

Recommendations of the SEC meeting to examine COVID-19 related proposal under accelerated approval process made in its 224st meeting held on 05.05.2022 at CDSCO (HQ), New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	4-18/Roche/PAC-R. Tocilizumab/2021-BD Tocilizumab Injection 80mg/4ml, 200mg/10ml,400mg/20ml	M/s Roche Products(I) Pvt limited	The firm didn't turn up for presentation.
2.	12-01/SIPL/PAC COVISHIELD /22-BD COVISHIELD TM [ChAdOx1 nCoV-19 Corona Virus Vaccine (Recombinant)]	M/s Serum Institute of India Pvt. Ltd.	<p>The firm presented their proposal for introduction of multi-dose presentation with preservative 2-PE for COVISHIELD (ChAdOxInCoV-19 Corona Virus Vaccine (Recombinant)) before the committee.</p> <p>After reviewing the initial lab testing data presented by the firm, the Committee asked the firm to present the comparative immunogenicity and safety data of existing formulation which can be used up to 6 hrs after opening versus the proposed formulation with preservative (2-PE) which is proposed to be used upto 28 days after opening. In this regard the firm stated that they need time to submit and present the said data.</p> <p>After detailed deliberation the committee agreed for the same and recommended that the firm may submit the above data to CDSCO for further review by the committee.</p>
New Drug Division			
3.	ND/CT-21/FF/2022/30074 Combi pack of Nirmatrelvir Tablets 150 mg + Ritonavir tablets 100 mg in India	M/s Optimus Pharma Pvt. Ltd.	<p>The firm presented their proposal along with the BE study results and Phase IV clinical trial protocol before the committee.</p> <p>During presentation the committee noted that there was more inter-subject variability in the BE results.</p> <p>After detailed deliberation, the committee recommended that the firm should submit clarification on the inter-subject variability of the data.</p> <p>Accordingly the firm should submit the details</p>

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FDC Division			
4.	FDC/MA/22/000005 combi kit of Aspirin gastro resistant tablets IP 150mg and Promethazine HCl tablets 5mg & Multivitamin – minerals tablets.	M/s Meyer Vitabiotics	The firm didn't turn up for presentation.