

Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 220th meeting held on 20.04.2022 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	X.11026/188/20-BD APAC Unfractionated Heparin-Serum Albumin Conjugate (APAC)	M/s Cadila Pharmaceuticals Limites , Ahmedabad	The Firm presented the proposed changes in Phase-I clinical Study protocol. After detailed deliberation, the committee recommended for amendment in the approved Phase-I study protocol with the following conditions: 1. Platelet factor mapping should be performed. 2. Dose Level 1, 2, 3 data should be presented before enrolling the patients in Dose level 4 (Multiple dose). 3. CBC and heparin induced thrombocytopenia tests should be included.
2.	CT/19/22 INO-4800	M/s. Inovio	The firm didn't turn up for presentation
New Drug Division			
3.	ND/MA/22/000023 Kit of Nirmatrelvir Tablets 150 mg + Ritonavir Tablets 100 mg	M/s Cipla Limited	In light of earlier SEC recommendations in meeting held on 23.02.2022, the firm presented protocol amendment in bioequivalence study protocol before the committee. After detailed deliberation, the committee did not recommend for protocol amendment as the justification presented was not adequate.
4.	ND/CT/22/000017 Almitrine and Ifenprodil	CSIR/CDRI	The applicant presented the Phase III clinical trial proposal before the committee. After detailed deliberation, the committee recommended that applicant should conduct Phase II trial in COVID-19 patients with statistically significant sample size and provide supportive documents including published literature for the Phase II trial for efficacy in COVID -19 patients as proof of concept. Accordingly, applicant should submit revised protocol for Phase II CT to CDSCO for further review by the committee.
5.	IND/CT/04/22/000005 Umifenovir	M/s Medizest Pharmaceuticals	In light of earlier SEC recommendations (COVID-19) meeting held on 21.03.2022, the firm presented their phase III Clinical trial

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
			<p>protocol amendment, before the committee.</p> <p>After detailed deliberation, the committee recommended for approval of the the Phase III Clinical trial protocol amendment, subject to the following conditions:</p> <ol style="list-style-type: none"> 1. The firm should revise the primary efficacy end point as prevention of hospitalization. 2. Sample size should be statistically significant and geographically distributed. 3. In the inclusion criteria patient age group should be 18-60 years. <p>Accordingly, the firm should submit the revised protocol to CDSCO.</p>
BA/BE Division			
6.	12-09/2022/BA-BE/Misc-07/DC, Co-packaged of Nirmatrelvir Tablets 150 mg + Ritonavir Tablets 100 mg	M/s Aurobindo Pharma Ltd. , Hyderabad-500038	<p>The firm presented the BE study protocol before SEC.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the proposed BE study with condition that sample size should be increased to 18 subjects.</p>