F.No. 12-01/19-DC(PT-195)

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Date: 21/12/2020

NOTICE

Subject: Permission to conduct BA/BE study and clinical trial – reg.

Under the provision of New Drugs and Clinical Trials Rules 2019, CDSCO receives applications for grant of permission to conduct clinical trial/BA-BE study as part of requirements for grant of permission to manufacture or import of new drugs.

Concerns have been raised and changes have been proposed for processing and approval of such applications for conduct of clinical trial/BA-BE permission simultaneously.

In this regard, it is to mention that, in general, such applications are processed in accordance with the New Drugs and Clinical Trials Rules, 2019, and if found satisfactory, permission to conduct BA/BE study and clinical trial are granted simultaneously, subject to condition that CT should be conducted after submission of BA/BE study result.

Yours faithfully,

(Dr. V.G. Somani)
Drugs Controller General (India)

To,

1. **All Stakeholders.**

F.No. 12-01/19-DC(PT-195)

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Date: 21/12/2020

NOTICE

Subject: Approval of FDCs containing new drugs – reg.

CDSCO receives and process application for approval of FDCs in accordance with the provisions of New Drugs and Clinical Trials Rules 2019.

Concerns have been raised that FDCs containing new drugs are approved only after approval of individual new drugs.

In this regard, it is clarified that there is no such requirement that approval process of new drug and FDC containing that particular new drug are sequential and first approval of new drug needs to be obtained followed by approval of FDC containing that particular new drug.

As per the requirements of Paragraph 4 of Second Schedule of the New Drugs and Clinical Trials Rules, 2019, the first group of Fixed Dose Combinations (FDCs) includes those in which one or more of the active ingredients are a new drug. For such Fixed Dose Combinations (FDCs) to be approved for marketing data to be submitted will be similar to data required for any new drug (including clinical trials). However, such issues are examined as case-by case basis depending of nature of the products, indication, etc in consultation with the SEC to ensure safety and efficacy of the FDC.

Yours faithfully,

(Dr. V.G. Somani)
Drugs Controller General (India)

To,

1. All Stakeholders.

F.No. 12-01/19-DC(PT-195)

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Date: 21/12/2020

NOTICE

Subject: Fixing of limit of impurities in the specification of INDs – reg.

CDSCO receives and process application for clinical trial of Investigational New Drugs (INDs) in accordance with the provisions of New Drugs and Clinical Trials Rules 2019.

Concerns have been raised regarding the fixing of limits of impurities in the specifications of such INDs.

In this regard, it is clarified that IP prescribes the general limits for impurities in the specifications. However, the applicant when submit scientific justifications in support of limits of impurities beyond that specified in IP, the same are considered and accepted.

Yours faithfully,

(Dr. V.G. Somani)
Drugs Controller General (India)

To,

1. All Stakeholders.

F.No. 12-01/19-DC(PT-195)

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Date: 21/2/2020

NOTICE

Subject: Pre-submission meeting – reg.

Under the provision of New Drugs and Clinical Trials Rules 2019, any person who intends to make an application for grant of licence or permission for import or manufacture of new drugs or to conduct clinical trial may, request by making an application in writing, for a pre-submission meeting with the Central Licencing Authority or any other officer authorised by the Central Licencing Authority for seeking guidance about the requirements of law and procedure of such licence or permission of manufacturing process, clinical trial and other requirements.

In this regard, it is to mention that as and when application for a pre-submission meeting is received, meetings are conducted and guidance about the requirements of law and procedure for licence or permission of manufacturing process, clinical trial and other requirements are provided by CDSCO in writing to the applicant, in accordance with the New Drugs and Clinical Trials Rules, 2019.

Yours faithfully,

(Dr. V.G. Somani)
Drugs Controller General (India)

To,

1. All Stakeholders.

F.No. 12-01/19-DC(PT-195)

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Date: 21/2/2020

NOTICE

Subject: Sub-acute toxicity study report for injectable products for BA/BE study in human for export - reg.

CDSCO receives and process application for permission to conduct BA/BE study in human for export.

Concerns have been raised that sub-acute toxicity study report in at least two species for minimum 14 days is required to be submitted for innovator products.

In this regard, it is clarified that sub-acute toxicity data for innovator products are neither required nor asked for conduct of BA/BE study in human for export.

Yours faithfully,

(Dr. V.G. Somani)
Drugs Controller General (India)

To,

1. All Stakeholders.

F.No. 12-01/19-DC(PT-195)

Government of India
Directorate General of Health Services
Central Drugs Standard Control Organization
Office of Drugs Controller General (India)
(New Drugs Division)

FDA Bhawan, Kotla Road,
New Delhi-110002
Date: 2/12/2020

NOTICE

Subject: Requirement of Stability Data for COPP – reg.

Certificate of Pharmaceutical Product (COPP) is issued under the WHO GMP Certification Scheme for the purpose of international commerce i.e. for registration of products in foreign countries.

Concerns have been raised regarding requirement of stability data on the commercial batches before grant of WHO GMP and COPP.

In this regard, it is clarified that if the stability data is generated during development stage as per the WHO guidelines, no further stability data on the commercial batches are required before grant of WHO GMP and COPP.

Yours faithfully,

(Dr. V.G. Somani)
Drugs Controller General (India)

To,

1. **All Stakeholders.**