Recommendations of the SEC (Gastroenterology & Hepatology) made in its 06th/24 meeting held on 20.06.2024 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/69/24 Online Submission (43308) EFRUXIFERMIN (EFX)	M/s. Klinera Global Services	The firm didn't turn up for presentation.
2.	CT/105/23 Online Submission (33163) JNJ-77242113	M/s. Johnson and Johnson Private Limited	The firm presented protocol amendment 3 dated 02 April 2024 protocol no. 7242113UCO2001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
Biological Division			
3.	E-17327 Infliximab powder for concentrate for solution for infusion 100mg	M/s. Reliance Life Sciences	The firm presented the clinical study report for the Phase IV study titled "A prospective, multi-centre, open label, phase IV study to evaluate safety and efficacy profile of Infimab™ in patients with moderate to severe Crohn's disease." vide Protocol No. RLS/PMS/2016/10 version 2.0 dated 04 May 2017. After detailed deliberation, the committee noted the results of the study
BA/BE Division			
4.	BABE/CT05/FF/2024 /41509 Rebamipide& Sodium Alginate Suspension (100mg & 500 mg per 10mL) and (100mg + 1000 mg per 10 mL)	M/s. Dr. Reddy's Laboratories Limited	The firm presented the Protocol No. CS23165, ver. 00 dated 05.01.2024 for BA/BE study for export purpose only. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BA/BE study for export purpose only.
New Drugs Division			
5.	ND/MA/23/000056 Elobixibat Tablets 5mg	M/s. Dr. Reddy's Laboratories Ltd.	The firm presented the Phase III clinical trial report of new drugs Elobixibat Tablets 5mg before the committee. After detailed deliberation, the committee recommended for the grant of permission to manufacture and market new drug drugs Elobixibat Tablets 5mg.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
6.	ND/MA/23/00000182 Linaclotide Capsules 290mcg	M/s. BDR Pharmaceuticals International Ltd.	The firm presented the proposal of grant of permission to manufacture and marketing of new drug Linaclotide Capsules 290mcg with justification for Bioequivalence and Phase III clinical trial waiver. After detailed deliberation, the committee noted that already one of the applicant has granted permission to conduct phase III clinical trial with BE waiver with proposed new drug Linaclotide Capsules vide SEC (Gastroenterology and Hepatology) dated 13.04.2022. Hence, the committee considered BE waiver only. However, the committee did not recommend the phase III clinical trial waiver and recommend that the firm should conduct phase III clinical trial. Accordingly, the firm should submit phase III clinical protocol for further consideration.
FDC Division			
7.	FDC/MA/19/000089 Sodium Alginate IP 250mg + Sodium Bicarbonate IP 133.5mg + Calcium Carbonate IP 80mg per 5mL Oral liquid	M/s. Naxpar Pharma Pvt. Ltd.	Firm's proposal could not be deliberated due to technical issue at their end.
8.	FDC/MA/24/000106 Combikit of Clarithromycin IP 500mg film coated tablet + AmoxycillinTrihydrate IP eq. to Amoxycillin 1000mg film coated tablet + Pantoprazole Sodium IP 40mg Enteric coated tablet	M/s. Malik Lifesciences Pvt. Ltd.	The firm presented their proposal along with request for Phase III CT waiver before the committee. The committee noted that: 1. FDC of Combipack each strips Contains: 1. Clarithromycin Tablets IP (2 Tablets) each Film Coated tablets contains: Clarithromycin IP 500mg, 2. Pantoprazole Tablets IP 40mg (2 tablets) Each enteric coated tablets contains: Pantoprazole Sodium IP eq. to Pantoprazole 40mg and 3. Amoxicillin Tablets USP 750mg (2 tablets) each film coated tablets contains: Amoxicillin Trihydrate IP eq. to Amoxicillin 750mg already declared as rational by Prof. Kokate committee. 2. A Clinical trial is registered on CTRI

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
			website CTRI/2011/11/002139 [Registered on: 17/11/2011] for the FDC of Comparator Agent as Amoxicillin 1000mg, Clarithromycin 500mg, Pantoprazole 40mg for 14 days twice daily and Intervention Amoxicillin 1000mg, Clarithromycin 500mg, Pantoprazole 40mg for 7 days twice daily. After detailed deliberation, the committee considered the Phase III CT waiver and recommended to conduct BE study. Accordingly, the firm should submit BE study protocol to CDSCO for further review by the committee.
9.	FDC/MA/24/000072 Pioglitazone Hydrochloride IP eq. To Pioglitazone 15mg/15mg + Ezetimibe IP 10mg/5mg tablets	M/s. Mankind Pharma	In light of the earlier SEC recommendation dated 14.05.2024, the firm presented their proposal along with in-vivo studies in animal model of NASH/NAFLD. Further, the firm informed that they have filed patent w.r.t subject FDC which is under review and publication. After detailed deliberation, the committee opined that the firm should submit the details of the patent filed along with more data published in peer reviewed journal on the subject FDC in the proposed indication, to CDSCO for further review by the committee.
SND Division			
10.	SND/MA/23/000273 Ursodeoxycholic Acid Tablets 150mg/300mg/ 450mg/600 mg	M/s. Abbott India Limited	In light of earlier SEC recommendations dated 14.05.2024. Now, the firm has stated that they had proposed Phase III clinical trial of Ursodeoxycholic acid tablet for indication of Non-Alcoholic Fatty Liver Disease (NAFLD) with transaminitis not on NAFLD only. Firm has also requested to reduce the sample size and duration of proposed clinical trial. After detailed deliberation, the committee noted that it is an inadvertent typographic error and to be corrected as NAFLD with transaminitis instead of NAFLD. However, other conditions the earlier SEC recommendation made on 14.05.2024 shall remain same.