

Recommendations of the SEC meeting to examine (COVID-19) related proposal under accelerated approval process made in its 239th meeting held on 16.11.2022 at CDSCO (HQ), New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drug Division			
1.	IND/CT/22/000011 Life Viro treat (Aqueous Chloride)	M/s Supreme Drug Pvt. Ltd.	<p>The firm presented the Phase III Interim Clinical trial report along with their request for permission for restricted use of the drug under emergency situation in the country, before the committee.</p> <p>After detailed deliberation, the committee recommended that, the firm should complete the Phase III Clinical trial and also include some Govt. centres as clinical trial sites.</p> <p>Accordingly, firm should submit the complete clinical report to CDSCO for further consideration.</p>
SND Division			
2.	SND/MA/22/000111 Nitric Oxide Nasal Spray	M/s Glenmark Pharmaceuticals	<p>In light of previous recommendation of SEC the firm presented their proposal (COVID-19) meeting dated 18.10.2022. The committee opined that the firm did not present any published literature on the effect of nitric oxide nasal spray in COVID-19 prophylaxis before the committee.</p> <p>After detailed deliberation the committee recommended that, the firm should comply with the recommendation of SEC held on 18.10.2022 for further evaluation by the experts.</p>