

Recommendations of the SEC meeting to examine (COVID-19) related proposal under accelerated approval process made in its 242th meeting held on 03.02.2023 at CDSCO (HQ), New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drug Division			
1.	F. No. ND/CT/22/000011 Life Viro Treat Aqueous chlorine solution (0.80000 to 1.2000 mg) Aerosol	M/s Supreme Drugs Pvt. Ltd (Formerly Supreme Industries)	<p>In light of earlier SEC recommendation dated 16.11.2022, 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.</p> <p>During the presentation the committee noted the interim results of the study and the firm's claim of significant improvement in respect of various parameters. However, there are some errors in the data presented by the firm.</p> <p>After detailed deliberation, the committee recommended that the firm should submit the data after necessary corrections and present the same before the committee for further consideration.</p>