Recommendations of the SEC (Gastroenterology & Hepatology) made in its 60th meeting held on 23.05.2023 at CDSCO HQ New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/23/000053 Vonoprazan Fumarate Tablet 20mg	M/s. Centaur	The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Vonoprazan fumarate tablets 20 mg along with Phase III clinical trial protocol and BE study waiver before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed Phase III clinical trial along with the waiver of BE study subject to following conditions: (1) Interim report on the safety of the drug at the end of 4 weeks to be submitted to check the renal function/nephrotoxicity associated with the study drug. (2) During clinical laboratory screening, the lab reference range has to be strictly adhered but not at the discretion of the PI. (3) During Screening, tests for Serum B12 and Serum Calcium to be included. (4) Women of child bearing age should use contraception except Oral contraceptive pills during the study period and if any patient becomes pregnant, will report immediately. (5) Grade A and B symptomatic patients for GERD especially will be enrolled. Accordingly, the firm should submit the revised protocol to CDSCO for grant of clinical trial permission.
2.	ND/MA/23/000060 Vonoprazan Fumarate Tablets 10mg and 20mg	M/s. Dr. Reddy's Laboratories Ltd.	The firm presented the proposal for grant of permission for manufacturing and marketing of the drug Vonoprazan fumarate tablets 10 mg and 20 mg along with Phase III clinical trial protocol and BE study report before the committee. The committee noted the BE study result as presented by the firm. After detailed deliberation, the committee recommended for grant of permission for conduct the proposed Phase III clinical trial subject to the following conditions: (1) Interim report on the safety of the drug at

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			the end of 4 weeks to be submitted to check the renal function/nephrotoxicity associated with the study drug. (2) During clinical laboratory screening, the lab reference range has to be strictly adhered but not at the discretion of the PI. (3) During screening, tests for Serum B12 and Serum Calcium to be included. (4) Women of child bearing age should use contraception except Oral contraceptive pills during the study period and if any patient becomes pregnant, should report immediately. (5) Grade A and B symptomatic patients for GERD especially will be enrolled. Accordingly, the firm should submit the revised protocol to CDSCO for grant of clinical trial permission.
SND Division			
3.	SND/MA/23/000086 Rabeprazole sodium Modified Release capsule 40mg	M/s. Dr. Reddy's Laboratories Ltd.	The firm presented the proposal for grant of permission for manufacturing and marketing of Rabeprazole Sodium modified release Capsules 40 mg for the treatment of patients with gastro-esophageal reflux disease (GERD) refractory to standard PPI therapy alongwith Phase III clinical trial protocol and comparative bioavailability study protocol before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the comparative bioavailability study as per the protocol presented by the firm. Further, the committee also recommended that the result of the comparative bioavailability study should be presented before the committee for further decision on grant of permission for conduct of the Phase III clinical trial.
FDC Division			
4.	FDC/MA/18/000006 Dicyclomine + Tapentadol (20mg + 50mg & 10mg + 25mg) tablets	M/s. Wockhardt	In light of earlier SEC recommendation dated 18.10.2022 & 22.02.2023, the firm presented the revised clinical trial protocol. After detailed deliberation, the committee recommended for grant of permission for conduct of the proposed Phase-III clinical

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			trial as presented by the firm. Committee also recommended that the result of the study should be submitted to CDSCO for further review by the committee.
5.	FDC/MA/23/000112 Alpha Amylase (Diastase) 100mg +Papain 60mg Capsules	M/s. Skymap Pharmaceuticals Pvt. Ltd.	The firm presented the proposal before the committee. The firm informed the committee that firm is already holding the product permission issued by the concerned State Licensing Authority. After detailed deliberation, the committee recommended that the proposal may be considered for re-deliberation after CDSCO take the necessary action as the firm has already obtained the product license from State Licensing Authority.
6.	FDC/MA/23/000115 Omeprazole as enteric coated pellets 10mg+Domperidone 10mg Capsules	M/s. Helios Pharmaceuticals	The firm presented the proposal before the committee. The firm informed the committee that firm is already holding the product permission from concerned State Licensing Authority. After detailed deliberation, the committee recommended that the proposal may be considered for re-deliberation after CDSCO take the necessary action as firm has already obtained the product license from State Licensing Authority.
GCT Division			
7.	CT/28/23 Online Submission (36674) VTX958	M/s. PSI CRO	The firm presented Phase-II clinical trial protocol no- VTX958-202, amendment-02, dated 29 Nov 2022, before the committee. After detailed deliberation, the committee recommended for grant of permission for conduct of the proposed study as presented by the firm.
8.	CT/138/22 Online Submission (34729) Tegoprazan 50mg tablets	Dr. Reddy's Laboratories Limited	The proposal was deferred for the next SEC meetings.
Medical Device Division			
9.	CT/MD04/2017 Study Title- "Fully	M/s. Bostan Scientific India Pvt. Ltd.	The proposal was deferred for the next SEC meetings.

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	Covered Self Expanding Metal Stents (FCSEMS) for Pancreatic Duct Strictures in Patients with Chronic Pancreatitis"		
10.	CI/MD/2021/50481 NOBIX System	M/s. CBCC Global Research LLP	The proposal was deferred for the next SEC meetings.
11.	IMP/MD/2023/81256 Faciotens Abdomen, Fasiotens Hernia, Fasiotens Paediatric	M/s. Olivine International	The proposal was deferred for the next SEC meetings.