

Recommendations of the SEC (Renal) made in its 03rd/25 _{meeting held on 18.03.2025 at CDSCO (HQ), New Delhi:}

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/52/23 Online Submission (37858) Iptacopan (LNP023)	M/s Novartis Healthcare Private Limited	The firm presented protocol amendment version 04 dated 30 Nov 2023 protocol no. CLNP023B12001B. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/159/24 Online Submission (47026) BAY-94- 8862/Finerenone	M/s Bayer Pharmaceuticals Pvt, Ltd	The firm didn't turn up for presentation.
Biological Division			
3.	BIO/CT04/FF/2024/4 6675 Retepase 3.6mg lyophilized powder for injection (2U)	M/s. Reliance Life Sciences Pvt. Ltd.	In light of earlier recommendations dated 20.08.2020, the firm presented the proposal to conduct Phase III clinical study titled "A Prospective, multi-center, open label, single arm, clinical study to evaluate the efficacy and safety of Retepase in complete restoration of patency and flow in dysfunctional tunneled cuffed/non-cuffed hemodialysis catheter vide Protocol No.: RLS/VAS/2024/07, Version 2.0 dated 27.11.2024. After detailed deliberation, the committee recommended to revise the proposed clinical study protocol with the following changes:- 1. Study design should include a comparator arm and sample size should be recalculated accordingly. 2. Efficacy endpoints should be well defined and efficacy analysis should be specified. 3. Study should include tunneled catheters only Accordingly, firm should submit revised protocol to CDSCO for further evaluation by the committee.