

Recommendations of the SEC (Gastroenterology & Hepatology) made in its 52nd meeting held on 20.09.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2022/32201 Itolizumab for Injection (r-DNA origin) 100 mg/vial	M/s. Biocon Limited	<p>The firm presented the clinical trial protocol titled “A Phase II randomized, double-blind, parallel-group, placebo and active-controlled, two treatment period study to evaluate the safety and efficacy of Itolizumab for the induction of remission in biologics naïve patients with moderate to severely active ulcerative colitis” vide protocol number BIO-ITOLIZ-207, Version 1.0, Dated 11-May-2022.</p> <p>The committee noted that the drug is already approved for active moderate to severe chronic plaque psoriasis and the firm has conducted a Phase I study (Bmab600-NHV-01-G-01) of the safety, tolerability, PK, PD, and bioavailability of Itolizumab in healthy volunteers at doses ranging from 0.4 to 3.2 mg/kg in Australia.</p> <p>After detailed deliberation, the committee recommended to grant permission to conduct the Phase II study as presented.</p>
SND Division			
2.	SND/MA/22/000547 Ursodiol Injection 625mg/25ml (25 mg/ml)	M/s. Shilpa Medicare	<p>The firm presented their proposal for Phase III CT protocol titled “A multicenter, double-blind, safety and efficacy of intravenous Ursodiol injection 625mg/25ml (25mg/ml) in severe alcoholic hepatitis patients” before the committee.</p> <p>After detailed deliberation, the committee opined that the data presented by the firm is inadequate w.r.t safety to go for clinical trial.</p> <p>The committee recommended that the firm should submit adequate safety data with available published literature in public domain for further review by the committee.</p>
FDC Division			
3.	FDC/MA/21/000129	M/s. Naxpar Pharma Pvt. Ltd.	As per condition mentioned in permission dated 07.09.2021, the firm presented the

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	Sodium alginate IP 500mg + Sodium Bicarbonate IP 213mg + Calcium Carbonate IP 325mg Oral suspension		PMS study protocol before the committee. After detailed deliberation, the committee recommended for conducting the PMS study. The results of the PMS study should be presented before the committee for review.
GCT Division			
4.	CT/49/20 Online Submission (18003) Mirkizumab	M/s. Eli Lilly	The firm presented the request for the waiver of the condition given under protocol amendment (c) approval dated 06.01.2022. The firm has submitted that enrollment was already completed on 24 Aug 2022. The committee noted that the condition under the protocol amendment (c) was a reiteration of the condition under the CT NOC dated 28.07.2020 and based on the earlier SEC recommendations, now the firm has no rationale to justify the waiver of the condition. Therefore, the committee did not recommend any waiver of condition.
5.	CT/126/20 Online Submission (19725) Brazikumab	M/s. Astra Zeneca	The firm presented the proposed clinical trial protocol D5272C00001 amendment version 7.0 dated 10 March 2022 before the committee. After detailed deliberation, the committee recommended for grant of permission of proposed clinical trial protocol amendment version 7.0 dated 10 March 2022 as presented.
6.	CT/31/16 Offline Submission (11913) Vedolizumab	M/s. PPD	The firm did not turn up for presentation.
Medical Device Division			
7.	CI/MD/2022/59479 Spyglass Discover Digital Catheter	M/s. Boston Scientific India Private Limited	The firm presented their proposal for the post market clinical investigation before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct post marketing clinical investigation in the country.

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8.	IMP/MD/2021/45970 Flat sheet mesh (Pearltene)	M/s. India Medtronic Pvt. Ltd	The firm did not turn up for presentation.