Recommendations of the SEC (Antimicrobial & Antiviral) made in its 131th meeting held on 31.10.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/23/000269 Levocarnitine IP 500mg + Methylcobalamin IP 1500mcg + Folic Acid IP 1.5mg + Vitamin E IP 200mg tablet	M/s. Windlas Biotech Limited	The firm presented their proposal along with request for BE & Phase III clinical trial waiver before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of the proposed FDC, subject to condition that the firm should conduct Active PMS study. Accordingly, the firm should submit Active PMS study protocol to CDSCO within 03 months of approval for review by the committee.
2.	FDC/MA/23/000205 Copper (II) nitrate Trihydrate 0.4% + Didecyl dimethyl ammonium chloride 80% Solution eq. to Didecyl dimethyl ammonium chloride 4.96% Liquid solution	M/s. Cedrus Bio-Products Pvt. Ltd.	In light of the earlier SEC recommendations dated 23.08.2023, the firm presented justification & rationality for the proposed FDC. After detailed deliberation, the committee noted The following: 1. The firm did not present any results of the antiviral activity of the proposed FDC. 2. The firm should submit scientific literature related to the inhalation exposure effects in humans of the proposed FDC. In view of above, the firm should submit above data to CDSCO for further review by the committee.
GCT Division			
3.	CT/93/23 38484 Cefefime-Tazobactum(FEP-TAZ)	M/s Wockhardt	The firm Presented Phase II/III Clinical Trial Protocol No. W-4282-303. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as per the proposed protocol presented by firm.
4.	CT/64/23 37765 EYU688	M/s Novartis	The firm Presented Phase IIa Clinical Trial Protocol No. CEYU688A12201. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as per the proposed protocol presented by firm.
New Drugs Division			

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
5.	ND/MA/22/000100 Methenamine Hippurate 1gm Tablet	M/s. Lyrus Life Science	In light with earlier SEC recommendation dated 22.03.2023 &27.09.2023, the firm presented Cell line study-In-vitro Cytotoxicity study (MTT Assay) of Methenamine Hippurate and repeated dose toxicity study data, published literature for the safety and efficacy of the drug and BE study data before the committee . After detailed deliberation, the committee recommended to present available toxicological data including repeated dose toxicity study data and available clinical study data on Indian population before the committee.