

Recommendations of the SEC (Gastroenterology & Hepatology) made in its 03rd/24 meeting held on 13.03.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/49/23 Online Submission (31066) PB016 and Entyvio®	M/s. Worldwide	The firm presented the proposal to increase the number of randomized patients India by 100 (in total 250) in respect to protocol number: PB016-03-01 After detailed deliberation, the committee recommended for approval to increase the number of randomized patients India by 100 (in total 250) as presented by the firm.
2.	CT/105/23 Online Submission (31218) JNJ-77242113	M/s. J&J	The firm presented protocol amendment 2 dated 31 October 2023 for protocol No. 77242113UCO2001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/28/24 Online Submission (42027) MORF-057	M/s. PSI CRO	The firm presented Phase 2 clinical study protocol No. MORF-057-203 version 2.0 dated 28 November 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm with condition that, equal No. of Govt. & private sites should be included in the study.
4.	CT/132/22 Online Submission (31209) GSK4532990	M/s. GSK Pharma	The firm presented protocol amendment 03 dated 18 January 2024 for protocol No. 218672. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm
Biological Division			
5.	BIO/CT21/FF/2023/3 7090 Adalimumab 100mg/ml	M/s. Enzene Biosciences Limited	In light of the earlier SEC recommendation dated 17.10.2023, the firm presented the proposal for approval of additional indications of Crohn's disease and Ulcerative colitis in adults by the way of extrapolation in line with the innovator product. After detailed deliberation, the

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			committee recommended for grant of approval of the proposed additional indications in adults.
6.	BIO/CT18/FF/2023/4 0566 Mirikizumab Injection 300mg/15mL solution in vial and 100mg/mL solution in PFS	M/s. Eli Lilly	The firm presented the proposal to import and market Mirikizumab Injection 300mg/15mL solution in vial and 100mg/mL solution in PFS indicated for the treatment of moderate to severe active ulcerative colitis in adults based on the results of global clinical trial conducted by the firm including Indian population. The committee noted that the drug is approved in USA, Europe, Canada, Japan, Australia and other countries. After detailed deliberation, the committee recommended for grant of marketing authorization to the firm for Mirkizumab Injection 300mg/15mL solution in vial and 100mg/mL solution in PFS subject to the condition that the firm should conduct Phase IV clinical trial in the country. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of marketing approval.
7.	BIO/CT18/FF/2022/3 5021 Ustekinumab solution for injection for subcutaneous administration	M/s. J & J Pvt. Ltd.	In light of the earlier SEC recommendation dated 18.04.2023, the firm presented the proposal for approval of additional indication of Crohn's disease. After detailed deliberation, the committee recommended for the proposed additional indication of ulcerative colitis.
8.	BIO/CT04/FF/2023/3 6848 Vedolizumab 300mg	M/s. Dr.Reddy's Laboratories Limited	The firm presented the revised protocol version 2.0 dated 09 th Feb 2024 for the conduct of Phase I clinical trial study of Vedolizumab 300mg/vial. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase I trial as per the revised protocol presented by the firm.
SND Division			
9.	SND/IMP/20/000021 Mesalazine Prolonged Release Tablets 500mg,	M/s. Ferring Pharmaceuticals Pvt. Ltd.	In light of earlier SEC recommendations dated 14.09.2023, the firm presented approved packaged insert from the country of origin (Switzerland) on 21.11.2022 with proposed changes like

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	Mesalazine Prolonged Release Granules 1gm & 2gm and Mesalazine Suppositories 1gm		urine discoloration, skin subcutaneous disorders etc. before the committee. After detailed deliberation, the committee recommended for proposed updation in package insert as follows: <ol style="list-style-type: none"> 1. Updation of the method of administration of mesalazine prolonged release granules 1g & 2g for use with Yogurt. 2. Update of package insert of PENTASA tablet (Mesalazine 500mg prolonged release tablets), granules (Mesalazine prolonged release granules 1g & 2g), and Mesalazine suppositories 1g.
10.	SND/IMP/23/000093 Ademetionine for Injection 400mg	M/s. Abbott Limited	The firm presented the proposal for grant of permission to import and marketing of Ademetionine for injection 400mg along with Phase-III clinical trial protocol before the committee. After detailed deliberation, the committee recommended to conduct Phase-III clinical trial as per protocol (protocol No. ADEM-323-0417, version No. 1.0, dated 18.12.2023) presented by the firm.
New Drugs Division			
11.	ND/IMP/23/000087 Etrasimod Tablets 2mg	M/s. Pfizer Products India Pvt. Ltd.	The firm didn't turn up for presentation.
FDC Division			
12.	FDC/MA/19/000089 Sodium Alginate IP 250mg + Sodium Bicarbonate IP 133.5mg + Calcium Carbonate IP 80mg per 5mL Oral liquid	M/s. Naxpar Pharma Pvt. Ltd.	In light of earlier SEC recommendation dated 17.02.2021 and as per condition of Form CT-23 dated 09.04.2020, the firm presented the Active PMS report before the committee. After detailed deliberation, the committee opined that the firm should submit source data of the Active PMS report to CDSCO for review by the committee.