File No. QMS/38/Misc/2024
Directorate General of Health Services
Central Drugs Standard Control Organization
(QMS Monitoring Division)

Dated:

Circular

07 AUG 2024

Subject: Implementation of Schedule M and WHO Technical Report Series (TRS) - regarding.

This is with reference to revision of Schedule M vide GSR No. 922(E) dated 28.12.2023 and various WHO TRS guidelines including WHO TRS 1044 Annexure-2 "WHO good manufacturing practices for sterile pharmaceutical products" which are published by WHO from time to time.

In this regard, it is requested that all manufacturers should take necessary steps for compliance with respect to various requirements as per above guidelines after due gap analysis.

This is for information and necessary compliance.

Yours faithfully,

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

To

1. All vaccine manufacturers/Sterile product manufacturers.
2. All State Drugs Controllers.
3. All Zonal / Sub Zonal offices of CDSCO.
4. CDSCO website.
5. DCG(I) guard file.