Recommendations of the SEC (Gastroenterology & Hepatology) made in its 42nd meeting held on 23.11.2021 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/CT21/FF/20/22016 Plecanatide tablet 3 mg	M/s. MSN Private Limited	In light of earlier SEC meeting recommendation dated 18/08/2021, the firm presented the clinical trial protocol and justification for waiver of the BE study before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as per the protocol presented before the committee.
SND Division			
2.	SND/MA/21/000468 Pantoprazole Powder for Oral Suspension 40 mg	M/s. Alkem Laboratories	The firm presented the proposal along with the BE study protocol. After detailed deliberation, the committee recommended for grant of permission for conduct of BE study as per the protocol presented.
3.	SND/MA/21/000295 Esomeprazole Dual Release Gastro Resistant Tablets 80mg	M/s. Sun Pharma	In light of earlier SEC meeting recommendation dated 18/08/2021, the firm presented the clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as per the protocol presented.
GCT Division			
4.	CT/127/20 Online submission (12324) Semaglutide	M/s. Novo-Nordisk	The firm presented protocol amendment version 9.0 dated 24/June/2021 before the committee. After detailed deliberation, the committee recommended for approval of the protocol amendment version 9.0 dated 24/June/2021.
5.	CT/19/21 Online submission (12185) LY3471851	M/s. Eli-Lilly	The firm presented protocol addendum 6 dated 10/Nov/2020 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol addendum with condition that firm should include at least 50 percent government clinical trial sites.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
6.	CT/126/20 Online submission (11517) Brazikumab	M/s. AstraZeneca	The firm presented protocol amendment 5.0 (Version 6.0) dated 26/March/2021 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
7.	CT/44/20 Online submission (12639) C254101	M/s. Pfizer	The firm presented protocol amendment 1.0 dated 30/August/2021 before the committee. After detailed deliberation, the committee recommended for approval of the protocol amendment 1.0 dated 30/August/2021.
8.	CT/131/21 Online submission (28532) BI 685509	M/s. Parexel	The firm presented Phase II clinical trial proposal before the committee. After detailed deliberation, the committee recommended that the firm should submit data regarding volume of HVPG done along with their complications at proposed two sites.
FDC Division			
9.	FDC/IMP/20/000088 Poloxamer 407 IH + Sodium chondroitin sulphate IH + Sodium hyaluronate IH (2.7%+3.12%+1.24%) oral liquid	M/s. Micro labs Ltd	The firm didn't turn up for presentation.
10.	FDC/MA/21/000224 Pantoprazole Sodium IP eq. to Pantoprazole +Acotiamide Hydrochloride trihydrate IP (as ER) IH (40mg+300mg) capsules	M/s. Akums Drugs and Pharmaceutical Ltd	The firm didn't turn up for presentation.