

Recommendations of the SEC (Renal) made in its 10th/24 meeting held on 12.11.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	GCT/CT04/FF/2023/37573 Online Submission (37573) LNP023 (Iptacopan)	M/s Novartis Healthcare Private Limited	In light of earlier SEC recommendation dated 09.08.2023 & 20.02.2024, now the firm presented phase IIIb clinical study protocol no. CLNP023B12001B, version 03 dated 25 July 2022. The firm presented unblinded data for CLNP023B12301 APPEAR-C3G Core study. After detailed deliberation, the committee recommended for grant of permission to conduct the extension part of the study as presented by the firm.
2.	GCT/PostAppr/2023/29948 Online Submission (29948) Atacicept	M/s Medpace Clinical Research India Pvt. Ltd	The firm didn't turn up for presentation.
3.	GCT/PostAppr/2024/35649 Online Submission (35649) Tebipenempivoxilhydrobromide (TBP-PI-HBr, previously known as SPR994)	M/s PSI CRO Pharma Pvt. Ltd.	The firm presented protocol amendment 3 version 4.1 dated 26 August 2024 protocol no. SPR994-305. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
4.	GCT/CT04/FF/2024/44642 Online Submission (44642) NNC0519-0130 B 34 mg/ml / placebo	M/s Novo Nordisk India Pvt. Ltd.	In light of earlier SEC recommendation dated 17.09.2024, the firm presented phase 2 clinical study protocol no. NN9541-7841 version 1.0 dated 22 May 2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with condition that the study shall be conducted in two arms only i.e. 8 mg and 18 mg.
Medical Device Division			
5.	IMP/MD/2022/53336 LKT Disposable	M/s. Renovate Biologics Private Limited	In light of earlier recommendation SEC (Cardiovascular & Renal) dated 11.01.2023; The firm has presented their

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	Perfusion Circuit, Kidney Transporter		<p>PMS data & safety and performance data for the proposed device. However, the committee observed that the data presented is inadequate to ensure the safety, effectiveness & performance of the device.</p> <p>The committee opined that the firm should present adequate clinical evidence detailed and PMS data on device in the country of origin and in other country along with India specific PMS data for use of device before it came under the regulation of Medical Device Rules 2017 and also certificate from end users for its performance & safety for taking necessary action in the matter.</p>
SND Division			
6.	SND/MA/23/000226 Tolvaptan Tablets 7.5 mg	M/s MSN Labs Private Limited	<p>In light of earlier SEC recommendation dated 20.08.2024, the firm presented the literature on additional efficacy data on Tolvaptan tablets 7.5 mg is approved in EMA.</p> <p>After detailed deliberation, the committee recommended for grant of permission for manufacturing & marketing of Tolvaptan tablets 7.5 mg considering the published data on efficacy studies submitted by the firm subject to condition that the firm shall conduct the Phase IV clinical trial for efficacy.</p> <p>Accordingly, the firm should submit Phase IV CT protocol within 3 months from the date of approval to CDSCO for further review by the committee.</p>
FDC Division			
7.	FDC/MA/23/000327 Dapagliflozin Prsopenediol Monohydrate eq. to Dapagliflozin + Telmisartan IP (10mg+40mg/ 10mg+80mg) tablet	M/s Exemed Pharmaceuticals	<p>In light of earlier SEC recommendation dated 20.02.2024, the firm presented their Phase III clinical trial report before the committee.</p> <p>After detailed deliberation, the committee opined that 1.Firm should submit the justification for the same efficacy reported at Telmisartan 40 and 80 mg arms. 2. Firm is required to confirm whether antihypertensive drug is given</p>

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			<p>except study medication.</p> <p>Accordingly, firm should submit above mentioned data to CDSCO for further review by the committee.</p>
8.	<p>FDC/MA/24/000133</p> <p>Dapagliflozin Propanediol eq. to Dapagliflozin 10mg + Eplerenone IP 25mg film coated tablets</p>	<p>M/s Exemed Pharmaceuticals</p>	<p>In light of earlier SEC recommendation dated 20.08.2024, the firm presented the proposal along with BE study report and Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee considered BE study report. As regard to Phase III clinical trial protocol, the committee recommended for the Phase III study with conditions that 1. patients history of polycystic kidney disease and/or renal artery stenosis will be excluded from the study 2. the sample size should be increased to 220 patients 3. percentage of changes in urine albumin, creatinine ratio should be at least 20% 4. study duration should be increased from 3months to 4 months.</p> <p>Accordingly, revised Phase III CT protocol should be submitted to CDSCO, for review. After approval from CDSCO, the firm should submit Phase III Clinical trial report for further review by the committee.</p>