Recommendations of the SEC (Cardiovascular & Renal) made in its 85th meeting held on 09.03.2021 & 10.03.2021 at CDSCO HQ New Delhi.

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	Import/Misc./ 208/2020-DC (Pt.1) Triple chamber Bag (LVP)	M/s. Baxter Pvt. Ltd.	The firm presented the proposal for update in package insert of the drug before the committee. After detailed deliberation committee recommended that firm should submit existing PI, changes approved by European Union in package insert and proposed changes in package insert in a tabular form for further review by the committee.
2.	ND/CT21/FF/2021/24162 Bempedoic Acid Tab 180 mg	M/s. Optimus Pharma Pvt. Ltd	The firm presented their proposal before the committee. After detailed deliberation committee recommended grant of permission to conduct BE study. Accordingly firm should submit the BE study report to CDSCO for further consideration.
Subsequent New Drugs Division			
3.	SND/MA/20/000265 Ticagrelor SR Tablets 120/180mg	M/s Mascot	The firm presented the BE Study protocol of Ticagrelor Sustained Release Tablets 120mg/180 mg. After detailed deliberation the committee recommended for grant of permission for conduct of Bioequivalence study as per the protocol presented. The clinical trial protocol should be presented before the committee alongwith the BE study results.
4.	SND/IMP/20/000105 Empagliflozin 10mg/25 mg tablet	M/s Boehringer Ingelheim India	The firm presented their proposal of Empagliflozin Tablets 10mg/25 mg for additional indication. After detailed deliberation the committee recommended for grant of permission for indication, 1. Heart failure 2. Empagliflozin tablets is indicated in adult patients with heart failure (NYHA class II-IV) and reduce ejection fraction with or without type 2 diabetes mellitus; • To reduce the risk of cardiovascular death and hospitalization for heart failure.

			For the approval of other indications applied by the firm. The firm is required to submit more clinical data to consider the matter further.
GCT Division			
5.	CT/62/19 Offline Submission (9288) LNP023	M/s. Novartis	In light of recommendation of earlier SEC dated 11.11.2020 & 12.11.2020. The firm presented their proposal for protocol amendment before the committee. After detailed deliberation, the committee recommended for approval of proposed Protocol Amendment version 05,dated 29 Apr 2020.
6.	CT/42/16 Offline Submission (6894) Daprodustat	M/s. PPD	In light of recommendation of earlier SEC dated 09.12.2020 & 10.12.2020.The firm presented their proposal for protocol amendment before the committee. After detailed deliberation, the committee reiterated the MOM of earlier SEC and noted that the change in the MACE non inferiority margin (NI), Sample size re-estimation and others changes related to this amendment including number of events etc, has no scientific justification. Hence the committee did not recommend for proposed protocol amendment.
7.	CT/43/16 Offline submission (6766) Daprodustat	M/s. PPD	In light of recommendation of earlier SEC dated 09.12.2020 & 10.12.2020,.the firm presented their proposal for protocol amendment before the committee. After detailed deliberation, the committee reiterated the MOM of earlier SEC and noted that the change in the MACE non inferiority margin (NI), Sample size re-estimation and others changes related to this amendment including number of events etc, has no scientific justification. Hence the committee did not recommend for proposed protocol amendment.
8.	CT/24/21 Online Submission (24074) Atrasentan	M/s. IQVIA RDS	The firm presented their proposal along with study protocol for phase III clinical trial before the committee. Innovation vis-à-vis Existing Therapeutic option: The Purpose of the study To evaluate the effect of atrasentan versus placebo on proteinuria levels at Week 24 Considering the main exclusion criteria of other associated glomerular disease and therefore

			proper assessment of primary end point of proposed clinical trial, patient who has got electron microscopic findings available ONLY should be in the study Accordingly Protocol should be appropriately modified and study sites should be reorganised based on the availability of Electron Microscopy diagnosis facility. Hence the committee did not recommend proposal in the present format.
FDC Division			
9.	FDC/MA/21/000018 Telmisartan IP 20mg/40mg/20mg/40 mg+Efonidipine IP 20mg/20mg/40mg/40 mg tablets	M/s Akums Drugs and Pharmaceutical Limited	Firm presented the BE and Phase III CT protocol before the committee. After detailed deliberation, committee opined that CT protocol presented was adequate. However, firm should revise the BE study protocol for conducting the BE study on the proposed higher strength. Accordingly, revised BE study protocol shall be submitted for further review by the committee.
10.	FDC/MA/20/000072 Telmisartan IP + Benidipine Hydrochloride (80mg + 4mg)Tablets	M/s. Akums Drugs	The firm did not turn up for the presentation.
11.	FDC/MA/20/000176 Chlorthalidone 6.25mg/6.25mg+Cilnidipine 10mg/10mg Olmesartan Medoxomil 20/40mg tablets	M/s Akums Drugs and Pharmaceutical Limited	The proposal was deferred.
12.	FDC/MA/21/000050 Calcium-3-methyl-2-oxo-velerate (Alpha Ketoanalouge to Isoleucine, Calcium Salt)134mg + Calcium-4-methyl-2-oxo-velerate (Alpha Ketoanalouge to leucine, Calcium Salt)	M/s. Rivpra Formulation Pvt. Ltd.	Firm presented their proposal before the committee. Committee noted that the FDC is already approved by DCGI in 2016 and the proposed FDC is in double strength. This proposed FDC in double strength will help in reducing the pill burden as CKD patients are already burdened with intake of large number of pills. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC.

	202mg + Calcium-2-oxo-3-Phenyl propionate (Alpha Ketoanalouge to Phenylalanine, Calcium Salt) 136mg + Calcium-3-methyl-2-oxo-butyrate (Alpha Ketoanalouge to Valine, Calcium Salt) 172mg + Calcium-DL-2-hydroxy-4-(methylthio)-butyrate (Alpha Hydroxyanalouge to Methionine, Calcium Salt) 118mg + L-Lysine Acetate USP 210mg +L-threonine USP 106mg +L-Tryptophan USP 46mg +L-Histidine 76mg +L-Tyrosine USP 60mg Tablets		
13.	FDC/MA/21/000042 Atorvastatin IP 40mg + Clopidogrel IP 75mg Capsules	M/s. Windlas Biotech Private Limited	Firm presented their proposal alongwith rationality and BE study protocol for the proposed additional strength and requested for Clinical trial waiver. After detailed deliberation, Committee recommended for grant of permission to conduct the proposed BE study. The results of BE study should be presented before the Committee for further consideration.
14.	FDC/MA/21/000049 Chlorthalidone IP 6.25mg/12.5mg + AzilsartanKamedoxomil IP 20mg/20mg tablets	M/s. Akums Drugs and Pharmaceutical Ltd.	Firm presented their proposal before the committee alongwith the request for BE Study and Phase III CT study waiver. The Committee opined that the proposed strengths in FDC may be sub-optimal. Further firm also did not present any published literature on the proposed strengths. After detailed deliberation, the committee recommended that firm should make a detailed presentation before the committee addressing the above points.
15.	FDC/MA/21/000009 Rivaroxaban 2.5mg	M/s. Windlas Biotech Pvt.	Firm presented their proposal before the committee. After detailed deliberation, the committee opined that both the individual drugs

	Aspirin 50mg tablets	Ltd.	in the FDC are used concomitantly but combining both the drugs in FDC form is not justified due to the safety issues. Hence, the committee did not recommend for approval of the proposed FDC
Medical Device Division			
16.	IMP/MD/2021/34169 LVAS Implant kit	M/s St. Jude Medical India Pvt. Ltd	Firm presented their proposal before the committee along with clinical data. After detailed deliberation, the committee recommended for grant of permission to import & market the HeartMate 3 in the country with condition that the firm shall submit PSUR after every six month to CDSCO. With regard to HeartMate II, committee opined that the firm shall submit the number of HeartMate II implanted in USA (country of origin) in year 2019 and 2020.
17.	IMP/MD/2020/32364 Transcatheter Bicaval Valve System	M/s Relisys Medical Devices Ltd.,	Firm presented their proposal before the committee. After detailed deliberation, the committee observed that the said product is not approved in any country, however its is implanted on compassionate ground. The committee recommended that firm shall conduct pivotal clinical investigation with the said product in India to established the safety, effectiveness and performance. Accordingly, the firm need to submit protocol for review by the committee.