

Recommendations of the SEC (Gastroenterology & Hepatology) made in its 57th meeting held on 22.02.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/MA/19/000035 Trientine Tetrahydrochloride Capsules 333 mg	M/s. Zenvision Pharma LLP	The firm presented its proposal for amendment in the approved therapeutic indication of Trientine Tetrahydrochloride Capsules 333mg. After detailed deliberation, the committee recommended grant of permission for amendment in the approved therapeutic indication on presented by the firm.
Biological Division			
2.	BIO/CT/22/000115 Ustekinumab pre-filled syringes 45mg/0.5ml, 90mg.ml and single use vial 130 mg/26 ml	M/s. Johnson & Johnson Pvt. Ltd.	The proposal was deferred for next meeting.
3.	BIO/IMP/22/000093 Ustekinumab pre-filled syringes 45mg/0.5ml, 90mg.ml and single use vial 130 mg/26 ml	M/s. Johnson & Johnson Pvt. Ltd.	The proposal was deferred for next meeting.
SND Division			
4.	SND/MA/22/000227 Amisulpride injection 5mg/2ml	M/s La-Renon Healthcare	The firm did not turn up for presentation.
5.	SND/MA/20/000083 Ursodeoxycholic Acid Tablets IP 150/300/450/600 mg	M/s Abbott India Limited	The proposal was deferred for next meeting.
FDC Division			
6.	FDC/MA/18/000006 Dicyclomine + Tapentadol (20mg + 50mg & 10mg +	M/s. Wockhardt	In light of the earlier SEC recommendation dated 18.10.2022. The proposal was decided for re-deliberation before the Committee w.r.t 1430 incidents reported for involving the seizure of Tapentadol.

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	25mg) tablets		After detailed deliberation, the committee recommended that: 1. Firm should present more data on drug abuse potential of Tapentadol. 2. Firm should present revised CT protocol by incorporating the mechanism to evaluate the drug abuse potential of Tapentadol. Accordingly, the firm should present the proposal before SEC.
GCT Division			
7.	CT/28/22 Online Submission (20917) Guselkumab (CNT01959)	M/s. Parexel	The proposal was deferred for next meeting.
8.	CT/142/22 Online submission (34813) AZD2693	M/s. Astra Zeneca	The proposal was deferred for next meeting.
9.	CT/102/22 Online Submission (33917) Filgotinib [GS-6034, Formerly GLPG0634	M/s. PRA	The proposal was deferred for next meeting.
10.	CT/124/20 Online Submission (19890) Brazikumab	M/s. Astra Zeneca	The proposal was deferred for next meeting.
11.	CT/138/22 Online Submission (34729) Tegoprazan 50mg Tab.	M/s. Reddy's	The proposal was deferred for next meeting.
12.	CT/15/17 Online Submission (20992) Dated 28/09/22 Filgotinib	M/s. Klinera	The firm did not turn up for presentation.