

**Recommendations of the SEC (Antimicrobial & Antiparasitic) made in its 03<sup>rd</sup>/26 meeting held on 11.03.2026 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>BA/BE Division</b>			
1.	BABE/CT05/FF/2025/53019  Tenofovir Alafenamide 90 mg Tablet	M/s Veeda Clinical Research Limited	Firm presented the BA/BE study Protocol No. 25-VIN-0361 Version No. 01 Protocol Date 21-JUL-2025 for export purpose only before the committee.  After detailed deliberation, the committee opined the following-  1) The firm should submit rational for the proposed formulation development along with adequate supportive published literature. 2) Firm should submit safety summary details from previously conducted studies on same product outside India including detailed information on the management of reported adverse events. 3) The protocol should clearly specify the inclusion and exclusion criteria with acceptable absolute normal values for liver function parameters.  Accordingly, the firm should submit above data for further review by the committee.
<b>New Drugs Division</b>			
2.	ND/CT/25/000129  Dalbavancin hydrochloride for Injection 500 mg	M/s GUFIC BIOSCIENCES LIMITED	In line with the condition of permission for manufacture and market of the drug, Dalbavancin hydrochloride for Injection 500 mg, the firm presented Phase IV clinical trial protocol (Protocol Number: CRS/25/007, Version No: 1.0, dated 20 November 2025) before the committee.  After detailed deliberation, committee recommended for grant of permission to conduct the proposed Phase IV study with the following conditions:  1) The inclusion criteria should clearly specify that trial participants must have culture confirmed infections caused by resistant gram-positive organisms. 2) The firm should specify in the protocol the management plan for patients whose systemic condition may require in-patient care for more than 72 hours. 3) Bacteriological assessment should be

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			<p>carried out at the end of treatment period.</p> <p>Accordingly, the firm should submit the revised protocol to CDSCO.</p>
<b>FDC Division</b>			
3.	<p>FDC/CT/25/000059</p> <p>Aztreonam 1.5 gm + Avibactam 0.5 gm Powder for concentrate for solution for infusion</p>	M/s Pfizer Limited	<p>In light of earlier SEC recommendation dated 09.12.2025 and as per condition mentioned in permission in Form CT-20 dated 05.03.2025; the firm presented revised Phase IV CT protocol with justification before the committee.</p> <p>After detailed deliberation, the committee opined that:</p> <ol style="list-style-type: none"> <li>1) Firm should include not less than 200 subjects.</li> <li>2) Firm should include more Government sites.</li> <li>3) Inclusion criteria should be Culture proven case of Carbapenem Resistant Enterobacterales (CRE) cases.</li> <li>4) The study protocol should clearly mention the method used to confirm CRE isolates.</li> </ol> <p>Accordingly, the firm should submit revised Phase IV clinical trial protocol to CDSCO for further review by the committee.</p>
4.	<p>FDC/MA/25/0s00209</p> <p>Avibactam Sodium (Sterile) eq. to Avibactam 500 mg + Meropenem Trihydrate (Sterile) IP eq. to Meropenem 1000 mg Injection</p>	M/s Protech Telelinks	The firm did not attend the meeting.
5.	<p>FDC/MA/23/000106</p> <p>E. office No.:133367</p> <p>Calcium Asparate 1120 mg + Magnesium Hydroxide IP 180 mg + Vitamin D3 IP 1000 IU tablet</p>	M/s Overseas Health Care Pvt. Ltd.	<p>In light of earlier SEC recommendation dated 10.06.2025 and as per condition of Form CT-23 dated 25.10.2023; the firm presented Active PMS report before the committee.</p> <p>After detailed deliberation, the committee noted and agreed to the result of the Active PMS report with condition that firm should mention in prescribing information that there are chances of increase in gastritis,</p>

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
			nausea and vomiting. Accordingly, firm should submit revised prescribing information to CDSCO.