

Recommendations of the SEC (Antimicrobial & Antiviral) made in its 11th meeting held on 26.11.2024 & 27.11.2024 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	GCT/CT04/FF/2024/45066 Online Submission (45066) Oxfendazole	M/s Indian Council of Medical Research	The firm did not turn up for the presentation.
BA/BE Division			
2.	BABE/CT05/FF/2023/39060 FDC of Pretomaid and Bedaquiline Tablets 200 mg/100 mg	M/s Macleods Pharmaceuticals Ltd.	In light of the earlier SEC recommendation dated 19.09.2024, the firm presented justification for the proposed FDC and data of relevant real world clinical studies & clarifications before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BA/BE study for export purpose only as presented by the firm with a condition to include safety and toxicity in the objective of the study. Accordingly the firm should submit revised protocol to CDSCO for review.
SND Division			
3.	SND/IMP/22/000003 Azelastrine Hydrochloride 1 mg/ml nasal spray	M/s Ursapharm India Pvt. Ltd.	The firm did not turn up for the presentation.
4.	SND/MA/22/000015 PVPI Nasal Spray 0.5%	M/s G.S.Pharmbutor	In light of earlier recommendation dated 23.08.2023, firm presented the clinical trial report having Protocol no. CT-CE-NS-2022, ver. no. 2.0 dated 29 Aug 2023 before the committee. After detailed deliberation, the committee expressed the concerns on the systemic absorption & toxicity due to release of Iodine from Povidone Iodine nasal spray. The committee opined that firm is required to present the systemic toxicity data included Thyroid function test for a prolonged period along with the reference

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			published literature.
5.	SND/CT/24/000052 VRP-034 (novel formulation of Polymyxin B 750,000 IU)	M/s Veeda Clinical Research Limited	<p>The firm presented the Phase I clinical trial Protocol no.23-VIN-0367; Version No.: 01 dated 18 Jan 2024 before the committee. The firm presented that applied drug is a novel formulation of Polymyxin B.</p> <p>After detailed deliberation, the committee opined to submit the revised study Protocol w.r.t. cut off values of KFT, Kidney injury markers (BUN, creatinine, Albumin and total protein), urinary biomarkers) for inclusion criteria, exclusion criteria and withdrawal of the subjects to CDSCO for further review by the Committee.</p>
6.	SND/MA/21/000548 Linezolid Sustained Release Tablets 1200mg	M/s. Akums Drugs and Pharmaceutical Limited	<p>The firm presented the proposal for grant of permission to conduct Post Marketing Surveillance study of the Linezolid Sustained Release Tablets 1200mg along with PMS protocol (Protocol No. VRL-CT-24-006, Version:0.1, Dated: 08.05.2024) before the committee.</p> <p>After detailed deliberation, the committee opined that the Post Marketing Surveillance study protocol should be revised with respect to following points-</p> <ol style="list-style-type: none"> 1. Secondary efficacy objective of the study shall be deleted. 2. Study population shall be increased. 3. Inclusion criteria shall be revised to describe all the strains of Gram-positive bacterial infection & word OR shall be removed from clinical and microbiological at S. no 1 of inclusion criteria. <p>Accordingly, the firm should submit revised protocol to CDSCO for further review by the committee.</p>
New Drugs Division			
7.	ND/MA/22/000088 Doravirine tablets 100mg	M/s Emcure Pharmaceuticals Limited	<p>In the light of earlier recommendation dated 28.02.2023, the firm presented the BE study report of the drug Doravirine tablets 100mg before the committee. The firm presented the rational for clinical trial waiver, approval of said drug</p>

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			<p>in more than 70 countries including US, EU, Japan, Australia and that the said drug included as treatment option in guideline such as DHSS guideline.</p> <p>The committee deliberated in detail the unmet medical need and the lower side effect profile with the drug.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture & market of drug Doravirine tablets 100mg subject to the following condition;</p> <ol style="list-style-type: none"> 1. In the package insert the paediatric patient age should be mentioned i.e. 12 to 18 years. 2. The firm should conduct phase IV clinical trial including all the age groups for which protocol should be submitted to CDSCO within 3 months of approval for further review by the committee.
8.	NDMA/24/000054 Tedizolid phosphate tablets 200 mg	M/s Sun Pharmaceuticals Industries Ltd.	<p>As per the condition no. 9 of manufacturing & marketing permission granted to the firm in Form CT-23 dated 19.07.2024, the The firm presented Post Marketing Surveillance (PMS) protocol for Tedizolid phosphate tablets 200 mg, before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Active PMS study subject to the condition that</p> <ol style="list-style-type: none"> 1. The study should enrol subjects with drug resistant cases like Gram positive organism MRSA, VRE, Penicillin resistant S. pneumonia etc <p>Accordingly, firm should submit revised protocol to CDSCO.</p>
FDC Division			
9.	FDC/MA/24/000159 Nitrofurantoin 100.0000milligram (mg) FlavoxateHydrochloride de 200.0000milligram (mg) Tablet	M/s Unicure India Ltd.	<p>The firm presented the proposal before the committee.</p> <p>After detailed deliberation, the committee opined the following:</p> <ol style="list-style-type: none"> 1. Firm should present the justification on rationality for the proposed FDC and its significant benefits. 2. Dosing schedule of the proposed FDC is not matching. 3. Flavoxate is not needed in all types of

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			<p>UTIs.</p> <p>4. Justification in light of standard therapeutic treatment guidelines should be presented.</p> <p>5. Scientific literature available from peer reviewed journal in support on combining this FDC.</p> <p>6. International approval status.</p> <p>Accordingly, the firm should submit above data for further review by the committee.</p>
10.	<p>FDC/MA/24/000205</p> <p>Amoxicillin Trihydrate IP eq. to Amoxicillin 600mg + Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 42.9mg uncoated orodispersible tablet</p>	M/s. Malik Life Sciences	<p>The firm presented the proposal along with justification for BE & phase III CT waiver before the committee.</p> <p>The committee noted that the FDC in proposed dosage form is not approved internationally.</p> <p>After detailed deliberation, the committee did not consider the justification for CT waiver and recommended to conduct Phase-III CT study with proposed FDC.</p> <p>Accordingly, the firm should submit Phase III CT Protocol for further review by the committee.</p>
11.	<p>FDC/MA/24/000245</p> <p>Meropenem Injection IP (Sterile Bulk) 1.500gm + Sulbactam Sodium IP (Sterile) 500mg powder for injectable solution</p>	M/s GUFIC BIOSCIENCES LIMITED	<p>The firm presented the proposal for the proposed FDC.</p> <p>After detailed deliberation, the committee opined that:</p> <ol style="list-style-type: none"> The firm should present the justification and essentiality for the proposed FDC. Scientific justification with rationality along with published literature in peer reviewed journals in support of FDC should be presented. Animal toxicity study data and Minimum Inhibitory Concentration (MIC) study data for the proposed FDC should be presented. <p>In view of above, the committee recommended that the firm should present the documents/justification for aforesaid points before the SEC for further review.</p>