

**Recommendations of the SEC (Cardiovascular) made in its 22<sup>nd</sup>/24 meeting held on 19.11.2024 at CDSCO (HQ), New Delhi:**

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>SND Division</b>			
1.	SND/MA/23/000240 Sacubitril & Valsartan tablet 25 mg	M/s Bajaj Healthcare Limited	In light of earlier SEC recommendation dated 18.07.2024, the firm presented justification and therapeutic rationale on the proposed low dose before the committee.  After detailed deliberation, the committee opined that justification provided by the firm is not an adequate. Therefore, the firm should submit more clinical trial data / interventional data of Sacubitril & Valsartan tablet 25 mg (12+ 13 mg) in larger adult population/subjects along with rational justification.
<b>FDC Division</b>			
2.	FDC/MA/23/000216 Eplerenone IP + Torsemide IP (25mg + 10mg + 25mg + 20mg) film coated tablet	M/s. Akums Drugs & Pharmaceutical Ltd.	The firm presented the proposal along with BE protocol and Phase III clinical trial protocol before the committee.  After detailed deliberation, the committee recommended to conduct BE Study. As regard to Phase III clinical trial protocol, the committee opined that: 1. Total study duration should be 24 weeks. 2. "Patients on diuretics other than mineralocorticoid receptor antagonist" should be removed from exclusion criteria.  Accordingly, BE study report should be submitted along with revised Phase III clinical trial protocol to CDSCO for further review by the committee.