MINUTES OF 55th MEETING OF THE TECHNICAL COMMITTEE HELD ON 30.04.2026 FROM 03:00 PM ONWARDS UNDER THE CHAIRMANSHIP OF DGHS FOR SUPERVISING CLINCAL TRIALS ON NEW CHEMICAL ENTITIES IN LIGHT OF DIRECTIONS OF THE HON'BLE SUPREME COURT OF INDIA ON 03.01.2013

Present:

1.	**Dr. Sunita Sharma** Director General of Health Services, Ministry of Health &Family Welfare, New Delhi.	**Chairman**
2.	**Dr. Desh Deepak** Professor and Head, Dept. of Chest & Respiratory Medicine, Ram Manohar Lohia Hospital, New Delhi.	**Member**
3.	**Dr. Pushpendra Verma** Professor, Dept. of TB & Chest Medicine, Lady Harding Medical College & Hospital, New Delhi.	**Member**
4.	**Dr. Nitesh Gupta** Associate Professor, Dept. of Pulmonary Medicine, VMMC & Safdarjung Hospital, New Delhi.	**Member**
5.	**Dr. Manikrao Ghadlinge** Professor & Head, Dept. of Pharmacology, Ram Manohar Lohia Hospital, New Delhi.	**Member**
6.	**Dr. Rajeev Singh Raghuvanshi**, Drugs Controller General(India), New Delhi.	**CDSCO**

The chairman welcomed the members of the Committee for 55th Technical Committee meeting. Thereafter, 01 proposal was placed before the Committee for deliberation. The Committee discussed the one proposal and gave its recommendation.

Minutes of 55th meeting of the Technical Committee held on 30.04.2026 from 03:00 pm onwards under the chairmanship of DGHS for supervising clinical trials on new chemical entities in light of directions of the Hon'ble Supreme Court of India on 03.01.2013

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT18/FF/2022/32804 Tezepelumab Solution for Injection (Tezspire 210 mg)	M/s. AstraZeneca Pharma India Limited	The firm's proposal for Marketing Authorization with waiver of local clinical trial was earlier discussed by the Subject Expert Committee (SEC) on 04.11.2022, 05.04.2023, and 16.12.2025. Wherein, the SEC recommended that the firm should conduct a Phase III clinical trial in India. However, the firm did not agree with this recommendation and requested a review by the Technical Committee. In this regard, the firm presented a proposal before the Technical Committee for the import and marketing of Tezepelumab Solution for Injection (210 mg), intended for subcutaneous administration, along with a request for a waiver of the local Phase III clinical trial. The proposed indication is as an add-on maintenance treatment for patients aged 12 years and older with severe asthma. The committee noted that the drug has already been approved in the USA, Switzerland, Brazil, Canada, the EU, Japan, and the UK, as presented by the firm. The committee observed the following: - a) The proposed therapy targets both T2 High and T2 Low asthma patients. However, the T2 Low subset represents a relatively small overall beneficiary population. b) The standard treatment options for severe asthma — inhaled bronchodilators and corticosteroids — are already available and widely used in clinical practice. Additionally, two biological therapies for T2 High Severe Asthma have already been

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			approved in India. c) The submitted data includes very limited number of Indian patients, which is insufficient to establish safety and efficacy to the Indian population. d) The proposal does not demonstrate any compelling unmet medical need or significant therapeutic benefit to justify waiver of the local Phase III clinical study in India. e) The current submission does not provide any substantial new evidence compared to previous submissions. After detailed deliberation, the committee does not recommend waiver of local clinical trials and recommended that, the firm should conduct Phase III clinical trials in adequate number of Indian population.