Recommendations of the SEC (Antimicrobial & Antiviral) made in its 133rd meeting held on 21.12.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-73/13-Dc Bedaquiline Tablets 100mg	M/s. Johnson & Johnson	The firm didn't turn up for presentation.
SND Division			
2.	SND/MA/21/000103 Polymyxin B for Injection IP 750000 (Lyophilized)	M/s. BDR Lifesciences Private Limited	The firm didn't turn up for presentation.
GCT Division			
3.	CT/144/23 Online Submission (39705) Curcumin (Biocurcumax) Biocurcumax =500.0000 milligram(mg) Not Applicable(NA) Active	M/s. ICMR-National Institute Of Malaria Research	The firm presented Phase IIa clinical trial protocol No. NIMR-Ipca/ARCU/PIIa-16. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the applicant with condition that following shall be submitted to CDSCO: 1. Outcome of most unexpected adverse events. 2. Methods for evaluation for parasitic clearance.
4.	CT/154/23 Online Submission (40712) Sisunatovir IR Tablets 100 mg	M/s. Pfizer	The firm presented Phase 2/3 clinical trial protocol No. C5241007. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm.
5.	CT/45/23 Online Submission (29879) Bemnifosbuvir (BEM) and Ruzasvir (RZR)	M/s. IQVIA	The firm didn't turn up for presentation.
6.	CT/156/23 Online Submission (40683) KLU156 with Coartem®	M/s. Novartis	The firm presented Phase III clinical trial protocol No. CKLU156A12301. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm.

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
7.	CT/159/23 Online Submission (40795) Cefepime/Zidebactam (WCK 5222 for Injection)	M/s. Wockhardt	The firm presented Phase II clinical trial protocol No. W-5222-202. After detailed deliberation, the committee recommended for grant of permission to conduct the clinical trial as presented by the firm.