

Recommendations of the SEC (Cardiovascular & Renal) made in its 127th meeting held on 07.06.2023 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/22/000242 Bisoprolol Fumarate IP5mg/2.5mg+ Cilnidipine IP 10mg/10mg Tablets	M/s. Ajanta Pharma Ltd.	The proposal was deferred as per firm's request.
2.	FDC/MA/20/000077 Azelnidipine 8mg/8mg/16mg/16mg + Metoprolol (SR) 25mg/50mg/25mg/ 50mgTablet	M/s. Akums drugs & Pharmaceuticals Ltd.	In light of the earlier SEC recommendation dated 11.10.2021, the firm presented the proposal before the committee along with details of study sites as well as raw data of clinical trial study results. The committee noted that the results presented were not validated and clinically untenable. After detailed deliberation, the committee recommended that the firm should submit detailed clarification/justification to CDSCO for further review by the committee.
3.	FDC/MA/22/000186 Ezetimibe IP 10mg + Rosuvastatin Calcium IP eq. to. Rosuvastatin 20mg film coated tablets	M/s. Akums drugs & Pharmaceuticals Ltd.	As per the condition mentioned in Form CT-23 dated 06.02.2023, the firm presented the proposal before the committee along with Phase IV clinical trial protocol. After detailed deliberation, the committee recommended that the firm should include following points in protocol: <ol style="list-style-type: none"> 1. The number of patients should not be less than 250. 2. The study should not be less than 12 weeks. 3. The study sites should contain large volume of cardiac patients. 4. The Principal investigators should be Cardiologist. Accordingly, the firm should submit the revised clinical trial protocol to CDSCO for further review by the committee.
5.	FDC/MA/23/000071	M/s. Ajanta	The proposal was deferred as per firm's request.

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	Bisoprolol Fumarate 5mg/5mg/2.5mg/2.5mg+Cilnidipine 10mg/10mg/10mg/10mg+Chlorthalidone 12.5mg/6.25mg/12.5mg/6.25mg tablets		
6.	FDC/MA/23/000098 Bisoprolol Fumarate IP 2.5mg/5mg/2.5mg/5mg+Telmisartan IP 40mg/40mg/40mg/40mg+Chlorthalidone IP 6.25mg/6.25mg/12.5mg/12.5mg film coated tablet	M/s. Ajanta Pharma Limited	The firm presented the proposal before the committee along with BE study protocol and Phase III clinical trial protocol. After detailed deliberation, the committee recommended that reference product should be the innovator's products for BE study. Accordingly, firm should submit revised protocol to CDSCO for further review by the committee. Further, the firm should submit BE study result to CDSCO for review by the committee for taking decision on the Phase III clinical trial protocol.
7.	FDC/MA/23/000127 Bisoprolol Fumarate 5mg/2.5mg+ Cilnidipine 10mg/10mg + Telmisartan 40mg/40mg tablets	M/s. Ajanta Pharma Limited	The proposal was deferred as per firm's request.
8.	FDC/IMP/23/000034 Calcium chloride dihydrate 3.6800 g/L + Magnesium chloride hexahydrate 2.4400 g/L + Sodium Chloride 6.4400 g/L + Sodium Hydrogen Carbonate 2.9200 g/L = Potassium Chloride 0.3140 g/L + Disodium Phosphate Dihydrate 0.2250 g/L Solution	M/s. Baxter India Pvt. Ltd.	The firm did not turn up for the presentation.
9.	FDC/MA/23/000162 Dapagliflozin 10mg/10mg/10mg/10mg + Bisoprolol	M/s. Eris Life Sciences	The firm presented the proposal before the committee along with the Phase III clinical trial protocol with request for BE study waiver. After detailed deliberation, the committee

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	fumarate 1.25mg/2.5mg/5mg/ 10mg		considered the request for waiver of BE study and recommended for grant of permission for conduct of the Phase III clinical trial. The result of the Phase III clinical trial should be presented before the committee for further review.
GCT Division			
10.	CT/34/23 Online Submission (36886) LY3502970	M/s. Eli Lilly	The firm presented its Phase III clinical trial protocol no J2A-MC-MACE GZGS before the committee. After detailed deliberation, the committee recommended that the proposal should be deliberated in presence of an endocrinologist.
11.	CT/136/22 Online Submission (25120) Zirconium Cyclosilicate	M/s. AstraZeneca	The firm presented its Protocol amendment 2.0 dated 05/11/2021 for clinical trial protocol no D9487C00001 before the committee. After detailed deliberation, the committee recommended for waiver of condition no. (ii & iii) of the CT NOC. Further for waiver of condition of CT NOC (i), the committee recommended that proposal is approved with condition that from India only those sites should be included which have online adequacy measurement in the machine and can capture the data to be utilized for analysis purpose. Dr. Sreejith Parameswaran did not participate in the deliberation.
Medical Device Division			
12.	MD/PostAppr/2023/ 13875 Edwards SAPIEN 3 - Edwards Commander Kit	M/s. Edwards Life Sciences Private Limited	The firm presented the proposal for change in indication of Edwards SAPIEN 3 - Edwards Commander Kit, before the committee. The committee observed that the data presented by the firm was not adequate for removing age restriction of 65 years from indication for the device in India. After detailed deliberation, the committee recommended that the proposal should be redeliberated with guidelines and clinical data, for the use of the device below 65 years of age.

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13.	CI/MD/2019/16718 Drug Eluting Stent, Imaging Catheter, Imaging Catheter kit	M/s. St. Jude Medical India Pvt. Ltd.	The firm presented the proposal before the committee for amendment in the protocol. After detailed deliberation, the committee did not recommend for change in protocol as the study is completed and presently it is in the stage of report preparation.
14.	CI/MD/2023/71389 Pressure Pace TM System	M/s. JSS Medical Research Asia Pacific Private Ltd.	In light of earlier SEC recommendation dated 10.05.2023, the firm presented the proposal before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct the proposed study in the country subject to the condition that the 50 % of the sites should be government institution.
15.	CI/MD/2023/83676 Cardia Care - Non Invasive Nerve Stimulator Device for AF	M/s. Dr. Reddy's Laboratories Limited	The firm presented the proposal to conduct pivotal clinical investigation of CardiaCare-Non Invasive Nerve Stimulator Device for Atrial Fibrillation, before the committee. After detailed deliberation, the committee recommended for the grant of permission to conduct the proposed study in the country subject to the condition that 50 % of the sites should be government institution.
FDC Division			
16.	FDC/MA/22/000363 Metoprolol Succinate SR 25mg/50mg + Dapagliflozin 5mg/10mg tablets	M/s. Eris (Internal discussion)	In light of the earlier SEC recommendation dated 19.04.2023, the firm submitted the revised clinical trial protocol. After detailed deliberation, the committee recommended for initiating the Phase III clinical trial for which NOC was already issued to the firm on 09.02.2023 by CDSCO.
17.	FDC/MA/23/000063 Dapagliflozin Propanediol monohydrate 5mg/5mg/10mg/10mg + Metoprolol Succinate IP eq. to	M/s. Exemed (Internal discussion)	The committee members discussed and recommended that firm should present the proposal along with BE/CT study protocol before the committee.

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	Metoprolol tartrate (ER) 25mg/50mg/25mg/ 50mg tablets		