

Recommendations of the SEC (Gastroenterology & Hepatology) made in its 54th meeting held on 23.11.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/20/00083 Ursodeoxycholic Acid Tablets IP 150mg/300mg/450mg/ 600mg	M/s. Abbott Healthcare	The firm presented the amendment of Phase III clinical trial protocol. After detailed deliberation, the committee recommended for grant of approval for protocol amendment and also opined that comments from Gynecology and Obstetrics experts should be taken before granting approval for protocol amendment. Dr. Pikee Saxena did not participate during the deliberation.
2.	SND/CT/22/000054 Ursodiol Injection 625 mg/25ml (25mg/ml)	M/s. Shilpa Medicare	The firm presented their proposal for the protocol titled “An open label, Phase-I, parallel, dose-escalation, comparative pharmacokinetic, safety and tolerability study of Ursodiol injection 625mg/25ml (25mg/ml) at different dose levels (600mg, 900mg, 1800mg and 3500mg) with oral administration of ACTIGALL (Ursodiol) capsules 300 mg (dose 900mg) in healthy subjects under fed conditions” before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study with condition that initially the study should be conducted in cohort I (600mg) and cohort II (900mg) and thereafter the applicant should submit interim report before the committee for further continuation of the trial.
3.	SND/MA/000295 Esomeprazole dual-release gastro resistant tablets 80mg	M/s. Sun Pharma	The firm presented the proposal for manufacturing and marketing of Esomeprazole dual-release gastro resistant tablets 80mg along with the results of the Phase III clinical trial. After detailed deliberation, the committee recommended for manufacturing and marketing of Esomeprazole dual-release gastro resistant tablets 80 mg “indicated For the treatment of moderate to severe refractory gastro-oesophageal reflux disease (GERD) for 4 weeks only.”

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GCT Division			
4.	CT/87/22 Online Submission (33556) VTX002	M/s. PSI CRO	The firm presented Phase II clinical trial protocol no-VTX002-201 before the committee. After detailed deliberation, the committee opined that the firm to submit clarification for the following- <ol style="list-style-type: none"> 1. 20 mg dose for corticosteroid is highest dose to screen the patients. 2. Rescue therapy for mayo score MMS. 3. Anaemia definition. 4. Patients on antiarrhythmic drugs to be included in exclusion criteria. 5. Blood count, WBC Count. 6. P_k Data.
5.	CT/106/22 Online Submission (33965) Bepirovirsen (GSK3228836)	M/s. GSK Pharma	The proposal was deferred for next meeting.
6.	CT/107/22 Online Submission (33966) Bepirovirsen (GSK3228836)	M/s. GSK Pharma	The proposal was deferred for next meeting.
7.	CT/132/22 Online Submission (34553) GSK4532990	M/s. GSK Pharma	The proposal was deferred for next meeting.
8.	CT/28/22 Online Submission (20917) Guselkumab (CNT01959)	M/s. Parexel	The proposal was deferred for next meeting.
FDC Division			
9.	FDC/IMP/19/000042 "Upper Chamber: Per 500ml Acetyl cysteine 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-	M/s. Otsuka Pharmaceuticals India Pvt. Ltd.	The proposal was deferred for next meeting.

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	<p>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-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</p> <p>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</p>		

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	<p>Hydrate JP0.570g+Sodium L- Lactate solution (60%) (as Sodium L-Lactate) USP 2.290g</p> <p>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</p> <p>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”.</p>		