

Recommendations of the SEC (Gastroenterology & Hepatology) made in its 10th/24 meeting held on 16.10.2024 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	GCT/PostAppr/2024/34833 Online Submission (34833) Diltiazem Hydrochloride Gel 2%	M/s Cliantha Research Limited	The firm presented protocol amendment version 04 dated 17.05.2024 protocol No. C2A01987. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	GCT/PostAppr/2024/34745 Online Submission (34745) Efruxifermin	M/s Klinera Global Services	The firm presented protocol amendment 2 dated 17.07.2024 protocol No. AK-US-001-0105. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	GCT/CT04/FF/2024/45087 Online Submission (45087) Miricorilant	M/s Klinera Global Services	The firm presented Phase II B clinical trial study protocol No. CORT118335-862 amendment 2 dated 23.05.2024, After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
4.	GCT/CT04/FF/2024/45173 Online Submission (45173) RO7790121	M/s Roche Products (India) Private Limited	The firm didn't turn up for presentation.
5.	GCT/CT04/FF/2024/45175 Online Submission (45175) RO7790121	M/s Roche Products (India) Private Limited	The firm didn't turn up for presentation.
Medical Devices Division			
6.	IMP/MD/2024/12031 5 pH Monitoring System & Accessories (Brand Name: Bravo)	M/s India Medtronic Private Limited	The firm presented the proposal for grant of permission to import and market the medical device viz. pH Monitoring System & Accessories "Bravo" under Form MD-27 manufactured by M/s Given

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			<p>Imaging, Inc., United States.</p> <p>The firm presented the data showing that the proposed device is approved and marketed for more than two years in countries viz. USA, Canada, Australia, EU, etc. Further, the firm has presented the clinical evidence and PMS (Post Marketing Surveillance) data of the proposed device.</p> <p>After detailed deliberation and based on the documents presented, the committee recommended for consideration of the said proposal.</p> <p>Accordingly, the firm shall submit a study protocol for conduct of Post Marketing Clinical Investigation within a period of six months from date of launch of the product in the country to have a clinical effectiveness data in Indian population.</p>
New Drugs Division			
7.	ND/CT/24/000064 Vonoprazan 20 mg tablets	M/s Hetero Labs Limited	<p>Firm presented their proposal for grant of permission to conduct phase IV clinical trial with new drug Vonoprazan 20 mg tablets before the committee.</p> <p>After detailed deliberation, the committee recommended for the grant of permission to conduct Phase IV clinical trial as per the presented protocol</p>
FDC Division			
8.	FDC/MA/24/000190 Vonoprazan Fumarate Tablets eq. to Vonoprazan 20mg + Acotiamide Hydrochloride Hydrate ER 300mg film coated Tablets	M/s Hetero Labs Limited	<p>The firm presented their proposal before the committee.</p> <p>After detailed deliberation, committee opined the following:</p> <ol style="list-style-type: none"> 1. The firm did not present the justification on rationality of the combination and its significant benefits. 2. The firm did not present any published literature from peer-reviewed journal w.r.t Vonoprazan along with Prokinetic drug. 3. The firm did not present any

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			<p>proof of concept study in support of significant clinical need of the FDC in the proposed indication.</p> <ol style="list-style-type: none"> 4. The firm did not present any data/literature w.r.t Drug-Drug-Interactions (known and/or expected) among the active ingredients present in the FDC. 5. The proposed FDC is not approved internationally. 6. There is no unmet need for proposed FDC. <p>In view of above, the committee did not recommend the proposal for proposed FDC.</p>