Recommendations of the SEC (Antimicrobial & Antiviral) made in its 07th/24 meeting held on 25.07.2024 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/CT/24/000032 Colloidal Nano Silver Gel (SilverSole)	M/s. Biosphere Clinical Research Pvt. Ltd.	In light of earlier SEC recommendation dated 21.01.2022, firm presented the proposal for the grant of permission to conduct Phase I clinical trial with drug Colloidal Nano Silver Gel (Silver Sole) along with Phase I clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase I clinical trial as per the protocol presented subject to the condition that the co-investigator of the study should be Pharmacologist.
2.	ND/CT/24/000029 Tedizolid Phosphate 200mg tablet and Tedizolid Phosphate for injection 200mg/vial	M/s. Hetero Labs Ltd.	The firm presented the proposal for grant of permission to conduct the Phase III clinical trial study for new drug Tedizolid Phosphate 200mg tablet and Tedizolid Phosphate for injection 200mg/vial for treatment of adult patients with Acute Bacterial Skin and Skin Structure Infections (ABSSSI) vide Protocol no.: HCR/III/TEDABS/03/2024, dated 26.03. 2024 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct Phase III clinical study as per protocol presented by the firm.
FDC Division			
3.	FDC/MA/23/000186 L-Alanyl L-Glutamine 20 gm (L-Alanine USP 8.2gm & L-Glutamine USP 13.46 gm) Sodium Chloride 0.9 gm per 100 ml with double chamber bag	M/s. Rusoma Laboratories Pvt. Ltd.	In light of earlier SEC recommendation dated 27.09.2023, the firm presented the proposal along with animal toxicity report. The committee noted that individual drugs are already approved by CDSCO. The firm has come with a Double-chambered transfusion bag containing Sodium Chloride and L-Alanyl L-Glutamine in 2 separate compartments of a plastic bag for ease of use. After detailed deliberation, the committee recommended for grant of permission for

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			manufacturing and marketing of the FDC with the condition to conduct the Phase IV clinical trial. Accordingly, the firm should submit Phase IV clinical trial protocol to CDSCO within 3 months of approval of the FDC for review by the committee.
SND Division			
4.	SND/MA/20/000215 Povidone Iodine Throat Spray 0.45% W/V	M/s. G.S. Pharmbutor Private Ltd.	In light of earlier SEC recommendation dated 27.09.2023, the firm presented the Phase III clinical trial report along with results before the committee. After detailed deliberation, the committee recommended for grant of permission for manufacturing and marketing of Povidone Iodine Throat spray 0.45% w/v for patients suffering from Tonsillitis and pharyngitis (throat infections).