



**DRUGS CONTROL ADMINISTRATION
Government of Telangana**



Circular. No. 09/DCA-Peshi/2024.

Dated : 28-05-2024

CIRCULAR

Sub: Collection of Plasma or any other biological matrices by Clinical Research Organizations, Bioavailability and Bioequivalence Study Centres from Blood Centres for bioanalytical purposes – Reg.

Ref: Letter dated: 04-04-2024 received from representatives of certain BA/BE Centres / CROs in Hyderabad.

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It has come to the notice of the Drugs Control Administration, Telangana, that certain BA/BE Centers and CROs are sourcing plasma and other biological matrices, such as blood and serum, for bioanalytical purposes, including bioanalytical method development and validation, and study sample analysis, from certain third-party entities who are collecting plasma and other biological matrices from Blood Centers without permission in an unauthorized manner. Such unauthorized collection, stocking, and sale of blood or blood components from Blood Centres is an offence punishable under the Drugs and Cosmetics Act, 1940.

The BA/BE Centres/CROs that hold requisite registrations issued by CDSCO may source plasma and other biological matrices **directly** from blood centers after making a contractual agreement/MoU indicating the roles and responsibilities of both BA/BE Centres/CROs and Blood Centres regarding the supply of plasma and other biological matrices.

The Contract Agreement / MoU for the collection of plasma and other biological matrices from blood centers for bioanalytical purposes, including bioanalytical method development and validation, and study sample analysis, shall be maintained by the BA/BE Centres/CROs along with the relevant Standard Operating Procedures (SOPs), and labels used in this regard.

Kanalaranah
28/5/2024

DIRECTOR GENERAL

To
All the BA/BE Centres, CROs in the State.
All the Blood Centres in the State.

Copy to :

All the Drugs Inspectors in the State are instructed to communicate to the Blood Centres, BA/BE Centres, CROs in their jurisdiction.
All the Assistant Directors in the State for information.
The Joint Director and all the Deputy Directors in the State for information.

Copy submitted to :

The Drugs Controller General (India), CDSCO, New Delhi for information. (by e-mail)
The Deputy Drugs Controller (India), CDSCO for information. (by e-mail)