Recommendations of the SEC (Gastroenterology & Hepatology) made in its 10th/25 meeting held on 24.07.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/104/24 Online Submission (40064) Bl 456906 solution for injection 0.5 ml	M/s.PAREXEL International Clinical Research Private Limited	The firm presented protocol amendment version 4.0 dated 14-Mar-2025 Protocol No.:1404-0044. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/105/24 Online Submission (40067) Bl 456906 solution for injection 0.5 ml	M/s PAREXEL International Clinical Research Private Limited	The firm presented protocol amendment 3.0 dated 13 March 2025 protocol no. 1404-0064. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
3.	BIO/CT04/FF/2025/48211 1. Mirikizumab 300 mg/15 mL (20 mg/mL) solution for infusion in a single-dose vial 2. Mirikizumab 100 mg/mL solution in a single-dose prefilled pen for subcutaneous use	M/s Eli Lilly and Company (India) Pvt. Ltd.	The firm presented the proposal to conduct Phase IV clinical trial titled "A Phase 4, 24-Week, Multicenter, Open-Label, Single-Arm Study to Evaluate the Safety of Mirikizumab in Adults with Moderately to Severely Active Ulcerative Colitis in India" vide Protocol No. IT-IN-AMCC, Version 1.0 dated 10.09.2024. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial as per the protocol presented by the firm
BA/BE Division			
4.	BABE/CT05/FF/2025/47898 Trientine Tetrahydrochloride 300 mg tablet equivalent to 150 mg of trientine (dose 150 mg ×4 tablet =600 mg)	M/s Synergen Bio Pvt. Ltd.	The firm presented the BA/BE study for export purpose only vide protocol No.002-25 Version No.:02 Date: 07 May 2025 before the committee. After detailed deliberation, the committee recommended for grant of permission for the conduct of the study for export purpose only.
SND Division			
5.	SND/CT/22/000042 Pantoprazole Dual-Release Gastro-	M/s Sun Pharma Laboratories Limited	In light of earlier SEC recommendations dated 20.07.2022, firm presented the Phase IV clinical trial report titled "Dual Release Gastro-Resistant Pantoprazole 80

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	Resistant Tablets 80 mg		mg for Treatment of Partial or Non-Responders to Standard Dose of Proton Pump Inhibitor (PPI) in Gastroesophageal Reflux Disease (GERD) – A Prospective pH-Metry/ Impedance Controlled Study" before the committee. Also, firm stated that said study was conducted to generate additional data/information and will not be used for any regulatory approvals. After detailed deliberation, the committee recommended to accept the result of the Phase IV CT study and same may not be used for regulatory approvals.
6.	SND/MA/25/000108 Ursodeoxycholic Acid Tablets I.P 300 mg & 450 mg	M/s. Abbott India Limited	Firm presented their proposal for grant of permission to conduct Phase III CT Protocol vide protocol No. UDIL-324-0556, Version 1.0 dated 19.03.2025 to evaluate the efficacy and safety of Ursodeoxycholic Acid Tablets for the proposed additional indication, i.e., Management of Hepatic Dysfunction Associated with Dengue Infection before the committee. After detailed deliberation, the committee recommended to submit the revised Phase III CT protocol with following changes to CDSCO. 1) Study design should be double blind and two arm parallel i.e. first arm consisting of the study drug + SOC and second arm consisting of placebo+ SOC. 2) Subjects with elevated AST/ALT enzyme levels due to reasons other than Dengue viral infections should be excluded. 3) Number of subjects should be increased to establish primary endpoint statistically significant. 4) Inclusion criteria for ALT level should

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			be 200 IU/L to 1000 IU/L. 5) Mean change in ALT level for secondary endpoint should be defined in detail. Accordingly, firm should submit the revised Phase III CT protocol to CDSCO for further review by the committee
New Drugs Division			
7.	ND/MA/25/000062 Resmetirom 60 mg, 80 mg and 100 mg	M/s Sun Pharma Laboratories Limited	The firm has presented the proposal for grant of permission to manufacture and market of Resmetirom Tablets 60 mg/ 80 mg /100 mg along with BE study report and Phase III Clinical Trial Protocol before the committee. After detailed deliberation, the committee considered the BE study results of Resmetirom Tablets 100 mg and recommended for grant of permission to conduct Phase III clinical trial of Resmetirom 60 mg, 80 mg and 100 mg as per protocol presented by the firm (Protocol No- ICR/25/013, Version No- 1.0 dated 09.06.2025. Accordingly, the firm should submit Phase III clinical trial report to CDSCO for further review by the committee
8.	ND/CT/25/000016 Zastaprazan citrate Tablets 20 mg	M/s Sun Pharma Laboratories Limited.	The firm has presented the protocol for grant of permission to conduct the Phase III clinical trial of Zastaprazan Citrate Tablets 20 mg before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III Clinical Trial as per the protocol presented by the firm. Accordingly, the firm should submit Phase III clinical trial report to CDSCO for further review by the committee
FDC Division			
9.	FDC/MA/24/000124 Dexlansoprazole (as enteric coated pellets)	M/s MSN Laboratories Private Limited	The firm presented the proposal before the committee. The firm informed that they already have

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	60 mg + Domperidone (as sustained release pellets) 30 mg capsule		product permission of the same FDC from the state license authority and is available in the market. After detailed deliberation, the committee opined that the firm should surrender the product permission issued by SLA and submit copy of cancelled product permission to CDSCO for necessary action in the matter