File No.: 12-01/20-DC (Pt.51)
Central Drug Standard Control Organization
Directorate General of Health Services
Ministry of Health and Family Welfare
New Drugs Division

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Notice

The FAQs on New Drugs & Clinical Trial Rules 2019 are already uploaded in the website of CDSCO. In this regard, concerns have been raised regarding applicability of the rules in case of drugs not considered as new drugs as well as submission and processing of applications for grant of permission to manufacture trial batches of new drug or investigational new drug for test and analysis, CT or BA/BE study.

In view of above, three Questions (No. 01, 47 & 65) are hereby updated and one additional question is included as under for bringing clarity in these aspects:

1. **Whether the New Drugs and Clinical Trial Rules, 2019 (NDs & CTs Rules, 2019) is applicable only for New Drugs and Investigational New drugs for human use?**

   Yes, the New Drugs & Clinical Trials Rules 2019, is applicable for new Drugs and Investigational New drugs for human use and not applicable for drugs which are not considered as new drugs or investigational new drugs.

   The regulation of New drugs for veterinary use will continue to be as per Part XA of the Drugs and Cosmetics Rules, 1945.

47. Is permission required to conduct a BA/BE study of a drug (not covered under the definition of new drug) in human subjects?

A new drug is approved in respect of its composition, dosage form, indication, use, patient population etc. A new drug is approved for marketing to be used for treatment of disease in patients or in certain cases in healthy persons for prophylactic use such as vaccine. Therefore, in case the drug is truly not a new drug, in respect of composition, dosage form, indication, use, patient population etc. no permission from CLA may be required for conduct of BA/BE study of such drug. However, it is expected that such

study needs to be conducted with due approval of the respective ethics committee and other applicable guidelines in this regard.

65. Where should I submit my application for obtaining permission to manufacture new drug or investigational new drug for test and analysis or CT or BA/BE study?

A. For Biological Drugs:

CDSCO, HQ, for test and analysis or CT or BA/BE study

B. For Drugs other than Biologicals:

(a) zonal office/sub zonal office for pure chemical test and

(b) zonal office/sub zonal offices or CDSCO HQ for CT or BA/BE study

Further, in case permission to manufacture new drugs / investigational new drug for CT or BA/BE study is obtained it shall automatically be considered as the permission issued for other chemical/physical test and analysis.

Examples:

(i) Case 1:
In case the application is for grant of permission to manufacture new drug or Investigational new drug for test and analysis, applicant shall submit its application to the respective Zonal Office / Sub Zonal Offices of CDSCO for grant of permission to manufacture the drug for test and analysis purpose only subject to condition that, in case the applicant intends to use the new drug or investigation new drug manufactured under the said permission for CT or BA/BE study in humans also, the same should be done after obtaining the necessary permission to conduct the CT or BA/BE study and ensuring that the product was manufactured in accordance with the principles of GMPs.

(ii) Case 2:
In case the application is for grant of permission to manufacture new drug / Investigational new drug for CT or BA/BE study in human, the applicant can submit application to the respective Zonal Office / Sub Zonal Offices of CDSCO for grant of permission to manufacture the drug for the CT or BA/BE study provided the applicant has already obtained permission to conduct the CT or BA/BE study, as the case may be, from CDSCO, HQ. However, in case the applicant intends to apply for permission to manufacture new drug / Investigational new drug for CT or BA/BE study in human to CDSCO, HQ, the applicant can do so and submit the application to HQ as well along with CT or BA/BE study permission, as the case may be both option is open for the

applicant for manufacturing for CT or BA/BE.

(iii) Case 3:
In case an applicant submits its application for permission to manufacture the test batches of new drug or investigational new drug along with application for grant of permission to conduct the CT or BA/BE study in humans to CDSCO, HQ, such application will be processed and disposed-off by the HQ.

123. where should I mention in the application regarding the site of manufacturing for test and analysis (which will finally appear in the permission given by your office).

It is required that applicant shall clearly mention in their application, the site where the product will be manufactured in the following fashion:

M/s. abc.....(name & address of the firm) having manufacturing premises for test and analysis at xyz.....(name & address of the manufacturing site for test and analysis).

V.G.S.

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