Recommendations of the SEC (Cardiovascular) made in its meeting held on 07.06.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/22/000302 Rosuvastatin Calcium IP eq. to Rosuvastatin+ Bempedoic acid (5mg+180mg, 10mg + 180mg, 20mg + 180mg) tablet	M/s. Exemed Pharmaceuticals (Internal discussion)	In light of earlier SEC recommendation dated 22.05.2024, the proposal is re-deliberated. The committee noted that higher strength of FDC (Rosuvastatin Calcium IP eq. to Rosuvastatin 40mg + Bempedoic acid 180mg tablet) has already been approved on 19.09.2022. After detailed deliberation, the committee opined that lower strength of FDC Rosuvastatin + Bempedoic acid 5mg+180mg, 10mg + 180mg, 20mg + 180mg tablet are also safe. The said strengths also have shown significant reduction in LDL cholesterol. Further, the experts also mentioned that Clear Harmony trial data provides substantial evidence that said FDC's have an acceptable safety profile. Based on the above facts, the committee opined that the permission for manufacturing and marketing may be granted in all proposed strengths i.e. FDC of Rosuvastatin + Bempedoic acid 5mg+180mg, 10mg + 180mg and 20mg + 180mg tablet.