

Recommendations of the SEC (Antimicrobial & Antiviral) made in its 121st meeting held on 23.12.2022 at CDSCO (HQ), New Delhi:

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	12-01/22-DC (Pt-307) Primaquine 7.5 mg/15mg tablets	NIMR,ICMR	The Principal Investigator presented the proposal of academic clinical trial before the committee proposed to be conducted in multiple centers in India. After detailed deliberation committee recommended for grant of permission to conduct the academic clinical trial in its presented form.
SND Division			
2.	SND/MA/21/000224 Liposomal Amphotericin B Injection 50mg/ml (Lyophilized)	M/s Natco Pharma	The firm presented active post market surveillance protocol for permission to conduct the active PMS study for the product Liposomal Amphotericin B Injection 50mg/ml (Lyophilized). After detailed deliberation, the committee recommended to conduct the active PMS study subject to following condition: <ol style="list-style-type: none"> 1. PMS study should include the comparison with the already marketed product with respect to the database on causality assessment, serious adverse events, adverse drug reactions and SUSAR (Suspected unexpected serious adverse reaction). 2. Protocol of the PMS study should have protocol number, version and date.
3.	SND/MA/22/000290 Dolutegravir Sodium Oral Film 5 mg/10 mg	M/s Laurus Labs Limited	The firm presented the BE study data of the Dolutegravir Sodium Oral Film 5 mg/10 mg. After detailed deliberation the committee recommended for approval of the permission for manufacture and marketing of Dolutegravir Sodium Oral Film 5 mg/10 mg indicated in combination with other antiretroviral agents for treatment of HIV infected adults, adolescents and children of at least 4 weeks of age or older and weighing at least 3Kg.
FDC Division			
4.	FDC/MA/22/000159	M/s. Zuventus Healthcare Ltd.	The firm did not turn up for the presentation.

S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
	Sodium Ascorbate eq. to Ascorbate acid IP 400mg 120mg + L-Lysine Hydrochloride USP 7.49mg eq. to L-Lysine USP +Ascorbic acid 50mg + Ascorbyl Palmitate 6mg Chewable tablet		
5.	FDC/MA/21/000232 Tinidazole 100mg +Norfloxacin 100mg suspension	M/s. Rivpra Formulation Pvt. Ltd	The firm did not turn up for the presentation.
Medical Device Division			
6.	IMP/MD/2021/42818 High-level disinfectant for thermasensitive instruments and endoscopy equipment (ANIOXYDE 1000LD)	M/s. Ecolab Food safety and Hygiene solutions private limited	In light of the earlier recommendation dated 24.02.2022, the firm presented their proposal before the committee. After detailed deliberation, the committee recommended for grant of import and market permission of the product in the country.