

Recommendations of the SEC (Gastroenterology & Hepatology) made in its 46th meeting held on 16.03.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/20/000071 Lidocaine 2% w/w + Diltiazem hydrochloride 2% w/w Gel	M/s. Abbott	The firm presented Phase III clinical trial report before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC.
GCT Division			
2.	CT/90/19 Topifexor (LJN452) & Licogliflozin (LIK066)	M/s. Novartis	The firm presented protocol amendment version 01 dated 18 Sep 2020 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.