

r-DNA-15011(12)/119/2026-eoffice (E-office no. 41325)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization

FDA Bhawan, Kotla Road,
New Delhi 110002

Dated: **12 OCT 2026**

Notice

Subject: Clarification regarding requirement of Export NOC for already approved r-DNA products – reg.

It has been observed that queries are being received from various stakeholders regarding the requirement of obtaining a separate Export NOC from CDSCO for export of already approved r-DNA drug products.

In this regard, it is hereby clarified that where a firm holds a valid Marketing Authorization in Form CT-23 for a particular r-DNA drug product and intends to seek product permission in Form 28-D for export purposes in respect of the same product, a separate Export NOC from CDSCO shall not be required, provided that:

1. the product is the same as the product already authorized under the valid Marketing Authorization;
2. there is no change in the approved composition, specifications, strength, dosage form, presentation, packaging configuration, manufacturing site, manufacturing process or other critical product particulars; and
3. the only difference is the brand name proposed exclusively for export purposes.

Since the product has already been evaluated and granted Marketing Authorization by the CDSCO, and there is no substantive change in the product or its approved quality attributes, the use of a different brand name exclusively for export purposes, by itself, shall not necessitate a separate Export NOC from CDSCO.

Accordingly, eligible applicants may directly submit an application for grant of product permission in Form 28-D for export purposes through the ONDLS portal to the concerned State Licensing Authority (SLA), without obtaining a separate Export NOC from CDSCO. The application shall thereafter be processed by the concerned authority and forwarded to the Central Licensing Approving Authority (CLAA), for consideration/approval, in accordance with the applicable statutory and regulatory requirements.

The above clarification shall be applicable only where the identity and approved quality attributes of the product remain unchanged and the proposed export-

specific brand name is the sole difference from the already authorized product.

For all other r-DNA products/cases not covered under the above clarification, the firm shall be required to obtain a Quantity-Specific Export NOC from CDSCO, as per the existing/established regulatory procedure.

All stakeholders are advised to take note of the above clarification and comply accordingly.



(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)
Cum Central Licensing Authority

To

1. All State/U.T Drugs Controllers
2. All Stakeholder