Recommendations of the SEC (Cardiovascular & Renal) made in its 134th meeting held on 21.09.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/23/000247 Telmisartan IP + Amlodipine Besilate IP eq. to Amlodipine + Bisoprolol Fumarate IP (40mg+5mg+2.5mg)/ (40mg+5mg+5mg)	M/s. Ravenbhel Healthcare Pvt. Ltd.	The firm presented their proposal before the committee along with BE study protocol. The committee noted that FDC of Telmisartan IP + Amlodipine Besilate has been taken as reference product in BE study protocol. After detailed deliberation, the committee recommended that in proposed BE study protocol reference product should be individual innovator`s product. Accordingly, firm should submit the revised BE study protocol along with Phase III CT protocol for further review.
2.	FDC/CT/23/000055 Zinc chloride 1050 µg/ml + Sodium fluoride 210.0 µg/ml + Potassium iodide 16.60 µg/ml + Sodium Molybdate dihydrate 4.850 µg/ml + Sodium selenite anhydrous 17.29 µg + Copper chloride dihydrate USP 102.3 µg/ml + Manganese chloride tetrahydrate USP 19.79 µg/ml + Ferric chloride hexahydrate 540.0 µg/ml + Chromic chloride hexahydrate USP 5.330 µg/ml concentrate for Solution for Infusion	M/s. Fresenius Kabi India	In light of the condition mentioned in permission in Form CT-20 dated 30.07.2020, the firm presented the Phase IV clinical trial study protocol before the committee. After detailed deliberation, the committee recommended as under that: 1. Protocol for administration of parenteral nutrition as per hospital policy should be presented. 2. Basis for calculation of sample size should be presented. 3. Inclusion criteria should be modified to select the patients appropriately. 4. Atleast 50% of the sites should be from government hospitals. 5. The proposal may be deliberated along with Surgeon and Intensivist in the next meeting. Accordingly, the firm should submit the revised Phase IV clinical trial study protocol to CDSCO for further review by the committee.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
3.	FDC/MA/19/000106 Efonidipine Hydrochloride Ethanolate +Telmisartan IP (20mg+ 20mg/ 20mg+40mg/ 40mg+40mg)	M/s. Zuventus Healthcare Ltd.	The firm did not turn up for presentation.
4.	FDC/MA/23/000195 Bisoprolol Fumarate I.P. 5mg/5mg + Perindopril Arginine 5mg/10mg Tablets	M/s. Servier India Pvt. Ltd.	The firm presented its proposal before the committee along with BE study protocol as well as justification for Phase III clinical trial waiver. After detailed deliberation, the committee recommended that the reference product should be changed to individual innovator drug in the BE study protocol. Accordingly, the revised BE study protocol should be presented before the committee for review and further consideration on clinical trial waiver.
5.	FDC/MA/22/000242 Bisoprolol Fumarate IP 5mg/2.5mg+ Cilnidipine IP 10mg/10mg Tablets	M/s. Ajanta Pharma Ltd.	In light of the earlier SEC recommendations dated 22.09.2022, the firm presented the BE study report along with Phase III clinical trial protocol before the committee. The committee considered the BE study report. After detailed deliberation, the committee recommended for conducting the Phase III clinical trial study. The result of the study should be presented before the committee.
6.	FDC/MA/23/000127 Bisoprolol Fumarate 5mg/2.5mg + Cilnidipine 10mg/10mg +	M/s. Ajanta Pharma Limited	The firm presented their proposal before the committee. After detailed deliberation, the committee recommended as under: 1. The firm should present the justification on rationality for

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	Telmisartan 40mg/40mg tablets		combining this FDC and its significant benefit along with recent supporting document/ literature. 2. Justification on dose titration with recent supporting document/ literature. 3. International approval status. 4. Recent scientific literature available from peer reviewed journal in support of combining the 3 drugs in this FDC. Accordingly, the firm should submit above data for further review by the committee.
7.	FDC/MA/22/000035 Bempedoic acid 180mg + Ezetimibe IP 10mg tablet	M/s. Mascot	In light of the condition mentioned in permission in Form CT-23 dated 09.11.2022, the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for conduct of the Phase IV clinical trial. The firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.
8.	04-03/2017-DC (Pt. Akums) Cilnidipine 20mg +Telmisartan IP 40mg film coated tablet	M/s. Akums Drugs & Pharmaceuticals Ltd.	In light of the condition mentioned in permission in Form CT-23 dated 06.01.2023, the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for conduct of the Phase IV clinical trial. The firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.
9.	FDC/MA/20/000077 Azelnidipine + Metoprolol (SR)	M/s. Akums Drugs & Pharmaceuticals Ltd.	The firm did not turn up for presentation.

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
	8mg/8mg/16mg/16mg + 25mg/50mg/25mg/ 50mg tablet		
10	FDC/MA/22/000132 Bempedoic acid 180mg + Ezetimibe 10mg tablets	M/s. Optimus Pharma Pvt. Ltd.	In light of the condition mentioned in permission in Form CT-23 dated 09.11.2022, the firm presented the Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for conduct of the Phase IV clinical trial. The firm should submit the Phase IV clinical trial report to CDSCO for further review by the committee.
11	FDC/MA/23/000063 Capagliflozin Propanediol Monohydrate 5mg/5mg/10mg/10mg+ Metroprolol Succinate IP eq. To Metoprolol tartrate (ER) 25mg/50mg/25mg/50mg tablets.	M/s. Exemed Pharmaceuticals	The firm did not turn up for presentation.