Recommendations of the SEC (Gastroenterology & Hepatology) made in its 06th/26 meeting held on 21.05.2026 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/51/26 Online Submission (55933) JNJ-78934804 (Golimumab + Guselkumab)	M/s. Johnson & Johnson Pvt. Ltd.	The firm presented phase III clinical study protocol No.: 78934804CRD3001 Original Protocol dated 19-MAR-2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/52/26 Online Submission (55966) JNJ-78934804 (Guselkumab 160 mg +Golimumab 80 mg)	M/s. Johnson & Johnson Pvt. Ltd.	The firm presented phase III clinical study protocol no.: 78934804UCO3001, Original Protocol dated 07 March 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
Biological Division			
3.	Receipt No.: E-132952 Ustekinumab Solution for injection for subcutaneous administration in pre-filled syringe 45 mg/0.5 ml, 90 mg/ml and Ustekinumab Solution for intravenous infusion in single use vial 130 mg/ 26 ml	M/s. Johnson and Johnson Private Limited.	The firm presented the report of Phase IV clinical trial study titled as "An Open Label, Multicentre, Phase IV Study of Ustekinumab to Evaluate Its Safety in Indian Subjects with Crohn's Disease (CD)" vide Protocol No.: CNTO1275CRD4045, Version Nil; dated 03 October 2022. The committee noted the results of aforesaid Phase IV study.
New Drugs Division			
4.	ND/MA/24/000169 Resmetirom Tablet (60 mg, 80 mg & 100 mg)	M/s. Exemed Pharmaceuticals	In light of the earlier SEC recommendation dated 22.05.2025, the firm presented Bioequivalence study report of Resmetirom Tablets 100 mg before the committee. After detailed deliberation, the committee considered the results of BE study presented by the firm. The firm should submit Phase III Clinical Trial results to CDSCO for further review by the committee.
5.	ND/MA/25/000170 Resmetirom Tablets	M/s. BDR Pharmaceuticals International	In light of earlier recommendation dated 11.02.2026, the firm presented revised Phase III Clinical Trial protocol (Protocol

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	60mg, 80mg & 100mg	PvtLtd.	No: SLS-CT-0014-25-RESM Protocol Version No: 02, dated 03 Mar 26) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III Clinical Trial as per revised protocol presented by the firm
6.	ND/MA/26/000024 Resmetirom Tablets 60 mg, 80 mg, 100 mg	M/s. Macleods Pharmaceuticals Ltd	The firm presented their proposal for grant of permission to manufacture and market Resmetirom Tablets 60 mg/ 80 mg /100mg along with BE study protocol (Protocol No.: BEQ-4140-RESM-2026, Version No.: 01, Date: 13th February 2026) and Phase III Clinical Trial study protocol (Protocol No.: CT-083-RESM-2025 Version no. 1.0 Date:03-Feb-2026), before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Bioequivalence study. Further, w.r.t. Phase III clinical trial, committee recommended that criteria for SGOT/SGPT level should be aligned with the INASL guideline. Also, per-protocol population analysis should be amended to include all the patient with more than 80% study treatment compliance. Accordingly, firm should submit revised Phase-III CT protocol to CDSCO. 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.
SND Division			
7.	SND/MA/25/000200 Linaclotide Capsules 72 mcg and 145 mcg	M/s. Precise Biopharma Pvt. Ltd.	The firm presented the proposal for grant of permission to manufacture and market Linaclotide Capsules 72 mcg and 145 mcg for the treatment of Chronic Idiopathic Constipation in adults before the committee. Linaclotide Capsules 72 mcg and 145 mg were approved in India on 21.04.2025 for the said indication and in-view of the challenges with the BE study, the firm proposed to conduct the clinical efficacy

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			study and presented the Phase III CT protocol. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III CT study as per protocol presented by the firm, subject to the following changes/conditions: 1. The firm shall consider a non-inferiority margin of 4.5% for sample size calculation, and accordingly revise the sample size. 2. The number of CT sites shall be increased in accordance with the revised sample size in the protocol. Accordingly, the revised protocol shall be submitted to CDSCO.
8.	SND/MA/23/000215 Ademetionine 1,4-Butanedisulfonate 500 mg Lyophilized powder for solution for injection	M/s. La Renon Healthcare Pvt. Ltd.	In light of the earlier SEC meeting dated 08.01.2026, the firm presented their proposal for grant of permission to manufacture and market Ademetionine 1,4-Butanedisulfonate 500 mg Lyophilized Powder for Solution for Injection along with the Phase III clinical trial report for the proposed indication, i.e., treatment of adults (18 years and above) with intrahepatic cholestasis in pre-cirrhotic and cirrhotic states. The Committee noted that Ademetionine 1,4-Butanedisulfonate 500 mg Lyophilized Powder for Solution for Injection is already approved in many countries such as France, Italy, Spain, Russia, and Germany, etc. for the same indication. Further noted that, in India, Ademetionine enteric coated tablets 200 mg/400 mg is approved on 01.09.2010 in India for the management of intrahepatic cholestasis and liver disease. After detailed deliberation, the Committee recommended for grant of permission to manufacture and market Ademetionine 1,4-Butanedisulfonate 500 mg Lyophilized Powder for Solution for Injection for the said indication. In addition, the committee also recommended that the firm shall conduct

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			a Phase IV Clinical Trial in patients with intrahepatic cholestasis for total period of 04 weeks, wherein the treatment with Ademetionine 1,4-Butanedisulfonate 500 mg Lyophilized Powder for Solution for Injection should be followed by oral drug. Accordingly, the protocol for the Phase IV study shall be submitted within three months from the date of grant of permission.
FDC Division			
9.	FDC/MA/25/000097 Tegoprazan 50 mg + Domperidone IP (as SR pellets) 30 mg capsule	M/s. Dr. Reddy's Laboratories Ltd.	The firm presented their proposal before the committee. After detailed deliberation, committee opined the following: 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 Tegoprazanalong 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. Accordingly, the firm should submit above data for further review by the committee