Recommendations of the SEC (Gastroenterology & Hepatology) made in its 07th/25 meeting held on 12.06.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/57/25 OnlineSubmission(49422) Pegozafermin	M/s Medpace Clinical Research India Pvt Ltd	The firm presented phase III clinical study protocol no.: BIO89 100 131 version No. 2.0 dated 16-JAN-2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
2.	CT/101/22 OnlineSubmission(39217) SAR443122	M/s Sanofi Healthcare India Private Limited	The firm presented for increase in number of subjects from India (40 to 60) protocol no. DRI16804. After detailed deliberation, the committee recommended for increase in number of subjects from India (40 to 60) as presented by the firm.
New Drugs Division			
3.	ND/IMP/23/000054 Carbon-14 urea 37 Kbq Capsules (Pytest capsules)	M/s. 3BMSDiagnostics Pvt.Ltd.	The firm presented the Phase III Clinical trial report for import and marketing of new drug Carbon-14 urea 37 Kbq Capsules (Pytest capsules) before the committee. The committee observed that the firm has conducted the study at only one site. After detailed deliberation, the committee recommended that more geographically distributed sites shall be included in the study.
4.	ND/MA/24/000113 Elobixibat Tablets 5 mg	M/s Exemed Pharmaceuticals	In light the earlier SEC recommendation dated 20.12.2024, firm presented bioequivalence study report of Elobixibat Tablets 5mg before the committee. The committee noted that Elobixibat Tablets 5mg is already approved for manufacture and market in India on 15-07-2024. After detailed deliberation, the committee considered Bioequivalence study results and recommended for grant of permission to manufacture and market of drug

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			Elobixibat Tablets 5mg.
5.	ND/MA/24/000162 Resmetirom Tablets 60mg, 80mg & 100mg	M/s Mankind Pharma Ltd	In light of earlier SEC recommendation dated 27.02.2025, firm presented BE study results and Phase III clinical trial protocol of Resmetirom Tablets (60 mg, 80 mg & 100 mg) before the committee. After detailed deliberation, the committee considered BE results presented by the firm and recommended for grant of permission to conduct Phase III clinical trial as per the protocol presented subject to the condition that firm should include sites preferably having liver disease management facility.
FDC Division			
6.	04-21/2010-DC (Pt. Sun) Pantoprazole Sodium IP eq. to Pantoprazole (Enteric coated pellets) 40mg + Levosulpiride (SR tablets) 75mg capsule	M/s Sun Pharma Laboratories Ltd.	In light of the condition mentioned in permission in Form 46 dated 27.01.2014, the firm presented proposal with the request to remove the condition that FDC shall be supplied in a Monocarton of 10 tablets per strip and each pack, package insert and other promotional literature shall bear the statement that "indicated for short term treatment of GERD in adult patients who do not respond to PPI alone" After detailed deliberation, the committee agreed for the removal of above said condition. However, the firm should print "indicated for short term treatment of GERD in adult patients who do not respond to PPI alone" on all packing materials including strip and outer carton.
7.	04-30/2018-DC Sodium Alginate IP 250mg + Sodium bicarbonate IP 133.5mg + Calcium carbonate IP 80mg per 5mL Oral Suspension	M/s Reckitt Benckiser Health Ltd.	Firm did not turn up for presentation.
8.	FDC/MA/24/000087 L-Isoleucine U.S.P. 0.33 % w/v + L-Leucine U.S.P. 0.4020 % w/v + L-Lysine hydrochloride U.S.P.	M/s Aculife Healthcare Private Limited	Firm did not turn up for presentation.

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	0.3190% w/v + L-Methionine U.S.P. 0.2200 % w/v + L-Phenylalanine U.S.P. 0.3080 % w/v + L-Threonine U.S.P. 0.2310 % w/v + L-Trytophan U.S.P. 0.0990 % w/v + L-Valine U.S.P. 0.3190 % w/v + L-Arginine U.S.P. 0.6320 % w/v + L-Histidine U.S.P. 0.2640 % w/v + Glycine U.S.P. 0.5660 % w/v + L-Alanine U.S.P. 1.1380 % w/v + L-Proline U.S.P. 0.3740 % w/v + L-Serine U.S.P. 0.2750 % w/v + L-Tyrosine U.S.P. 0.0220 % w/v solution for infusion		