

Recommendations of the SEC (Antimicrobial & Antiviral) made in its 02nd/25 meeting held on 13.02.2025 & 14.02.2025 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/06/25 Online Submission (47434) LXE408	M/s Novartis	The firm presented phase 1 clinical study protocol no.: CLXE408A12105 amendment version no. 1 dated 31-January- 2025. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
BA/BE Division			
2.	BABE/CT05/FF/ 2024/45078 Artesunate 200 mg, Sulfamethoxypyrazine 500 mg and Pyrimethamine 25 mg Tablets	M/s Ajanta Pharma Limited	The firm did not turn up for the presentation.
3.	BABE/CT05/FF/2024 /46847 Bismuth 140 mg + Tetracycline 125 mg + Metronidazole 125 mg Capsule	M/s Torrent Pharmaceuticals Ltd.	The firm presented BA/BE study Protocol No. PK-23-012 and PK-23-013 Version No. 02 Protocol Date 28-NOV-2024 for export purpose only. The matter was redeliberated in light of earlier recommendation of SEC (Antimicrobial & Antiviral) dated 27.09.2023 and 09-05-2024 for same fixed dose combination. The committee observed that the proposed study is a single dose BE study in healthy subjects for export registration purpose only. Also the said drug is approved in USA and EU. Therefore, the Committee recommended for conduct of proposed BA/BE study in healthy subjects for export purpose only.
SND Division			
4.	SND/MA/23/000153 Linezolid Dispersible Tablets 150 mg	M/s Macleods Pharmaceuticals Ltd	Under Discussion

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5.	SND/MA/24/000200 Linezolid Dispersible Tablets 150 mg	M/s Micro Labs Limited	Under Discussion
6.	SND/MA/24/000188 Polymyxin B 10,00,000 IU/vial	M/s.Venus Remedies Limited	The firm did not turn up for the presentation.
7.	SND/MA/24/000076 Tioconazole vaginal film 300 mg (Additional dosage form)	M/s. Hetero Healthcare Limited	In light of earlier SEC recommendation dated 22.08.2024, the firm presented justification for the development of proposed dose of 300 mg along with release pattern data of the proposed formulation, toxicity data, anticipated side effects and supportive clinical evidences before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical trial study as per the protocol presented on 22.08.2024 and submit the results for further deliberation.
New Drugs Division			
8.	ND/IMP/23/000073 Baloxavir Marboxil Tablets [20mg, 40mg & 80 mg]	M/s. Roche Products (India) Private Limited	The firm presented the re-deliberation proposal for grant of permission to import and market Baloxavir Marboxil Tablets [20mg, 40mg & 80 mg] along with justification for the waiver of Phase III clinical trial before the committee. The firm presented data on prevalence of influenza disease and Global Clinical trial data. The committee noted that the Indian patient's clinical data is not sufficient and acute uncomplicated influenza is not an unmet medical need. The drug is approved in countries like US, Japan, Canada, Australia. After detailed deliberation, the committee recommended for conduct of Phase III Clinical Trial in Indian population for the proposed indication. Accordingly, the firm should submit Phase III Clinical Trial protocol to CDSCO, for further review by the committee.
FDC Division			

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9.	FDC/MA/25/000017 Aztreonam USP 0.5gm + Avibactam (as sodium salt) 0.1670gm solution for infusion	M/s. Gufic Biosciences	The firm did not turn up for the presentation.
10.	FDC/MA/25/000018 Aztreonam USP 1.5gm + Avibactam (as sodium salt) 0.5gm solution for infusion	M/s. Gufic Biosciences	The firm did not turn up for the presentation.