

Recommendations of the SEC (Cardiovascular & Renal) made in its 102nd meeting held on 10.05.2022 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/22/000132 BisoprololFumerate Tablets 7.5 mg	M/s. Merck specialities	The firm did not turn up for presentation.
2.	SND/MA/20/000194 Ticagrelor SR Tablets 120/180mg	M/s. Exemed Pharma	The firm presented the BE study reports of Ticagrelor SR tablets 120mg and Ticagrelor SR tablets 180mg before the committee. After detailed deliberation, the committee opined that the firm should submit raw data of both BE studies for further review by the committee.
FDC Division			
3.	FDC/MA/22/000122 L-Tyrosine 30mg U.S.P. + L-Histidine 38 mg U.S.P. + L- Tryptophan 23 mg U.S.P + L-Threonine 53 mg U.S.P. + L- Lysine Acetate 105mg U.S.P. + Calcium-DL- 2-hydroxy-4- (methylthio)-butyrate 59mg + Calcium-3- methyl-2-oxobutyrate 86 mg + Calcium-2- oxo-3- phenylpropionate 68 mg + Calcium-4- methyl-2-oxovalerate 101 mg + Calcium-3 - methyl-2-oxovalerate 67 mg per 10 ml oral suspension	M/s. Rivpra Formulation Pvt. Ltd	The firm presented their proposal along with justification for the proposed FDC before the committee. The committee noted that the proposed FDC is already approved in tablet dosage form. After detailed deliberation, the committee recommended for grant of permission to manufacture and market the FDC in suspension dosage form.
4.	FDC/MA/22/000097 Metoprolol Succinate IP 23.75mg/47.50mg/23. 75mg/47.50mg eq. to Metoprolol Tartrate (as extended release) 25mg/50mg/25mg/50 mg + Amlodipine	M/s. Ajanta Pharma Ltd.	The firm presented their proposal along with BE and Phase III clinical trial study protocol before the committee. The committee noted that the firm proposed Phase III clinical trial on two higher strengths only. After detailed deliberation, the

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	Besilate IP eq. to Amlodipine 5mg/5mg/5mg/5mg + Chlothalidone IP 6.25mg/6.25mg/12.50 mg/12.50mg tablets		committee recommended for grant of permission for conducting the proposed BE study. As regard to the Phase III clinical trial, the committee recommended for grant of permission for conducting the proposed trial with the following conditions : 1. The firm should include ultrasound, renal Doppler to exclude secondary hypertension. 2. The firm should include echocardiogram test during screening procedure.
5.	FDC/MA/22/000108 Metoprolol Succinate IP 23.75mg/47.50mgeq to Metoprolol Tartrate (as extended release tablet) 25mg/50mg + Telmisartan IP 40mg/40mg + Amlodipine Besilate IP eq. to Amlodipine 5mg/5mg Tablets	M/s. Ajanta Pharma Ltd.	The firm did not turn up for presentation.
GCT Division			
6.	CT/40/22 Online Submission (31742) Inclisiran (KJX839)	M/s. Novartis	The firm presented Phase III b clinical trial protocol before the committee. Risk versus benefit to the patients- The safety profile of the study drug from preclinical and clinical studies justify the conduct of the trial. Innovation vis-a-vis existing therapeutic option- The primary objective of this study is to demonstrate the superiority of Inclisiran versus placebo, administered on top of maximally tolerated statin therapy, in reducing the total coronary atheroma volume assessed by CCTA from baseline to month 24. (Conducted as per imaging acquisition guidelines and reviewed by the imaging central reader). Unmet medical need in the country- Inclisiran (KJX839) is a cholesterol-lowering small interfering ribonucleic acid (siRNA) that inhibits the production of proprotein convertase

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			<p>subtilisin/kexin type 9 (PCSK9). It is a novel synthetic ribonucleic acid (RNA) small interference (SiRNA) therapeutic.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the study subject to condition that more study sites from government hospitals geographically distributed in the country should be included in the study.</p>
Medical Device Division			
7.	IMP/MD/2021/50727 Sirolimus Eluting coronary stent system (Orsiro Mission)	M/s Biotronik Medical Device India Pvt. Ltd.	The firm did not turn up for presentation.
8.	MD/PostAppr/2021/7704 Carpentier-Edwards Perimount Magna Ease	M/s Edwards Life Science India	<p>In light of earlier SEC recommendation dated 08.03.2022, the firm presented their proposal before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission for marketing the product for the proposed indication aligned with other countries viz Australia, Singapore etc.</p>