

¹ [SCHEDULE B

(See rules 7 and 48)

Fees for test or analysis by the Central Drugs Laboratories or State Drugs Laboratories

:

1. **I. Fees for test and assay of Drugs requiring use of animals**

	Rupees
Adrenocorticotrophic hormone assay	1000
Gonadotrophic hormone for LH activity	1000
FSH Activity	1000
Posterior pituitary extract or its synthetic substitute for oxytocin activity	400
Vasopressor activity	400
Insulin and insulin in combination for hypoglycaemic activity	2000
Hyaluronidase	500
Glucagon	2000
Heparin for anticoagulant activity	600
Protamine sulphate	300
Depressor or Histamine like substance	300
Pyrogen test	500
Antigenicity or foreign protein test	300
Abnormal or undue toxicity or safety test	200
Determination of Lethal doses, LD ₁₀ or LD ₅₀ in mice	800
Skin sensitivity/eye irrigation	250
Implantation test	2000

2. **Microbiological tests and assays -**

Bioassay of Antibiotic	400
Microbiological assay of vitamins	300
Phenol coefficient	300
Preservatives – Microbial challenge test	2000
Sterility test – Parenteral preparations	100
Surgical dressings	200
Syringes and needles	300
Transfusion and infusion sets or assemblies	400
Other sterile devices	

1. Subs. by G.S.R. No.478(E), dt. 7-8-1998.

3. Identification tests -

(a)	Chemical Methods	50
(b)	Microscopical	50
(c)	IR Spectroscopy	150
(d)	UV Spectroscopy	100
(e)	Chromotography	
	(i) Paper	100
	(ii) Thin layer	150
	(iii) Column	100
	(iv) GLC	250
	(v) HPLC	500
	(vi) Gel Filtration	300
(f)	Electrophoresis	
	(i) Paper and Cellulose acetate	200
	(ii) Polyacrylamide Gel, starch gel, agar gel	300 each

4. Physical tests –

(a)	Optical rotation, specific gravity, refractive index, weight per ml, fluorescence.	75 each
(b)	Viscosity	100
(c)	pH, Solubility, loss on drying, net content, ash, sulphated ash etc.	20 each
(d)	Absorbancy, wt/unit area (surgical), foreign matter, extractive value, thread count etc.	30 each
(e)	Uniformity of weight	
	(i) Tablets	15
	(i) Capsules	20
(f)	Acid value, iodine value, peroxide value, Saponification value, acetyl value.	100 each
(g)	Disintegration tests –	
	(i) Ordinary tablets	20
	(ii) Capsule	30
	(iii) Sugar Coated tablets	50
	(iv) Enteric coated tablets	100
(h)	Dissolution test	250
(i)	Uniformity of content.	500
(j)	Wt. per unit area (powder), particle size, count, methoxy value.	200 each
(k)	Limit test for impurities	100 each
(l)	Related substances	
	(i) TLC method	
	(A) Without reference standard	150
	(B) With reference standard	250

(ii) Gas Liquid Chromatography	
(A) Without reference standard	250
(B) With reference standard	350
(iii) High pressure Liquid Chromatography	100
(A) Without reference standards	500
(B) With reference standards	500
(m) Water (Karl Fisher)	200
(5) Assays -	
(a) General chemical methods	100 for each ingredient
(b) Non-aqueous/instrumental	200 for each ingredient
(c) Chromatography	
(i) TLC	250
(ii) Column	200
(iii) GLC	350
(iv) HPLC	500
(v) Gel filtration	400
(d) Nitrogen determination	200
(e) Medicinal gases	400
(6) Polymorph test -	300
(Content of polymorph A in chloramphenicol palmitate)	
Surgical sutures (Depending on number of tests to be carried)	200-500
Other miscellaneous tests	100-500
II Fees for Sera and Vaccine –	
Sterility test	100
Abnormal toxicity test	400
Specific toxicity test	800
Inactivation test (Rabies)	200
Potency testing of rabies vaccine	2025
Potency testing of pertussis fraction of DPT vaccine	2025
Potency testing of tetanus fraction of DPT/DT/TT vaccine	2500
Potency testing of diphtheria Fraction of DPT/DTE vaccine.	2700
Testing of antisera for the specific titre	1000
Potency testing measles/Mumps/Rubella vaccine	760 each
Testing of Oral Polio Vaccine (OPV) –	
Potency	4550
Identity	1000
Stability	800
Potency testing of Japanese Encephalitis Vaccine	3900
Potency testing of Snake	400
Venom serum	for each venom
Identity testing for vaccines/sera	
Cell culture (Other than OPV)	400
Other than cell culture	100

	Estimation of volume/pH/total solids/No. of organisms/Physical checking.	50 each
	Estimation of total proteins/aluminium content/phenol/formaldehyde/thiomersal/moisture.	200 each
	Pyrogen testing	500
	Stability test for vaccines other than Oral Polio Vaccine	4550
III	<i>Cosmetics</i> (The exact amount of the fee shall be determined by the Director of Laboratory or the Government Analyst, as the case may be).	400 – 1500
IV	<i>Rubber Condoms</i>	1000
IV	<i>Homoeopathic medicines:</i>	
	1. Identification test for raw material of botanical origin (other than assay of constituents).	125
	2. Identification test for raw material of chemical origin (other than assay)	100
	3. Limit test for drugs of chemical origin	150
	4. Assay of total alkaloids or of drugs of chemical origin	100
	5. Identification test for drugs of animal origins or microbiological.	100
	6. Fees for testing of Mother tincture, lower potencies upto 3x or equivalent.	100
	7. U.V. or I.R. or H.P.C.L. defect determination	75
	Determination of Biochemic drug through atomic absorbance spectrophotometer.	75

Note :-

1. For tests not listed in the Schedule, charges will be determined by the Director or the Government Analyst of the laboratory / institute as the case may be.

2. For the tests relating to Ayurvedic, Unani and Siddha medicines, charges will be determined by the Adviser (Indigenous System of Medicine), Director or Government Analyst of the Laboratory / Institute, as the case may be.]

1. Subs by G.S.R. 478 (E), dt:7.8.1998.

¹[SCHEDULE B(1)
(See rules 163F)

**FEES FOR THE TEST OR ANALYSIS BY THE PHARMACOPOEIAL LABORATORY FOR
INDIAN MEDICINE (PLIM) OR THE GOVERNMENT ANALYST**

	Type of testing/analysis	Cost of testing or analysis in Rupees
	(1)	(2)
1.	Test for sterility	250.00
2.	Abnormal toxicity or undue toxicity or safety test	750.00
3.	Determination of lethal does LD 50 to 10 on mice	2500.00
4.	Chemical test for each ingredient	500.00
5.	Disinfectants	1000.00
6.	Any other test requiring animal experimentation	500.00
7.	Microbiological assay	750.00
8.	Microscopic examination of single drugs	250.00
9.	Microscopic examination of raw material of compound drug	500.00
10.	Chemical identification as per Pharmacopoeia	250.00
11.	Disintegration of tablets and capsules	
	(a) ordinary	100.00
	(b) sugar coated	200.00
	(c) enteric coated	400.00
12.	Psychochemical Assays	300.00
13.	Test other than assay (limit tests for impurities, ash content, total solids, acid value, saponification value, loss on drying etc.) for each test.	100.00
14.	Optical rotation	250.00
15.	Refractive index	250.00
16.	Arsenic testing	250.00
17.	Paper chromatography	250.00
18.	Thin layer chromatography	300.00
19.	Column chromatography	2500.00
20.	Gas liquid chromatography	1000.00
21.	HPTLC restricted to single drugs qualitative	1000.00
22.	Atomical absorption spectrophotometry for Hg, Pb, As, Cd	500.00
23.	Cosmetics/ tails/ creams	500.00
24.	Identification test for raw material of plant origin (other than assay of constituents)	125.00
25.	Identification test for raw material of chemical origin (other than assay)	100.00
26.	Limit test for drug of chemical origin	150.00
27.	Other miscellaneous tests	1000.00

Note: Sample testing charges will be determined / revised by the Director or Government Analyst of the Pharmacopoeial laboratory for Indian Medicine, as the case may be, in consultation with the Department of Ayurveda, Yoga, Unani, Siddha and Homoeopathy, Ministry of Health and Family Welfare.

¹[SCHEDULE C

(See rules 23, 61 and 76 and Part X)

Biological and Special Products

1. Sera.
2. Solution of serum proteins intended for injection.
- ²[3. Vaccines for parenteral injections.
4. Toxins.
5. Antigen.
6. Antitoxins.
7. Neo-arsphenamine and analogous substances used for the specific treatment of infective diseases.
8. Insulin.
9. Pituitary (Posterior Lobe) Extract.
10. Adrenaline and Solutions of Salts of Adrenaline.
- ³[11. Antibiotics and preparations thereof in a form to be administered parenterally.]
- ⁴[12. Any other preparation which is meant for parenteral administration as such or after being made up with a solvent or medium or any other sterile product and which-
 - (a) requires to be stored in a refrigerator; or
 - (b) does not require to be stored in a refrigerator.]
13. Sterilized surgical ligature and sterilized surgical suture.
- ²[14. Bacteriophages.
- ⁵[15. Ophthalmic preparations.]
- ⁶[16. Sterile Disposable Devices for single use only.]

1. Amended by Notfn. No. F. 1-30/47-A, dt. 5-1-1950
2. Amended by Notfn. No. F. 1-8/60-D, dt. 31-8-1960
3. Subs. by No. G.S.R. 487(E), dt. 2.7.1984.
4. Amended by Notfn. No. F. 1-14/68-D, dt. 26-10-1968
5. Ins. by Notfn. No. G.S.R. 1242(E), dt. 17.9.1979
6. Ins. by Notfn. No. G.S.R. 109(E), dt. 22.2.1994.