Recommendations of the SEC (Gastroenterology & Hepatology) made in its 08th/25 meeting held on 25.06.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/132/22 Online Submission (39374) GSK4532990 Solution for injection, 200 mg/ml	M/s. GSK Pharma India Private Limited	The firm presented protocol amendment 04 dated 09 April 2025 protocol no. 218672. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
New Drugs Division			
2.	ND/MA/24/000173 Resmetirom Tablet 60/80/100 mg	M/s Ravenbhel Biotech	In light of the earlier SEC recommendation dated 17.03.2025, the firm presented revised Phase-III CT protocol of Resmetirom Tablet 60/80/100 mg, before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial with Resmetirom Tablet 60/80/100 mg as per the revised protocol presented. 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
3.	ND/MA/25/000028 Resmetirom Tablet 60/80/100 mg	M/s PURE & CURE HEALTHCARE Pvt. Ltd.	The firm presented the proposal for grant of permission for manufacture and market of the drug Resmetirom Tablets (60 mg, 80 mg & 100 mg) along with BE study protocol and Phase III clinical trial protocol, before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Bioequivalence study and Phase III clinical trial, as per the protocols presented. 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.

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FDC Division			
4.	FDC/MA/25/000070 Ursodeoxycholic Acid IP 300mg + Vitamin E Acetate IP 200 mg Tablets	M/s Abbott India Limited	The firm presented their proposal along with justification for BE waiver before the committee. After detailed deliberation, the committee opined the following: 1. The firm did not present evidence of efficacy of individual products as well as combination. 2. Published scientific literature in peer reviewed journal in support of essentiality and desirability of proposed FDC is not adequate. 3. The end point of the study was not related to condition of Non-Alcoholic fatty liver disease (NAFLD)/Metabolic dysfunction-associated steatotic liver disease (MASLD). 4. The proposed FDC is not approved internationally. Accordingly, the firm should submit above data/ documents for further review by the committee.
5.	FDC/MA/25/000099 Combikit of Clarithromycin IP 500mg + Amoxycillin Trihydrate IP Eq. to Amoxycillin 1000mg + Vonoprazan Fumarate Eq. to Vonoprazan 20mg film coated Tablets	M/s Malik Lifesciences Pvt Ltd	The firm presented their proposal along with justification for BE & Phase III CT waiver before the committee. The committee noted that the proposed Combikit is already approved in USA and individual drugs are already approved by CDSCO. Further firm informed that they also have product permission of individual drugs. After detailed deliberation, the committee considered the request for BE and Phase III CT waiver and recommend for grant of permission to manufacture and market the proposed Combikit with the condition that Active PMS should be conducted. Accordingly, the firm should submit Active PMS protocol to CDSCO within 3 months of approval of the Combikit for

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			review by the committee.
6.	FDC/MA/25/000130 Combikit of Amoxycillin Trihydrate IP Eq. to Amoxycillin 1000mg + Vonoprazan Fumarate Eq. to Vonoprazan 20mg film coated Tablets	M/s Malik Lifesciences Pvt Ltd	The firm presented their proposal along with justification for BE & Phase III CT waiver before the committee. The committee noted that the proposed Combikit is already approved in USA and individual drugs are already approved by CDSCO. Further firm informed that they also have product permission of individual drugs. After detailed deliberation, the committee considered the request for BE and Phase III CT waiver and recommend for grant of permission to manufacture and market the proposed Combikit with the condition that Active PMS should be conducted. Accordingly, the firm should submit Active PMS protocol to CDSCO within 3 months of approval of the Combikit for review by the committee.
7.	FDC/MA/25/000132 Combikit of Clarithromycin IP 500mg + Amoxycillin Trihydrate IP Eq. to Amoxycillin 500mg + Vonoprazan Fumarate Eq. to Vonoprazan 20mg film coated Tablets	M/s BDR Pharmaceuticals International Pvt Ltd	The firm presented their proposal along with justification for BE & Phase III CT waiver before the committee. The committee noted that the proposed Combikit is already approved in USA and individual drugs are already approved by CDSCO. Further firm informed that they also have product permission of individual drugs. After detailed deliberation, the committee considered the request for BE and Phase III CT waiver and recommend for grant of permission to manufacture and market the proposed Combikit with the condition that Active PMS should be conducted. Accordingly, the firm should submit Active PMS protocol to CDSCO within 3 months of approval of the Combikit for review by the committee.