

Recommendations of the SEC (Covid-19) made in its 04th/25 meeting held on 08.08.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/CT/22/000011 Aqueous Chlorine solution	M/s. SUPREME INDUSTRIES	<p>The firm presented the toxicity data and Phase III Clinical trial report before the committee.</p> <p>The committee noted that the toxicity data submitted by the firm is not in accordance with NDCT Rules, 2019 and sufficient studies have not been performed considering the first-time approval of the drug in the world.</p> <p>The committee recommended that firm should conduct toxicology studies like female reproduction and development study, Male fertility study, Teratogenicity study, Dermal toxicity, Allergenicity or Hypersensitivity study etc., in accordance with NDCT Rules, 2019.</p> <p>The committee reviewed the Phase III Clinical trial report and observed that the firm has enrolled 146 patients out of committed 184 patients and 135 patients were taken from one center. The Committee did not accept the Phase III Clinical Trial report.</p> <p>Further, the committee noted that there is no evidence of use of chlorine through Inhalation route in any part of the world and recommended for thorough toxicology evaluation in suitable animal models to establish the safety and efficacy of the product.</p>
2.	ND/CT/20/000072 Remdesivir for Injection 100 mg/vial	M/s. JSS Medical Research Asia Pacific Private Limited	<p>In light of the earlier recommendation of SEC (COVID-19) Dated 13.08.2020, firm presented Phase-IV CT study report of Remdesivir for Injection 100 mg/vial (Study No. REMD-ILS-4001 dated 09 Apr 2025), before the committee.</p> <p>After detailed deliberation, the committee considered the result of the Phase IV clinical study</p>
3.	ND/CT/20/000066 Chlorophyllin Tablet 750 mg	M/s. IDRS LABS PRIVATE LIMITED	The firm did not turn up for the presentation.