

Recommendations of the SEC (Renal) made in its 11th/25 meeting held on 13.11.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
BA/BE Division			
1.	BABE/CT05/FF/2025/47272 Mycophenolate sodium for injection 720 mg/vial, Mycophenolate sodium for injection 739 mg/vial, Mycophenolate sodium for injection 690 mg/vial	M/s. Lupin Limited	The firm presented the Study Protocol No. LBC-P-170-24 Version No.01 Date 14-Jul-2025 for export purpose only. After detailed deliberation, the committee opined that firm should submit the following: (1) Animal Toxicity data of other applied strengths also i.e., 739 mg/vial & 690 mg/vial of Mycophenolate sodium for injection. (2) Safety profile, Clinical Safety data, Immunotoxicity data of all applied strengths. Accordingly, the firm should submit the documents to CDSCO for further review by the committee.
New Drugs Division			
2.	ND/MA/25/000133 Daprodustat tablets 1 mg, 2 mg, 4 mg and 6 mg	M/s Sun Pharma Laboratories Limited	The firm did not turn up for the presentation.