

Recommendations of the SEC (Cardiovascular & Renal) made in its 108th meeting held on 25.08.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/21/000134 Bisoprolol 5mg/2.5mg+Telmisartan 40mg/40mg tablets	M/s. Micro Labs Ltd.	The firm has presented the Phase III clinical trial report and bioequivalence report before the committee. After detailed deliberation, the committee recommended that the firm should present details on sample size calculations and revise the analysis by using appropriate statistical tests.
2.	FDC/MA/22/000149 Rosuvastatin Calcium eq. to Rosuvastatin 5mg/10mg/20mg/40mg + Bempedoic acid 180mg/180mg/180mg /180mg tablets	M/s. Exemed Pharmaceuticals	In light of earlier SEC recommendation dated 09.06.2022 & 10.06.2022, the firm presented the bioequivalence report before the committee. The firm also presented the Phase III clinical trial data generated with the concomitant use of Rosuvastatin + Bempedoic acid. After detailed deliberation, the committee recommended for grant of permission for manufacture and market of the proposed FDC for the higher strength only i.e. Rosuvastatin Calcium eq. to Rosuvastatin 40mg + Bempedoic acid 180mg tablets with the condition to submit the Phase IV clinical trial protocol within 03 months from the date of approval.
GCT Division			
3.	CT/33/22 Online Submission (31451) Sibeprenlimab	M/s. George Clinical	The firm didn't turn up for presentation.
SND Division			
4.	SND/MA/22/000083 Polystyrene Sulphonate Jelly 20% w/w	M/s. Pharose Remedies	The firm didn't turn up for presentation.
5.	SND/MA/20/000265 Ticagrelor SR Tablet 120/180 mg	M/s. Mascot Laboratories	The firm presented bioequivalence study reports of Ticagrelor SR Tablet 120 mg and 180 mg before the committee. The committee noted that the firm has not presented the pharmacokinetics parameter of active metabolite of test and reference products.

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			After detailed deliberation, the committee opined that the firm should submit complete BE Study report along with raw data, pharmacokinetics parameter of active metabolite of test and reference products for further review by the committee. Also, firm should revise the use of terminologies appropriately.
6.	SND/MA/20/000210 Ticagrelor SR Tablet 180 mg	M/s. MSN Laboratories	In light of earlier SEC recommendation dated 08-02-2022 the firm presented the revised phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as per protocol presented by the firm.