
October 12, 2026

CDSCO

Approved r-DNA drugs exported under a new brand need no NOC

A CDSCO notice of October 12, 2026 says a CT-23 holder exporting the same r-DNA product under a new brand may apply in Form 28-D without an export NOC.

THE CENTRAL DRUGS Standard Control Organization (CDSCO), Directorate General of Health Services, issued a notice dated October 12, 2026 (r-DNA-15011(12)/119/2026-eoffice, E-office no. 41325) on whether a separate Export NOC from CDSCO is needed to export r-DNA drug products that

are already approved. The notice says stakeholders have been asking CDSCO about this. It is signed by Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India) cum Central Licensing Authority, and addressed to all State and Union Territory Drugs Controllers and all stakeholders.

KEY FACTS**AUTHORITY****CDSCO**

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Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services

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Notice, r-DNA-15011(12)/119/2026-eoffice (E-office no. 41325)

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The Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services, issued a notice dated October 12, 2026 (r-DNA-15011(12)/119/2026-eoffice, E-office no. 41325) on whether a separate Export NOC from CDSCO is needed to export r-DNA drug products that are already approved. The notice says stakeholders have been asking CDSCO about this. It is signed by Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India) cum Central Licensing Authority, and addressed to all State and Union Territory Drugs Controllers and all stakeholders.

Where a firm holds a valid Marketing Authorization in Form CT-23 for a particular r-DNA drug product and seeks product permission in Form 28-D to export the same product, a separate Export NOC from CDSCO is not required, provided three conditions are met. The product must be the same as the one authorized under the valid Marketing Authorization. There must be no change in the approved composition, specifications, strength, dosage form, presentation, packaging configuration, manufacturing site, manufacturing process or other critical product particulars. And the only difference must be the brand name proposed exclusively for export.

CDSCO gives its reasoning: the product has already been evaluated and granted Marketing Authorization, and a different brand name used only for export, with no substantive change in the product or its approved quality attributes, does not by itself call for a separate Export NOC. Eligible applicants may therefore submit the Form 28-D application for export directly through the ONDLS portal to the concerned State Licensing Authority (SLA). That authority processes it and forwards it to the Central Licensing Approving Authority (CLAA) for consideration or approval under the applicable statutory and regulatory requirements.

The clarification applies only where the identity and approved quality attributes of the product remain unchanged and the export-specific brand name is the sole difference from the authorized product. For all other r-DNA products and cases not covered, the firm must obtain a Quantity-Specific Export NOC from CDSCO under the existing procedure. The notice asks all stakeholders to take note of the clarification and comply. It does not state a separate date from which it applies.

Issued by	Central Drugs Standard Control Organization (CDSCO), Directorate General of Health Services
Document	Notice, r-DNA-15011(12)/119/2026-eoffice (E-office no. 41325)
Dated	October 12, 2026
Applies to	Firms holding a valid Marketing Authorization in Form CT-23 for an r-DNA drug product

Condition	Same product, no change in approved particulars, and only the export brand name differs
Application	Form 28-D on the ONDLS portal to the State Licensing Authority, forwarded to the Central Licensing Approving Authority
All other r-DNA cases	Quantity-Specific Export NOC from CDSCO still required
Signed by	Dr. Rajeev Singh Raghuvanshi, Drugs Controller General (India) cum Central Licensing Authority

[The notice](#) (PDF, 101 KB)

Source: [CDSCO's own copy](#).

Checked against the official copy on October 20, 2026.

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