

Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 216th meeting held on 08.03.2022 at CDSCO (HQ), New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
New Drug Division			
1.	ND/MA/20/000066 Remdesivir Injection 100 mg/20 ml	M/s Hetero	The firm presented their proposal with request for expansion of indication. After detailed deliberation, the committee recommended to submit Phase III CT protocol for expansion of the indication.
2.	12-01/20-DC(Pt-333) Anti-corona virus therapies	M/s St. John's, Bangalore	The firm didn't turn up for presentation.
SND Division			
3.	SND/CT/21/000084 1. Nitazoxanide Tablet 2000mg/day 2. Inhaled ciclesonide 640mcg/day 3. Artesunate and Amodiaquine (ASAQ) Tablet (Artesunate 200 mg/day and Amodiaquine 540mg/day) 4. Ivermectin Tablet 0.4mg/kg/day 5. Paracetamol 500mg upto 2g/day	M/s Qascent Research Solutions Private Limited	The firm presented the revised Phase III clinical trial protocol before the committee for approval. After detailed deliberation, the committee recommended that the firm should submit published evidence in support of the new study arm containing Fluoxetine showing efficacy on the COVID-19 patients.
GCT Division			
4.	CT/14/21 SNG001	M/s. Paraxel	The firm presented clinical trial protocol amendment version 5.0 dated 09-Sep-2021. After detailed deliberation the committee recommended for grant approval to the proposed clinical trial protocol amendment.
5.	CT/69/21 PF- 07321332 Ritonavir	M/s. Pfizer	The firm didn't turn up for presentation.