

Recommendations of the SEC (Cardiovascular & Renal) made in its 132nd meeting held on 29.08.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/23/000110 Bisoprolol Fumarate 5mg/2.5mg+Cilnidipine 10mg/10mg+Telmisartan 40mg/40mg tablets	M/s.Windlas Biotech Limited	<p>In light of earlier SEC recommendation dated 10.05.2023, the firm presented the justification and supporting literatures for combining three drugs in this FDC. The committee noted that the firm presented inadequate and old supporting literatures.</p> <p>After detailed deliberation, the committee again recommended that the firm should justify the following points before presenting the protocol:</p> <ol style="list-style-type: none"> 1. The firm should present the justification on rationality for combining this FDC and its significant benefit along with recent supporting document/literature. 2. Justification on dose titration with recent supporting document/literature. 3. International approval status. 4. Recent scientific literature available from peer reviewed journal in support of combining the 3 drugs in this FDC. <p>Accordingly, the firm should submit the detailed justification for the FDC along with more supportive literatures for further review by the committee.</p>
GCT Division			
2.	CT/65/23 Online Submission (37775) Atacicept	M/s. Medpace	<p>The firm presented Phase 2b/3, clinical trial protocol No. VT-001-0050 amendment 5 dated 23.02.23.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the trial.</p>
3.	CT/03/23 Online Submission (35499) Olezarsen (ISIS678354)	M/s. Medpace	<p>The firm presented Phase III, clinical trial protocol No. ISIS 678354-C56, protocol amendment 1 dated 10 August 2022.</p> <p>After detailed deliberation, the committee recommended that the firm should submit Interim analysis report for review by the committee.</p>

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			(Dr. Ajay U Mahajan did not participate in deliberation.)
4.	CT/91/22 Online Submission (26228) Macitentan 75mg Versus Macitentan 10mg	M/s. J&J	The firm presented protocol amendment 4, version 5, dated 04 April 2023 vide protocol no. AC-055-315. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by firm. (Dr. Santosh Satheesh did not participate in deliberation.)
Medical Device Division			
5.	IMP/MD/2022/53336 LKT Disposable Perfusion Circuit, Kidney Transporter	M/s. Renovate Biologics Private Limited	The firm presentation was not ready. They requested to put the proposal in next SEC.