File No.:VAC-11011(11)/10/2025-eoffice [E Comp. No.:27052]

Ministry of Health and Family Welfare
Directorate General of Health Services
Central Drugs Standard Control Organization (HQ)
(Biological Division)

FDA Bhawan, Kotla Road
New Delhi -110002
Date: 03 SEP 2025

Circular

Sub: Acceptance of the IBSC approval for seeking permission to manufacture test items for examination, test and analysis through form CT 10 as per the recommendation of the 314th RCGM meeting, dated 09.07.2025.

This is with reference to the letter no. PID-15011(11)/3//2021-PPB-DBT, dated 21.07.2015 from the Member Secretary, RCGM, Department of Biotechnology, Ministry of Science and Technology, Government of India (copy enclosed) on the subject matter for your information and further necessary action.

(Dr. Rajeev Singh Raghuvanshi)
Drugs Controller General (India)

To:

1. All Biopharmaceutical manufacturers (Vaccine/r-DNA/others).

भारत सरकार
विज्ञान और प्रौद्योगिकी मंत्रालय
जैव प्रौद्योगिकी विभाग
GOVERNMENT OF INDIA
MINISTRY OF SCIENCE & TECHNOLOGY
DEPARTMENT OF BIOTECHNOLOGY

सत्यमेव जयते

आज़ादी का अमृत महोत्सव

ब्लॉक-2, (6-8वाँ तल), एवं ब्लॉक-3, (4-5वाँ तल)
सी0जी0ओ0 कॉम्प्लेक्स लोधी रोड, नई दिल्ली-110003
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Tele : 011-24365071 Fax : 011-24362884
Website : http://www.dbtindia.nic.in

No. PID-15011(11)/3//2021-PPB-DBT **Dated: 21.07.2025**

To

The Drug Controller General of India,
Central Drugs Standard Control Organization,
FDA Bhawan, ITO,
Kotla Road, New Delhi- 110 002.

Subject: Acceptance of the IBSC approval for seeking permission to manufacture test items for examination, test and analysis through form CT 10… reg.

Sir,

In its 314th meeting of RCGM held on 09.07.2025, deliberated on the subject mentioned above, and recommended the following.

2. According to the Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017 (Refer page nos 28-30 of 148), category I experiments may be commenced after intimating the IBSC, while category II experiments may be initiated subsequent to the IBSC approval and an intimation to the RCGM. However, all category III and above GE experiments shall require prior authorization from IBSC and subsequent approval from the RCGM before the commencement of the experiments through submission of information in the prescribed proforma.

3. Given the same, Category I and Category II GE experiments in laboratory do not require RCGM approval and regulatory pathways as defined in the Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017 to be followed. However, the biopharma industries are still submitting form C1 for RCGM consideration to carry out R&D and submitting the corresponding RCGM approval letter to CDSCO in the process of seeking approval for examination, test & analysis and attaching the same with Form CT 10.

4. Therefore, it is requested to accept IBSC approval from Biopharma industries for submission of form CT 10 seeking permission for manufacturing of test items for examination, test and analysis in cases where the test item is generated using Category I and Category II GE Experiments as defined in the Regulations and Guidelines for Recombinant DNA Research and Biocontainment, 2017.

Yours faithfully,

(Dr. Nitin K. Jain)
Member Secretary, RCGM &
Scientist-'G', DBT

Copy to:

NIC-DBT for uploading on DBT website & IBKP