

Recommendations of the SEC meeting to examine (COVID-19) related proposal under accelerated approval process made in its 245th meeting held on 21.03.2023 at CDSCO (HQ), New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drugs Division			
1.	ND/CT/22/000011 Life Viro Treat	Supreme Drugs Pvt Ltd	In light of earlier SEC recommendation dated 03.02.2023, the firm presented the Phase III interim clinical trial report along with its request for permission for restricted use of drug under emergency situation in the country, before the committee. After detailed deliberation, the committee observed that the firm has presented statistically erroneous data and recommended that the firm should submit the final Phase III clinical trial report before the committee for further consideration.
FDC Division			
2.	FDC/MA/22/000005 Combikit of Aspirin GR tablets 50mg & Prothazine HCL tablets 5mg & Multivitamin-minerals Tablets	M/s Meyers Vitabiotics	The firm didn't turn up for presentation.