pellets/ bulk drugs product/ substance	41,400
95.		Change of registration status from one manufacturer / marketing authorization holder to another manufacturer / marketing authorization holder	72,700

Sr.	Regulatory function	Description	Fee (Rs.)
96.		Change of registration status from finished import to local contract manufacturing (per Product)	104,100
97.	Virtual Inspection	Inspection of manufacturer abroad for grant of registration.	100,000
98.	Pre-registration variation (Before issuance of registration certificate)	Change of title/name of manufacturer/marketing authorization holder	20,000
99.	Post-registration variation (After issuance of registration certificate)	Change of title/name of manufacturer/marketing authorization holder	20,000
100.		Change of Primary Container Closure System (local/Export)	20,700
101.		Change of Primary Container Closure System (import)	167,800
102.		Grant of additional pack for non-essential products human and veterinary products	13,400
Division of Licensing			
103.	Grant of drug manufacturing license	By way of basic manufacturing	62,600
104.		By way of semi-basic manufacturing	62,600
105.		By way formulation	206,900
106.		By way of repacking	123,000
107.	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	31,400
108.		By way of semi-basic manufacturing	31,400
109.		By way formulation	104,100
110.		By way of repacking	62,600
111.	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	10,100 per day surcharge, in addition to renewal fee
112.		By way of semi-basic manufacturing	
113.		By way formulation	
114.		By way of repacking	
115.	Site verification	Site inspection and verification	10,100
116.	Approval of layout plan / revision or extension of layout plan	Approval of layout plan / revision or extension of layout plan (per Section)	10,100
117.	Repacking of Drugs	Per Product	10,100

Sr.	Regulatory function	Description	Fee (Rs.)
118.	Approval of technical person	---	10,100
119.	Attestation of DML	---	10,100
120.	Issuance of NOC for equipment	---	10,100
121.	Issuance of Inspection book	---	10,100
122.	Grant of DML by way of experimental purpose	---	10,100
123.	Change of management/title of DML	By way of basic manufacturing	31,400
124.		By way of semi-basic manufacturing	31,400
125.		By way of formulation	104,100
126.		By way of repacking	62,600
127.	API enlistment	---	10,100
128.	Miscellaneous application	Any other application having commercial significance	10,100
129.	Grant of additional section	Application for constitution of panel for grant of additional section	10,100
130.	Endorsement of Site Master File	Endorsement of site master file for export purpose	25,000
Division of Medical Devices and Medicated Cosmetics			
131.	Enlistment / registration of medical devices including refurbished medical devices and renewal of enlistment / registration of single, set, IVD-Kit thereof	Enlistment of Class A medical device for local manufacture or import	6,700
132.		Renewal of enlistment of Class A medical device for local manufacture or import	6,700
133.		Registration of Class B, C & D medical device for local manufacture	28,000
134.		Renewal of registration of Class B, C & D medical device for local manufacture	13,400
135.		Registration of Class B medical device for import	34,700
136.		Renewal of registration of Class B medical for import	16,800
137.		Registration of Class C & D medical device for import	69,400
138.		Renewal of registration of Class C & D medical device for import	34,700
139.	Establishment Licenses	Establishment license to manufacture medical devices	137,600

Sr.	Regulatory function	Description	Fee (Rs.)
140.		Establishment license to import medical devices	28,000
141.		Renewal of establishment license to manufacture medical devices	69,400
142.		Renewal of establishment license to import medical devices	13,400
143.		Post licence variation for ELM	69,400
144.		Post licence variation for ELI	13,400
145.	Import Permits	Import permit for medical devices (Form-9)	6,700
146.	Miscellaneous	Any other application having commercial significance	10,100
147.	Outsourcing	Certificate to outsource manufacturing processes of medical devices for each contract acceptor	69,400
148.		Certificate to outsource analysis of medical devices for each contract acceptor	69,400
149.		Renewal of certificate to outsource manufacturing processes of medical devices for each contract acceptor	34,700
150.		Renewal of certificate to outsource analysis of medical devices for each contract acceptor	34,700
151.		Any change in particulars of certificate of outsourcing for analysis or manufacturing	34,700
152.	Enlistment / registration of medical devices applying as an in-vitro cluster (import)	Class A medical device for import	27900 (for 20 reagent/ control/calibrator) & 5,600 for each extra reagent/ control/ calibrator in cluster application with maximum fee limit of 100000
153.		Class B medical device for import	55900(for 20 reagent/ control/ calibrator) & 5,600 for each extra reagent/ control/

Sr.	Regulatory function	Description	Fee (Rs.)
			calibrator in cluster application with maximum fee limit of 150000
154.	Enlistment / registration of medical devices applying as an in-vitro cluster (local)	Class A medical device for local manufacture	27,900
155.		Class B medical device for local manufacture	55,900
156.	Renewal of enlistment / registration of medical devices as in-vitro cluster	Class A medical device for local manufacture	14,000
157.		Class B medical device for local manufacture	28,000
158.		Class A medical device for import	14000 (for 20 reagent / control/calibrator) & 2,800 for each extra reagent / control/ calibrator in cluster application with maximum fee limit of 50000
159.		Class B medical device for import	28000(for 20 articles / reagents) & 2,800 for each extra reagent / article in cluster application with maximum fee limit of 75000
160.	Post enlistment or registration variation of an in-vitro cluster (import)	Class A medical device for import	14000(for 20 reagent / control/calibrator) & 2600 for each extra reagent / control/ calibrator in cluster application with maximum fee limit of 50000
161.		Class B medical device for import	28000(for 20 reagent / control/calibrator) & 2600 for each extra reagent / control/calibrator in cluster application with maximum fee limit of 75000
162.	Post enlistment or registration variation of an in-vitro cluster (local)	Class A medical device	14,000
163.		Class B medical device	28,000
164.	Enlistment / registration of medical devices including refurbished medical devices as system / family / family of system having more than one medical	Class A medical device for import	28000 (for up to 20 medical devices / accessory / article) & 2800 for each extra

Sr.	Regulatory function	Description	Fee (Rs.)
	device		medical device / accessory / article with maximum fee limit of 100000
165.		Class B medical device for import	56000 (for up to 20 medical devices / accessory / article) & 5,200 for each extra medical device / accessory / article with maximum fee limit of 150000
166.		Class C & D medical device for import	112000 (for up to 20 medical devices / accessory / article) & 5,600 for each extra medical device with maximum fee limit of 200000)
167.	Enlistment / registration of medical devices including refurbished medical devices as system / family / family of system having more than one medical device	Class A medical device for local manufacture	28,000
168.		Class B medical device for local manufacture	56,000
169.		Class C & D medical device for local manufacture	112,000
170.	Renewal of enlistment / registration of medical devices including refurbished medical devices as system / family / family of system having more than one medical device	Class A medical device for import	14000 (for up to 20 medical devices / accessory / article) & 1400 for each extra medical device / accessory / article with maximum fee limit of 50000
171.		Class B medical device for import	28000(for up to 20 medical devices / accessory / article) & 2600 for each extra medical device / accessory / article with maximum fee limit of 75000
172.		Class C & D medical device for import	56000 (for up to 20 medical devices / accessory / article) & 2800 for each extra medical device with maximum fee limit of 100000)

Sr.	Regulatory function	Description	Fee (Rs.)
173.		Class A medical device for local manufacture	14,000
174.		Class B medical device for local manufacture	28,000
175.		Class C & D medical device for local manufacture	56,000
176.	Post enlistment or registration variation of medical devices including refurbished medical devices as system / family / family of system having more than one medical device for import	Class A medical device for import	14000 (for up to 20 medical devices / accessory / article) & 1300 for each extra medical device / accessory / article with maximum fee limit of 50000
177.		Class B medical device for import	28000 (for up to 20 medical devices / accessory / article) & 2600 for each extra medical device / accessory / article with maximum fee limit of 75000
178.		Class C & D medical device for import	56000 (for up to 20 medical devices / accessory / article) & 2600 for each extra medical device with maximum fee limit of 100000)
179.	Post enlistment or registration variation of local including refurbished medical devices as system / family / family of system having more than one medical device	Class A medical device for local manufacture	14,000
180.		Class B medical device for local manufacture	28,000
181.		Class C & D medical device for local manufacture	56,000
182.	Enlistment / registration of medical devices including refurbished medical devices and renewal of enlistment / registration of single, set, IVD-Kit thereof	Post enlistment or registration variation of class A local and import	7,000
183.		Post enlistment or registration variation of class B local	14,000
184.		Post enlistment or registration variation of class B import	18,000
185.		Post enlistment or registration variation of class C local	14,000

Sr.	Regulatory function	Description	Fee (Rs.)
186.		Post enlistment or registration variation of class C import	35,000
187.		Post enlistment or registration variation of class D local	14,000
188.		Post enlistment or registration variation of class D import	35,000
189.	Indenting under rule 72(2) of the MDR 2017	Indenting (per product)	10,000
190.	Pre-approval variation	Pre-enlistment or registration or licensing variation	10,000
191.	Grant of Licence	Fee for Site verification	10,000
Division of Legal Affairs			
192.	Appeal	Appellate Board	69,400
Central Drugs Laboratory			
193.	Dissolution Test (HPLC) (Per molecule)	---	22,500
194.	Limit Test (Trace elements) Titration	---	8,000
195.	Mass Spectroscopy	---	85,600
196.	Dissolution Sustained Release / Controlled Release by HPLC	---	32,100
197.	Dissolution Sustained Release / Controlled Release by spectrophotometer	---	21,400
198.	Dissolution Sustained Release / Controlled Release by Titration	---	18,200
199.	Element Assay by Atomic Absorption Spectroscopy (Per Element)	---	10,700
200.	TOC	---	10,700
201.	Visible Particulate Matter	---	4,300
202.	Sub Visible Particulate Matter	---	10,700
203.	Total Dissolve Organic Carbon	---	10,700
204.	Gas Chromatography	---	48,200
205.	Description (General)	---	1,100
206.	Identification (General)	---	1,600
207.	Identification (TLC)	---	5,400
208.	Identification (FTIR)	---	6,400
209.	Assay (Spectrophotometric)	---	8,600
210.	Assay (HPLC)	---	16,100
211.	Assay Titration (Simple)	---	4,300
212.	Assay Titration (Potentiometric)	---	6,400
213.	Bio Assay	---	9,600
214.	Weight variation /Mass variation	---	3,200
215.	Content Uniformity	---	32,100
216.	Dissolution Test (spectrophotometric)	---	16,100
217.	Disintegration Test (uncoated /film coated /sugar coated tablet and capsule)	---	4,300

Sr.	Regulatory function	Description	Fee (Rs.)
218.	Disintegration Test (Enteric coated tablet / capsule)	---	6,400
219.	Disintegration Test (Sustained Release tablet / capsule)	---	10,700
220.	pH Test	---	2,700
221.	Melting Point	---	3,200
222.	Loss on Drying	---	3,200
223.	Sulphated Ash	---	3,200
224.	Sterility Test (direct)	---	10,700
225.	Sterility Test (Filter)	---	12,800
226.	Endotoxin Test (gel Clot method)	---	12,800
227.	Endotoxin Test (Chromogenic method)	---	17,100
228.	Gravimetric Assay	---	6,400
229.	Appearance of solution (syringes)	---	1,600
230.	Acidity or Alkalinity	---	2,700
231.	Absorbance (Syringes)	---	3,200
232.	Reducing Substances	---	4,300
233.	Fiber Identification Test	---	2,100
234.	Absorbency (cotton)	---	2,100
235.	Color of aqueous extract	---	4,300
236.	Fluorescence Test	---	2,700
237.	Water soluble substance	---	6,400
238.	Warp thread and weft thread test (Bandage)	---	2,100
239.	Weight per unit area (bandage)	---	2,100
240.	Elasticity Test (crepe bandage)	---	3,200
241.	Clarity Test (parenterals)	---	2,100
242.	Optical Rotation	---	8,600
243.	Specific Gravity	---	4,800
244.	Refractive Index	---	4,300
245.	Acid Value	---	6,400
246.	Iodine Value	---	6,400
247.	Saponification Value	---	6,400
248.	Acetyl Value	---	6,400
249.	Hydroxyl Value	---	6,400
250.	Viscosity Test	---	5,400
251.	Friability Test	---	4,800
252.	Alcohol determination Test	---	9,600
253.	Water Content	---	5,000
254.	Conductivity Test	---	5,000
255.	Residue on ignition	---	3,000
256.	Test for auto disability (Syringes)	---	10,000
257.	Chromatographic purity	---	20,000
258.	Dissolution test for enteric coated tablet (HPLC)	---	30,000
259.	Dissolution test for enteric coated tablet (UV)	---	20,000
260.	Impurity Profiling	---	300,000

Sr.	Regulatory function	Description	Fee (Rs.)
261.	Specific rotation	---	10,000
262.	Delivered Dose uniformity (HPLC)	---	60,000
263.	Delivered Dose uniformity (UV)	---	40,000
264.	Aerodynamics particle size distribution (UV)	---	40,000
265.	Aerodynamics particle size distribution (HPLC)	---	60,000
266.	Microbial Enumeration test	---	15,000
267.	Others	---	10,700
National Control Laboratory for Biologicals			
268.	Lot Release (LT)	Lot Release on Summary Protocol Review only	30,000
269.		Lot Release on the basis of Summary Protocol Review and Testing/analysis	100,000
270.	Testing/Analysis	Testing other than Lot Release and Regulatory Testing	100,000

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

[No. F.11-2/2023-LA]

AAMAR LATIF,
Director (Legal Affairs).

The Manager,
Printing Corporation of Pakistan Press,
Islamabad.