October 28, 2026

CDSCO

Draft would require an authorized person for drug batch release

Draft G.S.R. 955(E) would require drug licence applicants to authorize a qualified person for batch release and keep batch release records under Schedule U.

G.S.R. 955(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. 854, dated October 29, 2026. The Central Government proposes to make the rules under sub-section (1) of section 33 of the Drugs and Cosmetics Act, 1940, after consultation with the Drugs Technical Advisory Board.

KEY FACTS

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

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G.S.R. 955(E), draft rules: the Drugs (..... Amendment) Rules, 2026



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The draft inserts a new rule 68C after rule 68B: "The applicant for the grant of a licence under this part shall authorize a person, for batch release in compliance to Schedule M, with appropriate qualification and experience. Records for batch release of each batch of the drugs manufactured shall be prepared as per the particulars given in Schedule U." It adds a proviso in the same words to rule 122G(1), after clause (iii), for an applicant for a licence under Form 28E. It adds "and records of batch release" to rule 74(d) and "and batch release" to rule 78(c)(i), each after the word "manufacture". In rules 74A(f), 74B(3) and 78A(3), and in paragraph J, Records, of Part XII-C of Schedule F, on the manufacture of blood products, it adds: "The licensee shall also keep records of batch release as per the particulars given in Schedule U of each batch of the drugs manufactured by him."

The draft adds a new entry IV to Schedule U, before its footnote: "Particulars to be recorded in Batch Release Certificate". It lists 21 items, set out in the table below, from the certificate number to the analytical report number. A "Certificate of Conformity" follows, in which the authorized person certifies, with date and signature, that the batch was manufactured, including packaging, and tested at the named sites in compliance with the GMP requirements under the Drugs Rules, 1945.

The draft does not say what qualification or experience the authorized person needs, beyond "appropriate", Rule 68C and the Form 28E proviso speak of the applicant for a licence; the draft does not say whether a licensee that already holds a licence must also authorize a person. The rules are to be called the Drugs (..... Amendment) Rules, 2026, with the number left blank, and would come into force three months after their 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-03112026-277607, 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.11014/16/2026-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. 955(E), draft rules: the Drugs (..... Amendment) Rules, 2026
Dated	October 28, 2026
Gazette	Extraordinary, Part II, Section 3, Sub-section (i), No. 854, October 29, 2026
Gazette ID	CG-DL-E-03112026-277607; the e-Gazette copy is dated November 3, 2026
Amends	Drugs Rules, 1945: new rule 68C; rules 74, 74A, 74B, 78, 78A and 122G; Schedule F, Part XII-C; Schedule U, new entry IV
Applies to	Applicants for and holders of drug manufacturing licences under the amended rules, including Form 28E
Requirement	Authorize a person with appropriate qualification and experience for batch release in compliance with Schedule M
Records	Batch release records for each batch, with the particulars in Schedule U
Batch Release Certificate	21 particulars and a Certificate of Conformity signed by the authorized person
Takes effect	Three months after publication of the final rules 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.11014/16/2026-DR

Schedule U, entry IV: particulars to be recorded in the Batch Release Certificate

No.	Particular
1	Certificate Number.
2	Name and dosage form of the product.

3	Active ingredient(s) and their amount(s) per unit dose.
4	Licence Number and date of issue.
5	Batch/ Lot number.
6	Batch/ Lot size.
7	Manufacturing date.
8	Expiry/ Re-test date.
9	Name and address of all manufacturing site(s).
10	Name and address of all testing site(s).
11	Name and address of marketer.
12	Details of qualified equipments have been used.
13	Details of Environmental Monitoring Records.
14	Details of Batch Manufacturing Records.
15	Details of Batch Packaging Records.
16	Details of Line Clearance.
17	Details of IPQC test reports.
18	Details of protocols for tests applied.
19	Certificate of Analysis.
20	Result of analysis.
21	Analytical report number.

The notification (draft rules) (PDF, 706 KB)

Source: Gazette of India, CG-DL-E-03112026-277607.

Checked against the official copy on November 7, 2026.

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