

Recommendations of the SEC (Gastroenterology & Hepatology) made in its 5th/26 meeting held on 14.05.2026 at CDSCO (HQ), New Delhi:

S. No.	File Number, name of drug, strength and dosage form	Name of firm	Recommendations
New Drugs Division			
1.	ND/MA/23/000141 Eluxadoline tablets 75 mg & 100 mg	M/s Sun Pharma Laboratories Limited	In light of earlier SEC recommendation dated 26.10.2023 and 11.02.2026, the firm has presented the Phase III Clinical trial report for manufacture and marketing of new drug Eluxadoline tablets 75 mg & 100 mg before the committee. The committee observed that Eluxadoline tablets was non inferior to comparator in treating patients with Diarrhoea-Predominant Irritable Bowel Syndrome in terms of percentage of composite responders based on improvements in worst abdominal pain (WAP) and stool consistency score (using BSFS) at Week 12. The study drug was safe and well tolerated. The package insert was also reviewed by committee and found to be as per requirements. After detailed deliberation, the committee recommended for the grant of permission for manufacturing and marketing of drug Eluxadoline tablets 75 mg & 100 mg. Further, the committee recommended that firm should give special emphasis in recording the adverse events profile of drug in Indian patients and submit the same in PSUR's.