

Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 231th meeting held on 04.07.2022 at CDSCO, HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drug Division			
1.	ND/MA/22/000016 Nirmatrelvir tablet co-packed with Ritonavir tablet 100 mg	M/s Zenera Pharma Pvt. Ltd.	<p>In light of earlier SEC (COVID-19) recommendation dated 09.02.2022, the firm presented their proposal along with the BE results before the committee.</p> <p>Considering the emergency & unmet medical need in Covid-19, the Committee recommended for grant of permission to manufacture and market the Combi pack of Nirmatrelvir Tablets 300mg (150mg x 2) and Ritonavir Tablets IP 100mg for restricted use under emergency situation in the country for treatment of adult patients COVID-19, with SpO2 >93% and who have high risk of progression of the disease including hospitalization or death subject to following conditions: -</p> <ol style="list-style-type: none"> 1. The drug should be sold by retail only under prescription of medical specialists. 2. The fact sheet containing the factual details about the drug, its restricted use under emergency situation, alternative therapy available etc. should be provided to the Health care professionals. 3. The Combi pack of Nirmatrelvir Tablets 300mg and Ritonavir Tablets IP 100mg is not authorized- <ol style="list-style-type: none"> i. For initiation of treatment in patients requiring hospitalization due to severe or critical COVID19. ii. For pre-exposure or postexposure prophylaxis for prevention of COVID-19. iii. For use longer than 5 consecutive days. 4. Phase IV clinical trial study should be conducted and accordingly, the firm should submit Phase IV Clinical trial study protocol within 3 months of the approval of the Drug.
2.	ND/MA/22/000008 Nirmatrelvir tablet co-packed with Ritonavir tablet 100 mg	M/s Optimus Pharma Pvt. Ltd.	<p>In light of earlier SEC (COVID-19) recommendation dated 06.06.2022, the firm presented their proposal along with the additional data on variation in Cmax values between the test product and reference product in the BE results before the committee.</p>

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3.	ND/CT/21/000079 101-PCG-005	M/s Laxai Life Sciences Pvt. Ltd.	<p>In light of earlier SEC (COVID) recommendation dated 09.02.2022, the firm presented the Phase-I protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase-I Clinical Trial.</p>
4.	ND/MA/22/00028 Cannabidiol Oral Solution 150mg/gm	M/s Zenera Pharma Pvt. Ltd.	The firm didn't turn up for presentation
SND Division			
5.	SND/IMP/22/000003 Azelastine	M/s Ursapharm	In light of the recommendation of SEC meeting held on dated 05-04-2022, the firm presented

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	Hydrochloride 1 mg/ml nasal spray	India Pvt. Ltd.	<p>the phase II clinical trial protocol.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase II clinical trial as per the protocol submitted by the firm.</p>
6.	12-01/2020-DC(Pt-NSRT-SND) Eflornithine (Eflornithine Granules 2.05 gm&5.0 gm)	M/s Navin Saxena Research & Technology	<p>The firm presented Phase II clinical trial report of Oral Eflornithine (NSRT2020) in the treatment of adult hospitalized moderate COVID-19 patients and requested for manufacturing and marketing permission of Eflornithine Granules 2.05 gm &5.0 gm.</p> <p>After detailed deliberation, the committee recommended that the firm should conduct Phase III clinical trial and accordingly Phase III clinical trial protocol should be submitted to CDSCO by the firm.</p>