Recommendations of the SEC (Gastroenterology & Hepatology) made in its 06th/25 meeting held on 23.05.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/141/24 Online Submission (46446) RO7790121	M/s Roche Products (India) Private Limited	In light of earlier SEC Recommendation dated 27.02.2025, the firm presented phase III clinical study protocol no. GA45331 version 1.0 dated 01 August 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. Dr. Vineet Ahuja and Dr. Govind Makharia didn't participate.
2.	CT/142/24 Online Submission (46507) RO7790121	M/s Roche Products (India) Private Limited	In light of earlier SEC Recommendation dated 27.02.2025, the firm presented phase III clinical study protocol no. GA45332 version 1.0 dated 22 August 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. Dr. Vineet Ahuja and Dr. Govind Makharia didn't participate.
3.	CT/28/24 Online Submission (38917) MORF-057	M/s PSI CRO Pharma India Pvt. Ltd	The firm presented protocol amendment version 3.0 dated 25 March 2025 protocol no. MORF-057-203. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	CT/125/22 Online Submission (38922) MORF-057	M/s PSI CRO Pharma India Pvt. Ltd	The firm presented protocol amendment version 3.0 dated 26 March 2025 protocol no. MORF-057-202. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
SND Division			
5.	SND/IMP/25/000019 Saccharomyces	M/s Dr. Reddys Laboratories Limited	Firm presented the proposal for import and market of Saccharomyces Boulardii CNCM I-745, 250 mg/ 8 ml powder and solvent for oral suspension for the

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	Boulardii CNCM I-745 250 mg/ 8 ml powder and solvent for oral suspension		- Treatment of acute infectious diarrhoea in adults and children. - Prevention and treatment of antibiotic associated colitis and diarrhoea. - In addition to vancomycin/ metronidazole treatment to prevent recurrence of Clostridium difficile disease (CDD). - Supportive in the treatment of diarrhea occurring in irritable bowel syndrome (IBS). Along with justification for BE waiver and CT waiver before the committee. The committee noted that Saccharomyces Boulardii 250 mg Sachets/ Capsules were already approved in India since 1997 and the applied product Saccharomyces Boulardii CNCM I-745, 250 mg/ 8 ml powder and solvent for oral suspension was approved in France, Hungary, Sweden and Bulgaria. After detailed deliberation, the committee recommended for grant of permission for import and market of Saccharomyces Boulardii CNCM I-745, 250 mg/ 8 ml powder and solvent for oral suspension with bioequivalence study waiver and clinical trial study waiver.
FDC Division			
6.	FDC/MA/25/000070 Ursodeoxycholic Acid IP 300mg + Vitamin E Acetate IP 200 mg Tablets	M/s Abbott India Limited	Firm did not turn up for the presentation.
7.	FDC/MA/24/000005 Domperidone Maleate IP eq. to Domperidone (10mg as immediate release and 20mg as sustained release) 30mg + Pantoprazole	M/s Akums Drugs & Pharmaceuticals Ltd.	In light of the earlier SEC recommendation dated 16.01.2024 & 17.01.2024, the firm presented the in-vitro study data/ test report before the committee. After detailed deliberation, the committee noted that 1. The Dissolution specification of Domperidone is not in line with the specifications mentioned in

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	Sodium IP eq. to Pantoprazole (As delayed release Tablet) 40mg uncoated bilayered tablet.		Indian Pharmacopeia (IP) for prolonged release tablets. 2. The presented data is not adequate to demonstrate the claim of Domperidone in both IR and SR form in the proposed FDC. Accordingly, the firm should submit above data for further review of the proposal.