

Recommendations of the SEC (Gastroenterology & Hepatology) made in its 08th/24 meeting held on 13.08.24 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/69/24 Online Submission (43308) Efruxifermin	M/s. KlinEra Global	The firm didn't turn up for presentation.
2.	CT/181/22 Online Submission (33775) ABX464 (Obefazimod)	M/s. IQVIA RDS (India) Private Limited	The firm presented protocol amendment version 5.1 dated 10 April 2024 protocol no. ABX464-105. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
SND Division			
3.	SND/MA/24/000115 Pancreatin Gastro-Resistant Capsules BP 35000 (Creon 35000) Intermediate strength	M/s. Abbott Healthcare Private Limited	The firm presented the proposal for manufacturing and marketing permission for Pancreatin Gastro Resistant Capsules BP 35000 along with justification for waiver of bioequivalence study & clinical trial study before the committee. The firm has informed that the proposed drug product other strengths Pancreatin Capsules (Creon 10000), Pancreatin Capsules (Creon 25000) & Pancreatin Minimicrospheres capsules (Creon 40000) are already approved by CDSCO since year 2001 in the country. The proposed strength Pancreatin Gastro-resistant Capsules BP 35000 is only for dose titration purpose only. After detailed deliberation, the committee recommended for grant of permission to manufacture and market Pancreatin Gastro-resistant Capsules BP 35000 (additional strength) with bioequivalence study and clinical trial study waiver subject to condition that firm should conduct Phase IV clinical trial. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 03 months from date of approval of the drug product for further review by the committee.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
4.	ND/IMP/23/000087 Etrasimod Tablets 2mg	M/s. Pfizer	<p>The firm presented its proposal for grant of permission to import and marketing of drug Etrasimod Tablets 2mg along with global clinical trial data including subset analysis data for Indian patients before the committee.</p> <p>The committee noted that Etrasimod Tablets 2mg is approved in countries like U.S.A., EU, Canada, Australia, Singapore, UK etc. The global clinical trial data including the subset analysis data for Indian patients demonstrate the efficacy and safety of drug for treatment of moderately to severely active ulcerative colitis.</p> <p>The committee opined that there is unmet medical need in the country.</p> <p>After detailed deliberation, the committee recommended for grant of permission to import and marketing of Etrasimod Tablets 2mg subject to the conditions that the firm should conduct Phase IV clinical trial for which protocol should be submitted to CDSCO within three months of approval of the drug for further review by the committee.</p>
5.	ND/MA/23/000167 Olsalazine Sodium Capsules 250mg and 500mg	M/s. Zuventus Healthcare Ltd.	<p>The firm presented proposal for grant of permission to manufacture and market Olsalazine Sodium Capsules 250mg and 500mg, indicated for Oral treatment of mild active ulcerative colitis and maintenance of remission, along with Bioequivalence study protocol and Phase III clinical trial protocol before the Committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct Bioequivalence study and Phase III clinical trial, as per the protocol presented.</p> <p>Further, the committee opined that the firm should submit Bioequivalence study report to CDSCO for review by the committee before initiating the Phase III clinical trial.</p>

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6.	ND/MA/24/00001 Vonoprazan Tablets 10mg/20mg	M/s. Macleods Pharmaceuticals Ltd.	<p>The firm presented proposal for grant of permission to manufacture and market Vonoprazan Tablets 10mg, 20mg along with Bioequivalence study protocol and Phase III clinical trial protocol before the Committee.</p> <p>The committee noted that Vonoprazan tablets 10mg/20mg approved by CDSCO on 08-05-2024.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct Bioequivalence study as per the protocol presented.</p> <p>Accordingly, the firm should submit the BE study report to CDSCO for further review by the committee.</p>
7.	ND/MA/24/000060 Eluxadoline Tablets 75mg and 100mg	M/s. MSN Laboratories	<p>The firm presented their proposal for grant of permission to manufacture and market Eluxadoline tablets 75 mg & 100 mg along with BE study report, Phase III clinical trial protocol and justification for CT waiver before the committee.</p> <p>After detailed deliberation, the committee did not agree for the waiver of Phase III clinical trial. Accordingly, the committee recommended for grant of permission to conduct the Phase III clinical trial as per the protocol presented.</p>
FDC Division			
8.	FDC/MA/24/000115 Combikit of Clarithromycin IP film coated tablet 500mg +Rabeprazole sodium IP 20mg Enteric coated tablet + Amoxicillin Trihydrate IP eq. to Amoxicillin Tablet 1000mg film coated tablet	M/s.Malik Lifesciences Pvt. Ltd.	<p>The firm presented the proposal along with justification for BE and Phase III CT waiver before the committee.</p> <p>The committee noted that similar drug combination i.e. Combikit of Clarithromycin IP 500mg + Esomeprazole Magnesium IP eq. to Esomeprazole 40mg + Amoxicillin Trihydrate IP eq. to Amoxicillin 1000mg is already approved by CDSCO.</p> <p>After detailed deliberation, the committee considered the request for BE and Phase III CT waiver and recommended for grant of permission for manufacturing and marketing of the proposed Combikit with the condition to conduct the Phase IV clinical trial.</p>

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			Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of approval of the proposed Combikit for review by the committee.
9.	FDC/MA/24/000131 Vonoprazan Fumarate eq. to Vonoprazan 20mg + Levosulpiride ER 75mg uncoated bilayer tablet	M/s. Hetero Labs Limited	<p>The firm presented their proposal before the committee.</p> <p>After detailed deliberation, committee opined the following:</p> <ol style="list-style-type: none"> 1. The firm did not present the justification on rationality of the combination and its significant benefits. 2. The firm did not present any published literature from peer-reviewed journal w.r.t Vonoprazan along with Prokinetic drug. 3. The firm did not present any proof of concept study in support of significant clinical need of the FDC in the proposed indication. 4. The firm did not present any data/literature w.r.t Drug-Drug-Interactions (known and/or expected) among the active ingredients present in the FDC. 5. The proposed FDC is not approved internationally. 6. There is no unmet need for proposed FDC. <p>Accordingly, the firm should submit above data for further review by the committee.</p>