Recommendations of the SEC (Gastroenterology & Hepatology) made in its 07th/26 meeting held on 16.06.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/28/24 Online Submission (43584) MORF-057	M/s. PSI CRO Pharma Pvt. Ltd	The firm presented protocol amendment version 4.1 dated 04 December 2025 protocol no. MORF-057-203. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm. Further, the committee recommended to submit available clinical trial data and the supporting evidence for the proposed dose revision to CDSCO for review.
2.	CT/125/25 Online Submission (44377) SPY001-001; SPY002-091	M/s. PSI CRO Pharma Pvt. Ltd	The firm presented the proposal for the approval of protocol (i.e., intervention specific appendices SPY003, SPY120, SPY130 and SPY230) for initiating part B of the study protocol no. SPY123-201. After detailed deliberation, the committee recommended for approval to continue with intervention specific appendices of the study as presented by the firm.
Biological Division			
3.	BIO/CT18/FF/2025/53185 Semaglutide Injection 0.25mg / 0.5mg /1mg /1.7mg /2.4mg	M/s. Novo Nordisk India Private Limited	The firm presented a proposal for grant of approval of additional indication (MASH and NASH) for Semaglutide Injection 0.25mg / 0.5mg /1mg /1.7mg /2.4mg [Brand Name: Wegovy] (r-DNA Origin). Indian sites were also included in global clinical trial NN9931-4553 (ESSENCE). The committee noted that the subject drug is approved in India since 20.04.2022 [Semaglutide Injection 0.25 mg, 0.5 mg, 1.0 mg, 1.7 mg & 2.4 mg; Solution for injection] in prefilled pen for chronic weight management in adults. Further; the committee noted that safety and effectiveness of semaglutide in combination with other MASH/NAFLD treatment drugs, have not been established. After detailed deliberation, the committee recommended for grant of conditional

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			approval for the proposed additional indication where subject drug is indicated for the treatment of noncirrhotic metabolic dysfunction-associated steatohepatitis (MASH), formerly known as nonalcoholic steatohepatitis (NASH), with moderate to advanced liver fibrosis (consistent with stages F2 to F3 fibrosis) in adults; considering the significant therapeutic advancement over the current standard of care, in-line with US accelerated approval for proposed indication subject to the following conditions: 1. Firm shall submit the complete Phase-III CSR for the subject confirmatory ESSENCE Trial NN9931-4553 (Part-2). 2. Continued approval for proposed indication is subject to verification of safety and clinical benefit in a subject confirmatory trial NN9931-4553 (Part-2) titled as "A randomized, double-blind, placebo-controlled, parallel-group 240-week trial in patients with metabolic dysfunction-associated steatohepatitis (MASH) with liver fibrosis to demonstrate clinical benefit on the composite endpoint of progression to cirrhosis, hepatic decompensation events, liver transplant, and mortality". Note: Accordingly the warning statement should be updated as "To be sold by retail on the prescription of an Internal medicine, Endocrinologist, Cardiologist, Gastroenterologist and Hepatologist only"
New Drugs Division			
4.	ND/MA/24/000024 Vonoprazan tablets 10 mg and 20 mg	M/s. Logos Pharma	The firm presented the proposal for grant of permission for manufacture and market of the drug Vonoprazan Tablets 10 mg and 20 mg along with BE study protocol (Project No.: 26-023, Version No. 01 dated 13 April 2026) before the committee. After detailed deliberation, the committee recommended agreed for conduct of

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			Bioequivalence study as per the protocol presented by the firm. Further, the committee recommended that firm may consider collecting 4 ml of blood instead of 5 ml for each sampling time point.
5.	ND/MA/25/000135 Zastaprazan Citrate Tablets 20 mg	M/s. Sun Pharma Laboratories Limited	The firm presented the proposal for grant of permission for manufacture and market of the drug Zastaprazan Citrate Tablets 20 mg along with Phase-III Clinical Trial Report and BE report before the committee. After detailed deliberation, considered the BE study results and Phase III Clinical Trial result as presented by the firm and recommended for the grant of permission to manufacture and market drug Zastaprazan Citrate Tablets 20 mg. The Committee also recommended that the drug should be sold by retail under the prescription of Registered Medical Practitioner.
6.	ND/MA/25/000188 Tribenoside and Lidocaine Hydrochloride Cream (5% w/w + 2.12% w/w	M/s. Sun Pharmaceutical Industries Limited	In light of earlier recommendation dated 18.12.2025, the firm presented revised Phase-III Clinical trial protocol of drug Tribenoside and Lidocaine Hydrochloride Cream (5% w/w + 2.12% w/w) (Protocol No. ICR/25/011, Version No. 2.0 dated 19/Mar/2026) before the committee. After detailed deliberation, committee recommended for grant of permission to conduct Phase III clinical trial as per the revised protocol presented by the firm. Accordingly, the firm should submit Phase III clinical trial results to CDSCO for further review by the committee
7.	ND/MA/25/000194 Resmetirom tablets 60 mg/80 mg/100 mg	M/s. Abbott Healthcare Private Limited	The firm presented the proposal for grant of permission for manufacture and market of the drug Resmetirom Tablets (60 mg, 80 mg and 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

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			III clinical trial, as per the 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
8.	ND/MA/26/000016 Resmetirom 60mg, 80mg and 100mg Tablets	M/s. Mascot Health Series Pvt. Ltd	The firm presented the proposal for grant of permission for manufacture and market of the 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 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
FDC Division			
9.	FDC/76/2026-eoffice Sodium alginate IP 250mg + Sodium bicarbonate IP 106.5mg + Calcium Carbonate IP 187.5mg chewable tablet Sodium alginate IP 250mg + Sodium bicarbonate IP 106.5mg + Calcium Carbonate IP 162.5mg per 5mL suspension	M/s. Reckitt Benckiser (India) Pvt. Ltd.	In light of earlier SEC recommendation dated 17.05.2022, the firm presented Active PMS report before the committee. After detailed deliberation, the committee noted and agreed to the result of the Active PMS report