October 28, 2026

CDSCO

Draft sets a no-growth limit for Grade A sterile areas

Draft G.S.R. 953(E) would replace Table 3 of Schedule M Part II, so Grade A clean areas for sterile products show no growth instead of under 1 CFU.

G.S.R. 953(E) IS A NOTIFICATION of the Ministry of Health and Family Welfare (Department of Health and Family Welfare), dated October 28, 2026, publishing draft rules further to amend the Drugs Rules, 1945. It appears in the Gazette of India, Extraordinary, Part II, Section 3, Sub-section (i), No. 852, dated October 29, 2026. The Central Government proposes to make the rules under sub-section (1) of section 12 and sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940, after consultation with the Drugs Technical Advisory Board. CDSCO lists it as a draft "for Revision of Microbial Contamination Limits for Grade A Areas under Schedule M to align with WHO Standards"; the draft's own text does not mention the WHO.

KEY FACTS

AUTHORITY
CDSCO

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Ministry of Health and Family Welfare (Department of Health and Family Welfare)

DOCUMENT
G.S.R. 953(E), draft rules: the Drugs (..... Amendment) Rules, 2026



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The draft substitutes Table 3, "Recommended limits for microbial contamination", under para 4.9 of Requirement 4 in Part II of Schedule M. Part II sets the specific requirements for the manufacture of sterile products, parenteral preparations (small volume injectables and large volume parenterals) and sterile ophthalmic preparations. The table gives limits in colony-forming units (CFU) for four methods: air sample (CFU/m3), settle plates of 90 mm diameter (CFU/4 hours), contact plates of 55 mm diameter (CFU/plate) and glove print of 5 fingers (CFU/glove).

The only change is to Grade A. In the Schedule M notified by G.S.R. 922(E) of December 28, 2023, the Grade A limit is "<1" for all four methods. The draft replaces those four figures with one entry, "No growth". The Grade B, C and D figures stay as they are, as the table below shows. Para 4.9 of that Schedule M, which the draft does not change, says the sampling methods and numerical values in the table "are not intended to represent specifications, but are for information only". The draft's table ends with the Grade D row and does not carry the two notes printed under the current table, that the figures are average values and that individual settle plates may be exposed for less than four hours; it does not say whether those notes stay.

The rules are to be called the Drugs (..... Amendment) Rules, 2026, with the number left blank, and would come into force from the date the Government specifies at the time of their final publication in the Official Gazette. The draft will be taken into consideration on or after the expiry of thirty days from the date copies of the Gazette containing it are made available to the public. Objections and suggestions may be addressed to the Under Secretary (Drugs), Ministry of Health and Family Welfare, U-6, Work Hall- C Wing, First Floor, Kartavya Bhawan-1, New Delhi, 110001, or emailed to drugsdiv-mohfw@gov.in.

The draft gives no end date for comments. Its e-Gazette ID, CG-DL-E-03112026-277619, and its digital signature date the copy November 3, 2026; thirty days counted from then end on December 3, 2026. It is signed by Pushpendra Rajput, Joint Secretary, under F. No. X.11014/23/2026-DR. No final rules had appeared by November 7, 2026.

Issued by	Ministry of Health and Family Welfare (Department of Health and Family Welfare)
Document	G.S.R. 953(E), draft rules: the Drugs (..... Amendment) Rules, 2026
Dated	October 28, 2026
Gazette	Extraordinary, Part II, Section 3, Sub-section (i), No. 852, October 29, 2026
Gazette ID	CG-DL-E-03112026-277619; the e-Gazette copy is dated November 3, 2026
Amends	Drugs Rules, 1945: Schedule M, Part II, Requirement 4, para 4.9, Table 3 (substituted)
Applies to	Manufacture of sterile products, parenteral preparations (small volume injectables and large volume parenterals) and sterile ophthalmic preparations
Grade A, proposed	No growth
Grade A, current	<1 for air sample, settle plates, contact plates and glove print (Schedule M as notified by G.S.R. 922(E), December 28, 2023)
Grades B, C and D	Unchanged
Takes effect	From the date the Government specifies at the time of final publication in the Official Gazette
Comment period	Thirty days from the date copies of the Gazette are made available to the public; no end date is given. Counted from November 3, 2026, the date of the e-Gazette copy, thirty days end on December 3, 2026
Send comments to	Under Secretary (Drugs), Ministry of Health and Family Welfare, Government of India, U-6, Work Hall- C Wing, First Floor, Kartavya Bhawan-1, New Delhi, 110001, or drugsdiv-mohfw@gov.in
Final rules	None by November 7, 2026
Signed by	Pushpendra Rajput, Jt. Secy.
File number	F. No. X.11014/23/2026-DR

Table 3: recommended limits for microbial contamination, current and proposed

Grade	Air sample (CFU/m3)	Settle plates, diameter 90 mm (CFU/4 hours)	Contact plates, diameter 55 mm (CFU/plate)	Glove print, 5 fingers (CFU/glove)	Proposed by the draft
A	<1	<1	<1	<1	No growth

B	10	5	5	5	Unchanged
C	100	50	25	--	Unchanged
D	200	100	50	--	Unchanged

The notification (draft rules) (PDF, 750 KB)

Source: Gazette of India, CG-DL-E-03112026-277619.

Checked against the official copy on November 7, 2026.

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