

Recommendations of the SEC (Antimicrobial & Antiviral) made in its 12th/25 meeting held on 25.11.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Medical Devices Division			
1.	IMP/MD/2025/146084 Antimicrobial wound dressing with copper oxide	M/s. B L Life sciences Pvt. Ltd	<p>The firm presented the proposal for Grant of permission to import the device viz, (Antimicrobial wound dressing with copper oxide) manufactured by M/s MedCu Technologies Ltd., Israel for marketing in the country. The product is approved and marketed in USA for more than two years.</p> <p>The firm has presented safety data, clinical data and PMS data generated on the said device globally before committee.</p> <p>After detailed deliberation, the expert recommended for consideration of the product for the proposed indications based on the prescription from Registered medical practitioner only and accordingly the IFU and label may be revised.</p>
New Drugs Division			
2.	ND/IMP/21/000091 Cranberry Juice extract equivalent to 36 mg of Proanthocyanidin	M/s. ANGLO-FRENCH DRUGS & INDUSTRIES LTD.	<p>The firm presented the proposal for grant of permission for Import and Marketing of the drug product Cranberry fruit juice extract capsules (Ellura Capsules), before the committee.</p> <p>After detailed deliberation, the committee opined that firm is required to specify the absolute quantity of four analytical markers and at least one Bioactive marker in finished product. Further, the firm needs to demonstrate batch to batch consistency and stability of the product as per the guidance document available on the IPC website. (https://ipc.gov.in/images/29.08.2025_Phytopharmaceutical-Drugs-General-Guidance-for-Development.pdf).</p> <p>Further, the firm should provide the supportive proof of concept evidence for the claimed indication and the bioavailability data of applied product for further consideration to assess whether applied product falls under purview of phyto-pharmaceuticals.</p>

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3.	ND-11012(19)/19/2025-eoffice Pretomanid Tablets 200 mg	M/s. Mylan Laboratories Ltd.	Could not be deliberated in the absence of the expert from TB division of MoHFW.
SND Division			
4.	SND/IMP/21/000062 Quaternary Ammonium –based disinfectant liquid 0.290 % w/w	M/s. Ecolab Food Safety And Hygiene Solutions Private Limited	In light of earlier SEC recommendation dated 31.01.2023, firm presented the comparative data of the applied product with already approved disinfectant. After detailed deliberation, the committee recommended for grant of permission to import and market the Quaternary ammonium-based disinfectant liquid 0.290 % w/w for disinfection of floor, walls and other hard surfaces.
5.	SND/IMP/21/000064 Hydrogen peroxide based disinfectant wipes 17.140% w/w	M/s. Ecolab Food Safety And Hygiene Solutions Private Limited	In light of earlier SEC recommendation dated 31.01.2023, firm presented the comparative data of the applied product with already approved disinfectant. After detailed deliberation, the committee recommended for grant of permission to import and market the Hydrogen peroxide based disinfectant wipes 17.140 % w/w for disinfection of floors, walls and other hard surfaces.
6.	SND/IMP/21/000058 Chlorine-based disinfectant concentrate 53.000 % W/W tablet	M/s. Ecolab Food Safety And Hygiene Solutions Private Limited	In light of earlier SEC recommendation dated 30.09.2021, the firm presented in-vitro efficacy study data, together with the detailed methodology adopted for efficacy assessment, as well as regulatory approvals status in various countries for the applied product, before the Committee. After detailed deliberation, the committee recommended for grant of permission to Import and market Chlorine-based disinfectant concentrate 53.000 % w/w tablet for the disinfection of floors, walls, and other hard surfaces.
FDC Division			
7.	FDC/MA/22/000407 Combikit of Part A: Darunavir Ethanolate IP eq. to Darunavir 800mg + Ritonavir IP	M/s. Emcure Pharmaceuticals Limited	In light of earlier SEC recommendation dated 13.03.2024, the firm presented the Active PMS study protocol before the committee. After detailed deliberation, the committee

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	100mg film coated tablet and Part B: Dolutegravir Sodium IP eq. to Dolutegravir 50 mg film coated tablet		<p>recommended for grant of permission to conduct the Active PMS study.</p> <p>Accordingly, the firm should submit the Active PMS study report to CDSCO for further review by the committee.</p>
8.	FDC/MA/24/000214 Ofloxacin IP 200 mg + Metronidazole IP (ER) 600 mg film coated tablets	M/s. Unique Pharmaceutical Laboratories	<p>In light of the earlier SEC recommendation dated 24.10.2024, the firm presented the proposal along with BE study report wherein the Test product (T) and Reference product (R) are not bioequivalent with respect to rate and extent of absorption for Metronidazole.</p> <p>After detailed deliberation, the committee did not consider the BE study report and opined that the firm should submit justification for the results of the BE study.</p> <p>Accordingly, the firm should submit fresh BE study protocol as per NDCT Rule 2019 to CDSCO for further review by the committee.</p>