

**Recommendations of the SEC (Cardiovascular & Renal) made in its 95<sup>th</sup> meeting held on 20.01.2022 at CDSCO HQ New Delhi:**

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>Biological Division</b>			
1.	BIO/CT/20/000036 Tenecteplase	M/s. Reliance Life Sciences Pvt. Ltd.	The committee opined that the proposal should be deliberated along with Neuro-Physician. The proposal was deferred to next SEC meeting.
<b>FDC Division</b>			
2.	FDC/MA/20/000137 Amlodipine Besylate IP eq. to Amlodipine IP 5mg/5mg/5mg +AzilsartanKamedoxomil eq to AzilsartanMedoxomil 20 mg/40mg/40mg tablets	M/s. Akums Drugs & Pharmaceuticals Ltd.	The firm didn't turn up for presentation.
<b>Medical Device Division</b>			
3.	IMP/MD/2021/46649 Embolic capture Guidewires (SENTINE L cerebral protection system)	M/s. Boston Scientific India Private Limited	The firm didn't turn up for presentation.
4.	CI/MD/2021/45487 Tensor Tip (Blood Pressure Monitoring Device)	M/s. Taevas Life Sciences Private Limited	In light of earlier SEC recommendation dated 08.12.2021 & 09.12.2021, the firm presented their proposal before committee.  After detailed deliberation, the committee recommended for grant of permission to conduct the post market clinical investigation subject to the following conditions: 1. There should be at least total 10 investigation sites located Pan India (North, East, West, South, Central) that should include 50% government institutions. 2. The title of the study should clearly include study objective i.e. "A comparative study between Tensor Tip MTX and commercial available reference devices by estimating hemodynamic and hematologic parameters to assess its efficacy".

