

Recommendations of the SEC (Cardiovascular & Renal) made in its 136th meeting held on 07.11.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/CT/21/000058 Ivabradine Prolonged Release Tablets 10mg & 15 mg	M/s. Abbott Healthcare Private Limited.	The firm didn't turn up for presentation.
FDC Division			
2.	FDC/MA/22/000171 Bempedoic acid 180mg + Rosuvastatin Calcium IP eq. to Rosuvastatin 40mg film coated tablet	M/s. Akums Drugs & Pharmaceuticals Ltd.	<p>In light of the condition mentioned in permission in Form CT-23 dated 15.02.2023; the firm presented the Phase IV clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee opined the following modification in CT Protocol:</p> <ol style="list-style-type: none"> 1. Inclusion criteria should be modified by including LFT, Lipid Profile, Serum Creatinine and Spot Urine Protein Creatinine Ratio (PCR). 2. Adequate time needs to be mentioned in the methodology to see the effects of the maximum tolerated dose of Atorvastatin 80 mg and Rosuvastatin 40 mg. 3. More government sites to be included which should be geographically distributed so that there should be 50% each from Government and Private sites. 4. Recalculate the sample size based on relevant literature specific to the study protocol. <p>Accordingly, revised Phase IV clinical trial protocol should be submitted to CDSCO for further review by the committee.</p>
3.	FDC/MA/22/000299 Metoprolol Tartrate IP (IR) + Sacubitril & Valsartan tri sodium salt hemi Pentahydrate 50mg/100mg+ 100mg/200mg tablets	M/s. Windlas Biotech Ltd.	<p>In light of the earlier SEC recommendation dated 10.11.2022, the firm presented their proposal along with the rationality and justification for the proposed FDC.</p> <p>After detailed deliberation, the committee opined the following:</p>

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			<p>1. The firm could not present the justification on rationality of the combination and its significant benefits.</p> <p>There were significant difference between the submitted proposal and the contents of the presentation.</p> <p>2. The proposed FDC is not approved anywhere in the world.</p> <p>3. The firm could not present clinical proof of concept and target patient population in which the proposed FDC will be administered.</p> <p>4. The firm should present recent scientific literature available from peer reviewed journal in support of combining the drugs in this FDC.</p> <p>Accordingly, the firm should submit above data for further review by the committee.</p>
4.	FDC/MA/23/000098 Bisoprolol Fumarate IP 2.5mg/5mg/2.5mg/5mg+ Telmisartan IP 40mg + Chlorthalidone IP 6.25mg/6.25mg/12.5mg/12.5mg film coated tablet	M/s. Ajanta Pharma Limited	<p>In light of the earlier SEC recommendation dated 07.06.2023, the firm presented its proposal along with revised BE study protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study.</p> <p>Accordingly, the firm should submit BE study report to CDSCO for further review by the committee for taking decision on the Phase III clinical trial protocol.</p>
5.	FDC/MA/23/000288 Dapagliflozin Propanediol Monohydrate eq. to Dapagliflozin + Bisoprolol Fumarate IP (10mg+1.25mg, 10mg+2.5mg, 10mg+5mg & 10mg+10mg) tablet	M/s. Exemed Pharmaceutical Ltd.	The firm didn't turn up for presentation.
6.	FDC/MA/23/000303 Dapagliflozin Propanediol Monohydrate eq. to	M/s. Pure and Cure Healthcare Pvt. Ltd.	<p>The firm presented the proposal along with BE study protocol before the committee.</p> <p>After detailed deliberation, the committee recommended that the</p>

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	Dapagliflozin + Metoprolol Succinate IP (ER) 5mg+25mg, 5mg+50mg, 10mg+25mg, 10mg+50mg film coated bilayered tablet		reference product should be changed to individual innovator drug in the BE study. Accordingly, the revised BE study protocol should be submitted to CDSCO, for review. Further, after approval from CDSCO the firm should submit BE study report for further review by the committee for taking decision on the Phase III clinical trial protocol.
7.	FDC/MA/23/000312 Eplerenone IP 25mg/25mg + Torsemide IP 10mg/20mg Tablet	M/s. Mascot Health Series Pvt. Ltd.	The firm presented the proposal along with BE study protocol before the committee. After detailed deliberation, the committee recommended that the reference product should be changed to individual innovator drug in the BE study. Accordingly, the revised BE study protocol should be submitted to CDSCO for review. Further, after approval from CDSCO the firm should submit BE study report for further review by the committee for taking decision on the Phase III clinical trial protocol.
Medical device Division			
8.	CI/MD/2021/50669 Pericardial Bioprosthesis (Dafodil (1 st Brand), Dafodil Neo (2 nd Brand), Flomeo (3 rd Brand), Freesia (4 th Brand))	M/s. Meril Life Sciences Private Limited	The firm presented 100 patients data on “Pericardial Bioprosthesis” device for which the firm was granted manufacturing license in Form MD-9 with the condition to submit said data within a period of one year as per the recommendation of the earlier SEC held on 11.10.2023 in presence of the cardiothoracic surgeon. The firm also submitted the study protocol for conduct of Post marketing follow up study on said device. After detailed deliberation, the committee satisfied with the data produced by the firm before the experts. Accordingly, the condition of the manufacturing license may be waived off. As regard to the proposed study the committee opined that the firm shall collect data from all patients where the product is sold and the firm shall include

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			at least 50% government sites in the said study.
9.	CI/MD/2023/96521 ADI COPD Device	M/s. Analog Devices India Private Limited	The firm presented their protocol no. ADI COPD-001, version 2.0 dated 19.04.2023, for conduct of Pilot Clinical Investigation on device “ADI COPD” before the committee. The said device is not yet approved by the Licensing Authority for marketing. After detailed deliberation, the committee observed that since the product is intended for home monitoring of patients with cardio pulmonary conditions such as COPD or CHF, therefore, the experts opined that the comments from experts from Respiratory medicine (Pulmonary) is also needs to be obtained before taking decision in the matter. Therefore, the committee recommended that the experts from the medicine (Pulmonary) may be co-opted in the forthcoming SEC (Cardiovascular & Renal) for detailed deliberation and recommendation in the matter.
BA/BE Division			
10	File No. 12-09/2023/BA-BE/MISC-30/DC (BABE/CT05/FF/2023/38758) Eplerenone + Torasemide Film coated Tablets 50 mg + 10 mg	M/s. Veeda Clinical Research Limited, Ahmedabad.	The firm presented their proposal along with the BE Study Protocol for export purpose. After deliberation, the committee recommended for the grant of permission to carry out the BE studies (for export purpose, only) as per the submitted protocol.