

Recommendations of the SEC (Gastroenterology & Hepatology) made in its 49th meeting held on 16.06.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/22/000028 Guselkumab (CNTO1959)	M/s Parexel	<p>The firm presented the proposal to conduct Phase II/III clinical trial (GALAXI study) protocol no: CNTO1959CRD3001, amendment 4 dated 21-JUL-2021 before the committee. The firm mentioned that India will be participating in the Phase III part (i.e. GALAXI 2 and GALAXI 3) of the trial.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial with condition that the firm should include more number of Govt. sites to have the sites geographically distributed in the country.</p>
FDC Division			
2.	FDC/MA/21/000224 Pantoprazole Sodium IP eq To Pantoprazole 40mg + Acotiamide Hydrochloride trihydrate IP (ER) IH 300mg capsules .	M/s Akums Drugs & Pharmaceuticals Ltd,	<p>In light of earlier SEC recommendation dated 17.12.2021, the firm presented their proposal alongwith revised Phase III CT protocol and BE study results before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III clinical trial with condition that refractive GERD should clearly be defined in inclusion criteria as per National ISG guidelines on GERD. The results of the study should be presented before the committee.</p>