Recommendations of the SEC (Gastroenterology & Hepatology) made in its 55th meeting held on 20.12.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/CT/22/000063 Tegoprazan 50 mg tablet	M/s Dr. Reddy's	The firm presented its proposal for the grant of permission to conduct Phase I clinical trial of Tegoprazan 50 mg tablet along with Phase I clinical trial protocol (protocol no. 108-22,version No:1, dated-18th OCT 2022). After detailed deliberation, the committee opined that:- 1. Tegoprazan is gastric acid-pump blocker. 2. Tegoprazan tablet 50 mg is approved in **South Korea in 2018** for the treatment of gastro-esophageal reflux disease, **China in 2022 for erosive esophagitis** andin **Philippines** in 2022 for treatment of erosive gastro-esophageal reflux disease (GERD), non-erosive GERD, gastric ulcer/ peptic ulcer and / or antibiotic combination therapy for Helicobacter pylori eradication in patients with chronic atrophic gastritis. 3. Firm presented data on the non clinical PK/PD, safety pharmacology, acute and repeated dose toxicity, reproductive toxicity and developmental toxicity study, genotoxicity, carcinogenecity study, 4. Firm also presented data on clinical safety, efficacy, pharmacokinetic, and pharmacodyanamic. In view of the above, the committee recommended for the grant of permission to conduct Phase I clinical trial of Tegoprazan 50 mg tablet as per the protocol presented.
Biological Division			
2.	BIO/CT/22/000115	M/s Johnson & Johnson Pvt. Ltd.	The proposal was deferred for next meeting.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Ustekinumab Pre-filled syringes 45 mg/0.5 ml, 90 mg/ml and Single use vial 130 mg/ 26 ml.		
SND Division			
3.	12-29/2022-Dc (Pt-Misc-SND) Ademetionine powder for solution for injection 400mg	M/s Abbott Healthcare	The proposal was deferred for next meeting.
4.	SND/MA/22/000227 Amisulpride injection 5mg/2ml	M/s La-Renon Healthcare	The proposal was deferred for next meeting.
GCT Division			
5.	CT/48/21 Online Submission (16965) NNC0194-0499	M/s. Novo-Nordisk	In light of earlier SEC meeting held on 20-07-2022, the applicant has presented protocol amendment version 3.0 dated 14-10-2021 for protocol no NN9500-4656 before the committee. After detailed deliberation, the committee recommended for approval of proposed protocol amendment version 3.0 dated 14-10-2021 for protocol no NN9500-4656.
6.	CT/87/22 Online Submission (33556) VTX002	M/s. PSI CRO	The firm presented Phase II clinical trial protocol no-VTX002-201, with clarification inlight of earlier SEC meeting dated 23.11.2022before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study.
7.	CT/106/22 Online Submission (33965) Bepirovirsen (GSK3228836)	M/s. GSK Pharma	The applicant presented Phase III clinical trial protocol no 202009, dated 29-08-2022 (B- Well 1) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study with following conditions- 1. The study should be conducted initially in 20 subjects from India. The applicant

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			should submit safety data of these 20 Indian subjects along with recommendations of independent data safety monitoring committee/board to CDSCO for further review by the committee. Once data would be reviewed by the SEC, trial might be continued. 2. Being a placebo controlled trial, SoC/background therapy should be provided to the trial subjects free of cost throughout the conduct of the trial.
8.	CT/107/22 Online Submission (33966) Bepirovirsen (GSK3228836)	M/s. GSK Pharma	The applicant presented Phase III clinical trial protocol no 219288, dated 29-08-2022 (B-Well 2) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study with following conditions- 1. The study should be conducted initially in 20 subjects from India. The applicant should submit safety data of these 20 Indian subjects along with recommendations of independent data safety monitoring committee/board to CDSCO for further review by the committee. Once data reviewed by SEC, trial might be continued. 2. Being a placebo controlled trial, SoC/background therapy should be provided to the trial subjects free of cost throughout the conduct of the trial.
9.	CT/28/22 Online Submission (20917) Guselkumab (CNT01959)	M/s. Parexel	The proposal was deferred for next meeting.
10.	CT/132/22 Online Submission (34553) GSK4532990	M/s. GSK Pharma	The applicant presented Phase IIb clinical trial protocol no 218672, amendment 01 dated 29-09-2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the study as presented.
11.	CT/49/20 Online Submission (21429)	M/s. Eli Lilly	The firm presented their proposal for protocol amendment (e) dated 23-Feb-2022 for protocol no: I6T-MC-AMAMbefore the committee.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Mirikizumab		After detailed deliberation, the committee recommended for approval of proposed protocol amendment.
12.	CT/129/22 Online Submission (34566) Guselkumab (CNTO1959)	M/s. J&J	The proposal was deferred for next meeting.
13.	CT/43/19 Online Submission (20433) Mirikizumab	M/s. Eli-Lilly	The firm presented their proposal forprotocol amendment (b) dated 21-July-2022 for protocol no: I6T-MC-AMAP before the committee. After detailed deliberation, the committee recommended for approval of proposed protocol amendment.
14.	CT/101/22 Online Submission (33858) SAR443122	M/s. Sanofi Healthcare	The proposal was deferred for next meeting.
15.	CT/125/22 Online Fresh File MORF-057	M/s. PSI CRO	The firm presented Phase IIb clinical trial protocol no-MORF-057-202, Protocol version 1final 01JULY2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase IIb study.
FDC Division			
16.	FDC/MA/19/000015 Levosulpiride 75 mg + Rabeprazole Sodium 40 mg capsules	M/s. Akums Drugs & Pharmaceuticals Ltd.	The proposal was deferred for next meeting.
17.	FDC/MA/22/000084 Combikit of Amoxycillin Tablets 1000mg+ Clarithromycin Tablets 500mg + Esomeprazole 40mg Tablets	M/s Malik Lifesciences	The proposal was deferred for next meeting.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
18.	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-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 HydrateJP0.771g+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	M/s Otsuka Pharmaceuticals India Pvt. Ltd.	The proposal was deferred for next meeting.

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	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-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".		