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New test fees for government drug laboratories

G.S.R. 407(E) replaces Schedules B and B(1) of the Drugs Rules, 1945 with new fees for test or analysis at government drug laboratories, rising 5% a year.

THE MINISTRY OF HEALTH and Family Welfare (Department of Health and Family Welfare) issued notification G.S.R. 407(E), dated May 22, 2026, making the Drugs (Third Amendment) Rules, 2026. It is published in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 366, dated May 25, 2026. The Central Government made the rules under sections 12 and 33 of the Drugs and Cosmetics Act, 1940, after consultation with the Drugs Technical Advisory Board. They come into force "after three months from the date of their publication in the Official Gazette". The notification gives no calendar date; counted from the Gazette's date of May 25, 2026, that is about August 25, 2026.

KEY FACTS

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The rules substitute two schedules of the Drugs Rules, 1945. Schedule B (see rules 7 and 48) sets the "fees for test or analysis by the Central Drugs Laboratories or State Drugs Laboratories". Its Part-A covers tests and assays of drugs in six groups: tests requiring the use of animals, microbiological tests and assays, identification tests, physical tests, assays, and "Other miscellaneous tests" at ₹300-1500. Part-B lists 89 tests for sera and vaccines, and Part-C seven tests for homeopathic and herbal medicines. Schedule B(1) (see rule 163 F) lists 25 fees for test or analysis by the Pharmacopoeial Laboratory for Indian Medicine (PLIM) or the Government Analyst. Neither schedule lists a test for cosmetics.

Some examples: an HPLC assay costs ₹1,500, a quantitative bacterial endotoxin test ₹4,500, and the determination of lethal doses, LD10 or LD50, in mice ₹25,000. In Part-B, the potency test for the hepatitis B component costs ₹12,000, and the two highest fees, ₹45,000 each, are for "Potency for tetanus Vaccine" and "Potency testing of Diphtheria component"; "Protocol Scrutiny" costs ₹2,500. In Schedule B(1), HPLC costs ₹4,000 each and a pesticide residue test ₹6,000.

Each schedule ends with a note that the fees "shall automatically increase by 5% annually". Neither note says from which date the yearly rise is counted, whether each rise builds on the last, or how the new figures will be published. For tests not listed in Schedule B, the Director or the Government Analyst of the laboratory or institute determines the charges. Under Schedule B(1), sample testing charges are determined or revised by the Director, Pharmacopoeia Commission for Indian Medicine and Homoeopathy, or the Government Analyst of its Central Laboratory, in consultation with the Ministry of AYUSH.

The rules finalize draft G.S.R. 52(E), dated January 22, 2026. Copies of that Gazette were made available to the public on January 27, 2026, with thirty days for objections and suggestions, and the notification records that none were received. The fees are the same as in the draft; the draft would have come into force on final publication. The notification does not print the fees it replaces, so it gives no comparison with the old figures. It is signed by Harsh Mangla, Joint Secretary, under F. No. X.11014/14/2025-DR-Part(2).

Issued by	Ministry of Health and Family Welfare (Department of Health and Family Welfare)
Document	Notification G.S.R. 407(E), the Drugs (Third Amendment) Rules, 2026
Dated	May 22, 2026
Published	Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 366, May 25, 2026
Takes effect	After three months from publication in the Official Gazette; counted from May 25, 2026, about August 25, 2026
Amends	Schedules B and B(1) of the Drugs Rules, 1945 (substituted)
Applies to	Test or analysis by the Central Drugs Laboratories or State Drugs Laboratories (Schedule B), and by the Pharmacopoeial Laboratory for Indian Medicine (PLIM) or the Government Analyst (Schedule B(1))
Schedule B	Part-A, tests and assays of drugs; Part-B, 89 tests for sera and vaccines; Part-C, 7 tests for homeopathic and herbal medicines
Schedule B(1)	25 items, from ₹100 to ₹25,000
Yearly increase	Fees "shall automatically increase by 5% annually" (both schedules)
Tests not listed in Schedule B	Charges determined by the Director or the Government Analyst of the laboratory or institute
Draft	G.S.R. 52(E), January 22, 2026; copies available January 27, 2026; no objections or suggestions received
Legal basis	Sections 12 and 33 of the Drugs and Cosmetics Act, 1940, after consultation with the Drugs Technical Advisory Board
File number	F. No. X.11014/14/2025-DR-Part(2)
Signed by	Harsh Mangla, Joint Secretary

Selected fees in the new Schedules B and B(1)

Schedule and item	Test	Rupees
Schedule B, Part-A, 1(15)	Determination of Lethal doses, LD10 or LD50 in mice	25000
Schedule B, Part-A, 2(5)(a)	Sterility test: Parenteral preparations (without membrane filtration)	1000
Schedule B, Part-A, 2(10)(b)	Bacterial Endotoxin Test: Quantitative	4500

Schedule B, Part-A, 4(10)(b)	Dissolution test: H.P.L.C.	1500
Schedule B, Part-A, 5(3)(d)	Assays: Chromatography: H.P.L.C.	1500
Schedule B, Part-B, 1(9)	Potency Hepatitis B component	12000
Schedule B, Part-B, 1(36)	Potency for tetanus Vaccine	45000
Schedule B, Part-B, 1(89)	Protocol Scrutiny	2500
Schedule B, Part-C, 1(7)	U.V. or I.R. or H.P.L.C or H.P.T.L.C determination	500
Schedule B(1), 17	HPLC Pressure liquid Chromatography	4000 each
Schedule B(1), 24	Test for pesticide residue (Organochlorine pesticide, Organophosphorus Pesticide, pyrethroids pesticide)	6000

The notification (PDF, 1.5 MB)

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