Recommendations of the SEC (Gastroenterology & Hepatology) made in its 50th meeting held on 20.07.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/22/000182 Sucralfate Suspension 500mg/5ml	M/s. Zuventus Healthcare	The firm presented their proposal of manufacture and marketing permission of Sucralfate Suspension 500mg/5ml for already approved indication "indicated in the treatment of gastric duodenal & benign ulcer" with BE and local CT waiver before the committee. The committee noted that Sucralfate tablets is very old drug and already marketed in India since many years back. Sucralfate Suspension 500mg/5ml is also available in India and different countries like USA, Canada, France etc. The drug formulation is also approved with other drugs as FDC and available in Indian Market. After detailed deliberation, the committee recommended for grant of manufacture and marketing permission of Sucralfate Suspension 500mg/5ml for already approved indication "indicated in the treatment of gastric duodenal & benign ulcer".
2.	SND/CT/22/000042 Pantoprazole Dual Release Gastro-Resistant Tablet 80 mg	M/s. Sun Pharma	The firm presented their proposal with Phase IV clinical trial protocol of already approved drug product Pantoprazole Dual-Release Gastro-Resistant Tablets 80mg before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase IV clinical trial of Pantoprazole Dual-Release Gastro-Resistant Tablets 80mg as per the protocol presented.
FDC Division			
3.	FDC/MA/18/000006 Dicyclomine + Tapentadol (20mg + 50mg & 10mg + 25mg) Capsules	M/s. Wockhardt	In light of earlier SEC recommendation dated 24.04.2019, the firm presented the Phase III CT Protocol before the committee. After detailed deliberation, the committee

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			recommended that the firm should include following points in the CT protocol: 1. The indication should be revised as severe acute pain for a period not exceeding 5 days. 2. The patient with abdominal colicky pain should be excluded in exclusion criteria by ultrasonography and abdominal CT. 3. The patient with somatic or skeletal spasmodic pain should be included in inclusion criteria. In view above, the firm should submit revised Phase III CT Protocol including the above mentioned points for further review by the committee.
4.	FDC/MA/21/000149 Sodium Alginate IP 1000mg + Potassium Hydrogen Carbonate PhEur 200mg Oral suspension	M/s. Naxpar Pharma Pvt. Ltd.	In light of earlier SEC recommendation dated 17.02.2022, the firm presented the revised PMS protocol before the committee. After detailed deliberation, the committee recommended that the firm should conduct the PMS study and the result of the same should be presented before the committee.
5.	FDC/IMP/19/000042 "Upper Chamber: Per 500ml Acetyl cycteine JP 0.202g+Glycine JP 0.885g+ L-Alanine USP 1.200g+L-Arginine 1.575g +L-Aspartic acid BP 0.150g+L-Glutamic acid BP 0.150g+L-Histidine USP 0.750g+L-Isoleucine JP 1.200g+L-Leucine JP 2.100g+L-Lysine Hydrochloride JP 1.965g+L-Methionine JP0.585g+L-Phenylalanine JP1.050g+L-Proline USP0.750g+L-Serine USP 0.450g+L-	M/s. Otsuka Pharmaceuticals India Pvt. Ltd.	In light of earlier SEC recommendation dated 14.10.2020, the firm presented the Phase III CT report before the committee. After detailed deliberation, the committee recommended for grant of permission to import and market the proposed FDC with condition to conduct the Phase IV clinical trial study. Accordingly, Phase IV clinical trial study protocol should be submitted within 03 months from the date of approval for review by the committee.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Threonine JP 0.855g+L-Tryptophan JP 0.300g+L-Tyrosine USP 0.075g+L-Valine JP 1.200g+Dibasic potassium Phosphate USP 0.501g+Dibasic Sodium Phosphate HydrateJP 0.771g+Sodium Citrate Hydrate JP0.285g+Sodium L-Lactate solution (60%) (as Sodium L-Lactate) USP 1.145g Upper Chamber: Per 1000ml Acetyl cycteine JP g+Glycine JP 1.770g+ L-Alanine USP 2.400g+L-Arginine USP 3.150g +L-Aspartic acid BP 0.300g+L-Glutamic acid BP 0.300g +L-Histidine USP 1.500g+L-Isoleucine JP 2.400g+L-Leucine JP 4.200g+L-Lysine Hydrochloride JP 3.930g+L-Methionine JP1.170g+L-Phenylalanine JP 2.100g+L-Proline USP 1.500g+L-Serine USP 0.900g+L-Threonine JP 1.710g+L-Tryptophan JP 0.600g+L-Tyrosine USP 0.150g+L-Valine JP 2.400g+Dibasic potassium Phosphate USP 1.002g+Dibasic Sodium Phosphate HydrateJP 1.542g+Sodium Citrate Hydrate JP0.570g+Sodium L-Lactate solution (60%) (as Sodium L-		

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	Lactate) USP 2.290g Lower Chamber Solution: Per 500ml Calcium Chloride Hydrate JP -0.184g GlucoseUSP- 37.499g Magnesium Sulfate Hydrate JP -0.308g Thiamine Chloride Hydrochloride JP-0.96mg Zinc sulphate Hydrate JP 0.70mg Lower Chamber Solution: Per 1000ml Calcium Chloride Hydrate JP -0.368g Glucose USP-74.998g Magnesium Sulfate Hydrate JP -0.616g Thiamine Chloride Hydrochloride JP-1.920mg Zinc sulphate Hydrate JP 1.400mg Large Volume Parenteral"		
6.	FDC/MA/22/000065 Magnesium hydroxide 165mg + Calcium Carbonate 800mg + Famotidine 10mg chewable tablet	M/s. Overseas Health Care Pvt. Ltd.	In light of earlier SEC recommendation dated 13.04.2022, the firm presented the BE report before the committee. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the proposed FDC with condition to conduct the PMS study. Accordingly, the PMS protocol should be presented before the committee for review.
GCT Division			
7.	CT/48/21 Online Submission (16965) NNC0194-0499	M/s. Novo-Nordisk	The firm presented their proposal of major protocol amendment 3.0 dated 14 Oct 2021 under the Study Protocol no. NN9500-4656 before the committee. After detailed deliberation, the committee recommended to complete the study and

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			submit report after completion of the study.
Additional Proposal –SND Division			
8.	12-69/2018-DC (Pt-Intas-SND) Tacrolimus Lipid suspension for injection 4 mg /vial	M/s. Intas Pharmaceuticals	The firm presented their proposal of interim analysis report of Phase III clinical trial of Tacrolimus Lipid suspension for injection 5mg/vial before the committee. The proposed indication is mild to moderate active left sided/distal ulcerative colitis refractory to Mesalamine treatment. After detailed deliberation, the committee opined that the firm should submit the final report after completion of the ongoing Phase III clinical study to CDSCO for further review by the committee.