

Recommendations of the SEC (Covid-19) made in its 250th meeting held on 17.10.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drugs Division			
1.	ND/CT/21/00007910 1-PGC-005	M/s Laxai Life Sciences Pvt. Ltd.	<p>In light of earlier SEC (COVID) recommendation dated 09.02.2022, 04.07.2022 & 15.11.2022, the firm presented the Report of Phase-I PK (Protocol no. ICS/LAX/2022-004) of 101-PGC-005 in blood & Urine sample in healthy subjects, Report for the Phase-II study and protocol no. ICS/LAX/2023-002 dated 28.07.2023 to evaluate CSF PK for 101-PGC-005 in Healthy subject and Protocol amendment for Phase II/III in Moderate COVID-19 (Protocol no.: ICS/LAX/2022-005 Ver. 2.0 dated 02.08.2023).</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase-III clinical trial as per protocol presented by the firm. Also the levels of LDH, D-Dimer and other inflammatory Bio-markers to be specified.</p> <p>The committee also recommended for the grant of permission to conduct clinical study for Phase-I (CSF) PK study in 06 Healthy Indian Subjects (protocol No. ICS/LAX/2023-002; Ver. 01 dated 28.07.2023).</p> <p>Further the firm is advised to submit Animal toxicity data as per requirement of the New Drugs and Clinical Trials Rules, 2019 to CDSCO.</p>
GCT Division			
2.	CT/76/22 S-217622	M/s IQVIA	<p>The firm Presented protocol amendment version 5.0 amendment 4 dated 24 Feb 2023 with increase the number of subjects for protocol number: ACTIV-2d/a5407, before the committee</p> <p>After detailed deliberation, the committee recommended for approval of the proposed amendment as presented by firm.</p>

