

Recommendations of the SEC (COVID-19) made in its 04th meeting held on 23.12.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/82/24 Online Submission (40490) Ensitrelvir, S-217622	M/s Clinnex	In light of earlier SEC Recommendation dated 29.08.2024, now the firm presented Phase III clinical study (STRIVE) INSIGHT protocol number: 018 / ACTIV version: 1.0, 11th November 2022 Appendix E -1: Shinogi Protease Inhibitor S -217622 (Ensitrelvir) version 2.0 dated 09 August 2023. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm.
New Drugs Division			
2.	ND/CT/21/000040 RP7214	M/s. JSS Medical Research Asia Pacific Pvt. Ltd.	The firm presented Phase II clinical trial study report Titled: A Randomized, Double-blind, Placebo-controlled, Phase 2 Study to Evaluate the Efficacy and Safety of oral RP7214, a DHODH inhibitor, in Patients with Symptomatic Mild SARS-CoV-2 Infection (CSR_RP7214-2101, Version 1.0 dated 04.08.02022) before the committee. After detailed deliberation, the committee noted that there is no statistically significant difference between treatment arm and placebo arm. Hence, it is concluded that Investigational New Drug (IND) RP7214 did not show therapeutic efficacy in patients with symptomatic SARS-Cov-2 infection.
3.	ND/CT/22/000038 Ramatroban	M/s. JSS Medical Research Asia Pacific Pvt. Ltd.	The firm presented the proposal for protocol amendment (Protocol no. RAMBAN-1) version 2.0 dated 30 May 2024 before the committee. After detailed deliberation, the committee agreed for the revised study questionnaire. However, regarding addition of CT sites outside India, the committee advised the firm to submit the proposal to GCT division of CDSCO for further necessary

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			action.