Recommendations of the SEC (Analgesic & Rheumatology) made in its 05th/24 meeting held on 02.05.2025 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/90/23 Online Submission (38667) Anifrolumab (MEDI-546)	M/s. AstraZeneca	The firm did not turn up for presentation.
2.	CT/60/24 Online Submission (42902) BMS-986165 Deucravacitinib	M/s. BMS	The firm presented Phase III clinical trial study protocol No.: IM011-246 protocol amendment 02 dated 07-09-2023. After detailed deliberation, the committee recommended for the grant of permission to conduct the trial as presented by the firm.
3.	CT/61/24 Online Submission (42924) BMS-986165 Deucravacitinib	M/s. BMS	The firm presented Phase III clinical trial study protocol No.:IM011-247 protocol amendment 02 dated 07-09-2023. After detailed deliberation, the committee recommended for the grant of permission to conduct the trial as presented by the firm.
4.	CT/52/24 Online Submission (42736) KSHB002 125 mg	M/s. Kashiv Biosciences	The firm presented Phase III clinical trial study protocol No.:MW240002, version 1.0 dated 28-03-2024. After detailed deliberation, the committee recommended for the grant of permission to conduct the trial as presented by the firm.
BA/BE Division			
5.	File No. 12-09/ 2024/BA-BE/ MISC-13/DC BABE/CT05/FF/2023 /40156 Ketorolac Tromethamine Sustained Release Tablet 30 mg	M/s. Dr. Reddy's Laboratories Limited,8-2-337, Road No. 3, Banjara Hills, Telangana (India) -500034	In light of earlier SEC recommendation dated 13.03.2024, the firm presented the proposal along with justification of study design with regard to comparability of pharmacokinetics of immediate release vs sustained release dosage form with supportive documents before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BA/BE study for export purpose only.
SND Division			

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
6.	SND/MA/23/000241 Paracetamol Oral Suspension 500mg/5ml	M/s. Naxpar Pharma Private Limited	In light of earlier SEC recommendations dated 03.04.2024, the firm presented bioequivalence study protocol (protocol No.: TBS-04-24-825 version No.:1.0 Dated: 11.04.2024) before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct bioequivalence study as per protocol presented by the firm.
FDC Division			
7.	FDC/MA/22/000341 Paracetamol IP 325mg + Tapentadol Hydrochloride IP 50mg (as extended release) tablet	M/s. MSN Laboratories	The firm presented the proposal before the committee. After detailed deliberation, the committee opined that: 1. The firm should present Literature demonstrating better safety profile and less chance of dependence with the proposed FDC. 2. The firm should present Literature demonstrating lesser adverse event/ side effect profile with the proposed FDC. 3. The firm should present more data on drug abuse potential of Tapentadol. 4. The firm should present International approval status of the proposed FDC. Accordingly, the firm should submit above data to CDSCO for further review by the committee.