

Recommendations of the SEC (Cardiovascular) made in its 20th/24 meeting held on 22.10.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
BA/BE Division			
1.	BABE/CT05/FF/2024 /44013 FDC of Torsemide and Spironolactone 5mg/25 mg	M/s Cipla Limited	<p>The firm presented the protocol No. 0327-11-23, version No. 01, Dated 13-MAR-2024 for BA/BE study for export purpose only.</p> <p>After detailed deliberation, the committee opined that the firm needs to submit the published literature about 5mg dose of Torsemide and 25 mg dose of Spironolactone in patient population for further review by the committee.</p>