

Recommendations of the SEC (Gastroenterology & Hepatology) made in its 03rd/26 meeting held on 12.03.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/21/26 Online Submission (54640) SPY001-001, SPY002-091, SPY003-207	M/s. PSI CRO Pharma Pvt. Ltd.	The firm presented Phase II clinical study protocol no. SPY123-202, version no. 1.1 dated 29 January 2026. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm. Dr. Vineet Ahuja did not participate in the discussion.
New Drugs Division			
2.	ND/28/2026-eoffice Vonoprazan Tablets 10 mg/ 20 mg	M/s. Dr. Reddy's Laboratories Ltd.	The firm presented their proposal for amendment in the warning statement, mentioned under condition no. 3 of the permission to manufacture and market Vonoprazan Tablets 10 mg and 20 mg, before the committee. After detailed deliberation, the committee agreed for the amendment in warning statement from "To be sold by retail only under the prescription of Gastroenterologist only" to "To be sold by retail only under the prescription of Registered Medical Practitioner".
SND Division			
3.	SND/MA/22/000219 SND/CT21/FF/2022/33053 Tofacitinib Extended Release Tablets 11 mg & 22 mg	M/s. MSN Laboratories Private Limited.	In light of earlier SEC recommendation dated 11.11.2025, firm presented the BE study report of Tofacitinib Extended-Release Tablets 22 mg along with justification for BMI in the study subjects before the committee. After detailed deliberation, the committee accepted the BE study report of Tofacitinib Extended-Release

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			Tablets 22 mg. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the applied product.