Recommendations of the SEC (Gastroenterology & Hepatology) made in its 16th/25 meeting held on 11.12.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/115/25 Online Submission (51359) Icotrokinra (JNJ-77242113)	M/s. Johnson & Johnson Pvt. Ltd.	In light of earlier SEC recommendation dated 08.10.2025, The firm presented phase III clinical trial protocol no. 77242113UCO3001 Amendment 1 dated 24 July 2025. After detailed deliberation, the committee opined that the firm shall submit the revised protocol based on the following observation for further review by the committee: In view of study design, Induction phase is 12 weeks and Maintenance study is 40 weeks (total 52 weeks) and long term extension study is 248 weeks. Icotrokinra clinical non responders Participants at Week 1-12 will enter the Maintenance Study from induction phase and continue to receive Icotrokinra daily dosing: a) Clinically non-responders patients in maintenance phase, Protocol should be mentioned in Schedules of Activities (SoA) visit in second week itself. Also, not mentioned clearly about measures to take complete mayo score in first two weeks (or) partial Mayo score in next two weeks for clinical non-responders patients and those patients should be discontinue by fourth weeks in the maintenance phase. b) The patients waiting period has not provided in the maintenance phase for participants those who are clinically non-responders in the induction phase for the continuation of medication in the patients how long will wait in the maintenance phase. (Only mentioned visit at 0, 4 and 8 weeks).
2.	CT/157/25 Online Submission (52787)	M/s. Clinical Trials Eli Lilly and Company India Pvt. Ltd.	The firm presented phase III clinical trial protocol no. protocol no.: N1T-MC-MALO amendment (a) dated 22 SEP 2025.

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	LY3298176 (Tirzepatide) LY3437943 (Retatrutide)		After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1. Interim analysis of safety data shall be submitted to CDSCO every 36 weeks till study duration. 2. Independent DSMB (country specific) shall be organized to closely monitor the safety related issues and quarterly report submitted to the Ethics Committee and CDSCO. Dr. Amit Goel and Dr. Rohit Gupta didn't participate.
BABE Division			
3.	BABE/CT05/FF/2025/ 50922 Trientine dihydrochloride oral solution 225 mg/mL (Equivalent to 150 mg/mL Trientine).	M/s. Actimus Biosciences Private Limited.	The firm presented the BA/BE study vide protocol No. TRIE-054 -25, Version: 00 Date: 08 July 2025 for export purpose only before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct of the study for export purpose only with condition that only those female subjects having a normal hemoglobin level before check in of each period to be enrolled in the study. Accordingly, the firm shall revise the protocol and submit to the CDSCO for review.
New Drugs Division			
4.	ND/MA/25/000067 Eluxadoline tablets 75 mg & 100 mg	M/s. PURE & CURE HEALTHCARE Pvt. Ltd.	In continuation to earlier SEC meeting dated 29.07.2025, firm presented BE study protocol of Eluxadoline Tablet 100 mg, under Fed Condition (Protocol No. BIOS/2025/176, Version no. 01, dated 25.09.2025), before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct BE study as per the protocol presented. Accordingly, the firm should submit the BE study report to CDSCO for further review by the committee, before initiating Phase-III clinical trial.

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5.	ND/MA/25/000135 Zastaprazan citrate Tablets 20 mg	M/s. Sun Pharma Laboratories Ltd.	The firm presented their proposal for grant of permission to manufacture and market drug, Zastaprazan citrate tablet 20 mg indicated for the treatment of Erosive gastroesophageal refluxdisease (GERD) along with the Bioequivalence study protocol (protocol No. 247-25, Version-01, Dated: 25.08.2025) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the bioequivalence study as per the protocol presented by the firm. The firm should submit the BE study report to CDSCO for further review by the committee.
SND Division			
6.	SND/CT/25/000123 Vonoprazan Tablets 10 mg and 20 mg	M/s. Torrent Pharmaceuticals Ltd.	The firm presented their proposal along with protocol for grant of permission to conduct Phase IV clinical Trial of Vonoprazan tablets 10 mg and 20 mg for approved indication before the committee. After detailed deliberation, the committee recommended to revise the protocol to increase the sample size considering the adequate distribution for each strength and indication. Clinical trial sites should be geographically distributed including 50% of Government sites. Accordingly, firm should submit the revised protocol to CDSCO for further review by the committee within 15 days.
FDC Division			
7.	FDC/MA/24/000106 Combikit of Clarithromycin IP 500 mg film coated tablet + Amoxycillin Trihydrate IP eq. to Amoxycillin 1000 mg film coated tablet +Pantoprazole Sodium IP 40 mg Enteric	M/s. Malik Lifesciences Pvt. Ltd.	In light of the earlier SEC recommendation dated 23.04.2025, the firm presented the proposal along with BE study report before the committee. After detailed deliberation, the committee considered the BE study report and recommended for grant of permission for manufacturing and marketing of the proposed FDC.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	coated tablet		
8.	FDC/MA/23/000224, FDC/80/2025-eoffice Sodium Alginate IP 250 mg + Sodium Bicarbonate IP 133.5 mg + Calcium Carbonate IP 80 mg per 5 ml suspension	M/s. Mascot Health Series Pvt. Ltd.	As per the condition mentioned in Form CT-23 dated 22.02.2024, the firm presented Active PMS protocol before the committee. After detailed deliberation, the committee recommended for conducting the Active PMS study. The result of the study should be submitted to CDSCO for review by the committee.