

Recommendations of the SEC (Antimicrobial & Antiviral) made in its 106th meeting held on 26.11.2021 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/IMP/21/000081 Plazomicin 50mg/ml injection	M/s. Cipla Private limited	<p>The firm presented the proposal for import and marketing of the drug with local clinical trial waiver before the committee.</p> <p>The committee observed that, justification for local clinical trial waiver was not adequate as per rules and there is no unmet medical need for the proposed indication in the country.</p> <p>After detailed deliberation, the committee did not recommend for local clinical trial waiver and opined that, the firm should conduct Phase III clinical trial in the country.</p> <p>Accordingly, the firm should submit the Phase III clinical trial protocol to CDSCO for further review by the committee.</p>
SND Division			
2.	SND/MA/21/000501 Biapenem for Injection 300mg	M/s. BDR Pharmaceuticals	<p>The firm presented the proposal for manufacturing and marketing of the drug Biapenem for injection 300mg for the proposed additional indication in the treatment of complicated intra-abdominal infection and lower respiratory tract infection with local clinical trial waiver before the committee.</p> <p>After detailed deliberation, the committee recommended that the firm should conduct Phase III clinical trial for the proposed additional indications.</p> <p>Accordingly, the firm should submit Phase III clinical trial protocol for review by the committee.</p>
FDC Division			
3.	FDC/MA/20/000232 Tinidazole 100mg + Norfloxacin 100mg suspension	M/s. Rivpra Formulation Pvt. Ltd	The firm didn't turn up for presentation.
GCT Division			

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4.	CT/33/20 Online Submission (12674) Gepotidacin to Nitrofurantoin	M/s. PPD	The firm presented clinical trial protocol amendment 02 dated 14 Apr 2021 (Protocol number- 212390) before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
Medical Device Division			
5.	IMP/MD/2021/4815 Soluscope PA	M/s. Ecolab Food Safety & Hygiene Solutions Hygiene Solution Private Limited	The firm presented the proposal before the committee. After detailed deliberation, the committee recommended for grant of license for import of the proposed product in the country.