

Recommendations of the SEC (Gastroenterology & Hepatology) made in its 56th meeting held on 17.01.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000056 Elobixibat 5mg Tablets	M/s. Dr. Reddy's Laboratories Ltd.	The firm presented results of Bioequivalence study before the committee. After detailed deliberation, the committee recommended to initiate Phase-III clinical trial study as per approved protocol (Protocol No. DRL-IND-NDA03-ELO/2022, version: 1.0 dated: 11.03.2022).
2.	ND/MA/22/000191 Vonoprazan Tablets 10 mg/ 20 mg	M/s Hetero Labs	The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Vonoprazan Tablets 10mg/20mg along with Phase III clinical trial protocol and BE study waiver before the committee. After detailed deliberation, the committee agreed for waiver of BE study and recommended for grant of permission to conduct the proposed Phase III Clinical trial as per the proposed protocol.
Biological Division			
3.	BIO/CT/22/000115 Ustekinumab Pre-filled syringes 45 mg/0.5 ml, 90 mg/ml and Single use vial 130 mg/ 26 ml.	M/s Johnson & Johnson Pvt. Ltd.	The proposal was deferred for next meeting.
SND Division			
4.	SND/MA/22/000227 Amisulpride injection 5mg/2ml	M/s La-Renon Healthcare	The firm didn't turn up for presentation.
FDC Division			
5.	FDC/IMP/19/000042 Upper Chamber: Per 500ml Acetyl cysteine JP	M/s. Otsuka Pharmaceuticals India Pvt. Ltd.	As per the condition of Form CT-20 dated 02.08.2022, the firm presented its proposal along with justification for Phase IV clinical trial waiver. The committee noted that the firm conducted Phase III clinical trial study on

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	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 JP 1.050g+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 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		approximately 150 subjects and the report of the study was already reviewed by the committee before approval of the product. After detailed deliberation, the committee recommended to consider the firm's request for Phase IV CT study waiver.

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	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		
6.	FDC/MA/19/000015 Levosulpiride 75 mg + Rabeprazole Sodium 40 mg capsules	M/s. Akums Drugs & Pharmaceuticals Ltd.	In light of earlier SEC recommendation dated 14.01.2021, the firm presented their proposal along with BE protocol. After detailed deliberation, the committee recommended for conducting the BE study. The result of the study should be presented before the committee for further review.
7.	FDC/MA/22/000084 Combikit of Amoxicillin Tablets 1000mg +	M/s Malik Lifesciences	The firm presented their proposal along with request for Phase III CT study waiver. The committee noted that the Combikit is already approved by TGA, Australia. After detailed deliberation, the committee

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	Clarithromycin Tablets 500mg + Esomeprazole 40mg Tablets		recommended for grant of permission to manufacture and market the combikit with condition that firm should conduct the Phase IV clinical trial. The Phase IV clinical trial protocol should be submitted to CDSCO within three months from the date of approval for review by the SEC.
GCT Division			
8.	CT/28/22 Online Submission (20917) Guselkumab (CNT01959)	M/s. Parexel	The proposal was deferred for next meeting.
9.	CT/129/22 Online Submission (34566) Guselkumab (CNT01959)	M/s. J&J	The firm presented its proposal for Phase III clinical trial vide protocol No. CNT01959UCO3004, amendment 2 dated 16/08/2022 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct of clinical trial as presented with the condition that if the subject's health deteriorates during the treatment part, the rescue medicines should be reimbursed by the sponsor or provided free of cost till the end of the study period.
10.	CT/101/22 Online submission (33858) SAR443122	M/s Sanofi Healthcare	The firm presented its proposal for the Phase II Clinical Trial vide protocol No. DRI16804, version 2 dated 08-June-2022 before the committee. After detailed deliberation, the committee recommended for the grant of permission for the conduct of clinical trial as presented with the condition that: If patient health deteriorates during the treatment part, he should be reimbursed for the rescue medicines by the sponsor till the end of the study period (52 weeks).
11.	CT/142/22 Online submission (34813)	M/s. AstraZenica	The proposal was deferred for next meeting.

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	AZD2693		
12.	CT/102/22 Online Submission (33917) FILGOTINIB [GS-6034, FormerlyGLPG0634]	M/s. PRA	The proposal was deferred for next meeting.
13.	CT/10/22 Online Submission (30032) Zinc Sulfate Tablets 20 mg	M/s. EDEMER GLOBAL PRIVATE LIMITED	<p>The firm presented its proposal for the Phase III clinical trial vide protocol No. EGPL-CT/PR-001/21 version 00 dated 09-May-2022 before the committee. After detailed deliberation, the committee opined that the proposed trial is India specific and does not appear to be a global clinical trial and proposed sites are located in one part of India only. There should be CT sites geographically distributed all across India.</p> <p>The dose/dosage form of study drug is also not justified. For the pediatric patients less than 6 months age, giving half tablet of 20 mg is not justified. 10 mg dosage form of the clinical batch as IP to be developed and available for the study.</p> <p>The WHO reference documents is required for the proposed 5 point scale.</p> <p>Therefore, the committee did not recommend to grant the permission to the proposed clinical trial protocol as presented.</p>
14.	CT/124/20 Online Submission (19890) Brazikumad	M/s. AstraZeneca	The proposal was deferred for next meeting.
SND Division			
15.	SND/CT/21/000020 Saroglitazar Tablet 4mg	M/s. Cadila Healthcare	<p>The firm presented its proposal of revised protocol of Phase IV clinical trial of Saroglitazar Tablets 4mg alongwith summary of changes in amended protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission for</p>

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			amendment in already approved CT NOC Vide No. SND/152/2021 dated 17.11.2021 as per amended protocol (Protocol no. SARO.21.003, version No. 5.0, dated 12.11.2022) as presented by the firm.