

Recommendations of the SEC (Antimicrobial & Antiviral) made in its 129th meeting held on 23.08.2023 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/22/000015 Povidine Iodine Nasal Solution 0.5% w/v	M/s.G.B. Pharmabutor Private Ltd.	In light of earlier SEC recommendations dated 23.02.2022 & 24.02.2023, the firm presented Phase III clinical trial protocol before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III clinical trial subject condition that the firm should include Thyroid function test in inclusion criteria.
FDC Division			
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.	The firm presented their proposal before the committee. After detailed deliberation, the committee noted that: <ol style="list-style-type: none"> 1) The firm did not present any rationality and justification along with scientific peer reviewed literature w.r.t applied FDC. 2) Chronic exposure data and its toxicity on human beings was not presented. 3) Study protocol along with supporting documents should be submitted to demonstrate the Antiviral activity of the proposed FDC. In view of above, the firm should submit above data for further review by the committee.
3.	FDC/MA/23/000188 Abacavir Sulphate 60mg + Dolutegravir Sodium 5mg + Lamivudine 30 mg tablet for oral suspension	M/s. APL Health Care Ltd.	The firm presented their proposal along with BE study report before the committee. After detailed deliberation, the committee noted that firm has not presented any clinical data on Indian Population and hence, recommended that the firm should conduct Phase III CT study for the proposed FDC. Accordingly, the firm should submit Phase III clinical trial protocol to CDSCO for review by the committee.