Recommendations of the SEC (Cardiovascular) made in its 9th/24 meeting held on 07.05.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/17/20 Online Submission (26510) TQJ230	M/s. Novartis	In light of earlier SEC recommendation dated 07.03.2024 wherein the committee had approved version 04 dated 10.05.2023, the firm presented protocol amendment version 05 dated 19.09.2023 protocol No. CTQJ230A12301. After detailed deliberation, the committee recommended for approval of protocol amendment version 05 dated 19.09.2023 as presented by the firm.
2.	CT/45/24 Online Submission (42369) Bakinrenone/ Dapagliflozin	M/s. AstraZeneca	The firm presented phase III clinical study protocol no. D6402C00012 CSP version 2.0 dated 11.01.2024 and protocol addendum IND-1 version 1.0 dated 06.03.2024. After detailed deliberation, the committee opined that the firm shall present following for further review of committee: 1. Complete phase I and phase II data of the study 2. Justification for not including renal parameters as primary or secondary efficacy endpoints 3. Justification for wide dose ranges (15 mg and 40 mg) of Balcinrenone.
3.	CT/64/21 Online Submission (31938) Tirzepatide	M/s. Eli Lilly	The firm presented protocol amendment © dated 14. 02.2024 protocol no. I8F-MC-GPID. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
BA/BE Division			
4.	File No. 12-09/2024/ BA-BE/MISC-30/DC BABE/CT05/FF/2023 /41882 Diltiazem Hydrochloride Topical Gel (4%w/w)	M/s. Veeda Clinical Research Limited, Ahmedabad - 380015	The firm presented the protocol No.: 23-VIN-0573 Version No.01 dated 06.02.2024 for BA/BE study for export purpose only. After detailed deliberation, the committee opined that the firm is required to submit the following information / data / documents: 1. Safety & preclinical data of applied product Diltiazem Hydrochloride Topical Gel (4%w/w) of sponsor. 2. Rational for study design in which comparing test product Diltiazem Hydrochloride Topical

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			Gel (4%w/w) Vs Reference product CARDIZEM Tablets 120 mg in healthy subjects. Accordingly, the firm should submit the above information/data for re-deliberation by the SEC.
SND Division			
5.	SND/IMP/23/000037 Empagliflozin Tablets 10mg/25mg	M/s. Boehringer Ingelheim India Private Limited	The firm presented the proposal for uniformity in package insert and product label with respect to condition No. 3 (Warning condition) of the permission in its applications (SND/IMP/20 /000105, SND/IMP/22/000001 & SND/IMP /23/000037) for import and marketing before the committee. The firm has informed that they hold permission for following indications and warning condition: 1. Permission No. IMP/SND/21/000097 dated 22.09.2017 for the indication: "To reduce the risk of cardiovascular death plus hospitalization for heart failure in adults with heart failure and reduced ejection fraction" with "WARNING: To be sold by retail on the prescription of RMP only" which shall be in red box. 2. Permission No. IMP/SND/22/000033 dated 05.05.2022 for the indication: "To reduce the risk of cardiovascular death and hospitalization for heart failure in adults with heart failure subject to condition that the drug should be prescribed only to the patients with eGFR more than 30ml/min/1.73m^2" with "WARNING: To be sold by retail on the prescription of RMP only" which shall be in red box. 3. Permission No. IMP/SND/24/000001 dated 18.01.2024 for the indication: "To reduce the risk of sustained decline in eGFR (only for patients with eGFR 30-90 ml/mim/1.73m2), end-stage kidney disease, cardiovascular death, and hospitalization in adults with chronic kidney disease at risk of progression" with "WARNING: To be sold by retail on the prescription of Cardiologist, Nephrologist only" which shall be in red box.

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			After detailed deliberation, the committee recommended for change in warning condition for Empagliflozin tablets 10mg only – "To be sold by retail on the prescription of a Medical Specialist only", for sake of uniformity. Further, the firm should submit updated prescribing information, product label and product carton to CDSCO.
New Drugs Division			
6.	ND/IMP/23/000058 Cleviprex (Clevidipine) 0.5 mg/mL emulsion for injection	M/s. Paviour Pharmaceuticals	The firm presented the proposal for grant of permission to import and market Cleviprex (Clevidipine) 0.5 mg/ml emulsion for injection for indicated reduction of blood pressure when oral therapy is not feasible or not available along with the request for Phase-III Clinical Trial waiver before the committee. After detailed deliberation, the committee opined that there is no unmet medical need as several therapies are available in the country. Accordingly, the committee did not recommend for Phase-III Clinical Trial waiver and also recommended that the firm should conduct Phase-III clinical trial for the proposed indication and accordingly, the firm should submit the Phase-III clinical trial protocol to CDSCO for further consideration.
FDC Division			
7.	FDC/MA/23/000231 Metoprolol Succinate IP 23.75mg eq. to Metoprolol Tartrate 25mg (ER) + Telmisartan IP 40mg + Amlodipine Besilate IP eq. to Amlodipine 5mg film coated bilayered tablet	M/s. Ajanta Pharma Ltd.	In light of the earlier SEC recommendation dated 09.08.2023, the firm presented the proposal along with BE study protocol before the committee. After detailed deliberation, the committee recommended the following: 1. Minimum sample size should be 72 subjects. 2. Washout period should be 28 days. 3. Reference drug should be changed to individual three drugs separately. Accordingly, the revised BE study protocol should be submitted to CDSCO, for review by the committee.
8.	FDC/MA/22/000363 Metoprolol Succinate	M/s. Eris Lifesciences Limited	In light of earlier SEC recommendation dated 23.04.2024, the firm presented the source data w.r.t Vital Signs (Body Temperature, Pulse rate,

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	SR 25mg/50mg + Dapagliflozin 5mg/10mg tablets		Systolic BP and Diastolic BP) of the 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.
9.	FDC/MA/23/000247 Telmisartan IP + Amlodipine Besilate IP eq. to Amlodipine + Bisoprolol Fumarate IP (40mg+5mg+2.5mg)/ (40mg+5mg+5mg) film coated tablet	M/s. Ravenbhel Healthcare Pvt. Ltd.	In light of earlier SEC recommendation dated 20.12.2023, the firm presented the proposal along with BE study report and Phase III clinical trial protocol before the committee. After detailed deliberation, the committee opined that the firm should submit source data of the BE study report. As regard to Phase III clinical trial protocol, the committee opined that firm should change the reference arm where three drugs are given separately. Accordingly, the firm should submit source data of BE study report and revised Phase III clinical trial protocol to CDSCO for further review by the committee.