

Recommendations of the SEC (Gastroenterology & Hepatology) made in its 41st meeting held on 21.10.2021 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/74/21 Online Submission (26706) dated 01/07/21 Brazikumab	M/s. AstraZeneca	The firm presented their proposed Phase II clinical trial vide protocol no.; D5272C00002, Amendment 2 (Version 3.0) before the committee. After detailed deliberation, committee recommended for grant of permission to conduct the study with condition that the firm should include atleast 50% government sites in the proposed study.
2.	CT/90/19 Online Submission (12401) dated 5/08/21 Tropifex(LJN452) & Licogliflozin (LIK066)	M/s. Novartis	In light of earlier recommendation of SEC dated 17 June 2021, the firm presented the proposed Phase IIb protocol CLJN452D12201C amendment Version 01 dated 18 Sep 2020 (ELIVATE) with rationale before the Committee. After detailed deliberation, the Committee reiterated the earlier recommendations and opined that the firm should present the study data of FLIGHT-FXR (CLJN452A2202) and TANDEM (CLJC242A2201J) study before the committee for further review of the proposed amendment.
3.	CT/124/20 Online Submission (11359) dated 23/04/2021 Brazikumab	M/s. Astrazeneca	The firm presented the proposed Phase IIb/III amended study Protocol D5271C00001, Amendment 4 (Version 5.0) dt. 24-FEB-2021 (INTREPID Lead In study) before the Committee. During presentation the firm stated that there was no proposal for increase in the number of subjects from India. After detailed deliberation, the Committee recommended for grant of approval for the proposed protocol amendment with condition that the firm should include atleast 50% government sites in the study.
Medical Device Division			
4.	MFG/MD/2021/3533 8VGM HAEMOSEAL POWDER	M/s. Shaili Endoscopy	The firm presented their proposal before the committee. The committee noted that the product is not approved in any country. After detailed deliberation, the committee recommended that the firm needs to conduct multi centric clinical

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			investigation in India. Accordingly, the firm should submit protocol for clinical investigation to CDSCO for further review.
5.	CI/MD/2021/45153 Transcutaneous Implant Evacuation System (TIES®)	M/s. IR Innovate Research Private Limited	The firm presented their proposal for pivotal clinical investigation before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the pivotal clinical investigation of the proposed medical device in the country.
6.	CI/MD/2021/45534 RESOLV Endoscopic Hemostat System	M/s. Shreyaas Health care Products Private Limited	The firm presented their protocol for clinical investigation before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical investigation of the proposed medical device as per the proposed protocol in the country.
7.	CI/MD/2020/32939 Portable Endoscope	M/s. HCL Technologies Limited	In light of earlier SEC recommendations dated 17.06.2021, the firm presented their proposal for pilot clinical investigation before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed feasibility study subject to condition that firm should follow all the standard protocols for disinfection of the medical device. Accordingly, firm should submit data generated from the study to CDSCO for further consideration.
8.	IMP/MD/2021/39706 Endoscopic full-thickness resection kit	M/s. Morulaa HealthTech Pvt Ltd	The firm presented their proposal before the committee. Committee noted that the proposed medical devices are already imported and marketed in India and also approved in other countries like USA, EU etc. After detailed deliberation, the committee recommended for grant of permission to import and market the proposed medical devices.