Recommendations of the COVID-19 SEC made in its 102th meeting held on 17.08.2020 under accelerated approval process at CDSCO - HQ, New Delhi

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/CT/20/00037 Itolizumab 25 mg/5 ml solution for intravenous infusion in vial	M/s Biocon Biologicals Limited	The firm presented their proposal for the approval of new strength and new dosage form. After detailed deliberation, the committee recommended that the firm should present the safety and efficacy data with the new formulation through i.v route of administration before the committee.
2.	BIO/CT21/FF/2020/20922 Itolizumab	M/s Biocon Biologicals Limited	In light of the recommendations of SEC meeting held on 30.07.2020, firm presented revised Phase IV clinical trial protocol before the committee. After detailed deliberation, the committee recommended for the grant of permission for conduct of the proposed study. Dr. Sushant H. Meshram & Dr. Debashish Hota did not participate in the deliberation.
SND Division			
3.	SND/IMP/20/000198 Thymosin α-1 for injection 1.6 mg	M/s Gufic Biosciences Limited	In light of earlier recommendation of the SEC dated 05.08.2020, firm presented the Phase III Clinical trial protocol for Thymosin α-1 for injection 1.6 mg. After detailed deliberation, the committee recommended for grant of permission to conduct the Phase III Clinical trial subject to the following conditions: 1. The study should be Double

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			blind with placebo arm. 2. Clinical improvement based on ordinal scale should be additional primary end point and same should be deleted from the secondary endpoint. 3. SoC in different sites should be standardized as far as practicable.
New Drugs Division			
4.	12-01/20-DC (Pt-301) Ledipasvir/Daclatasvir + Sofosbuvir	Dr. Dhruva Chaudhary (Academic trial)	The applicant presented their proposal for conduct of academic clinical trial After detailed deliberation the committee recommended for grant of NOC for conduct of the proposed study as per the protocol presented.
5.	ND/CT/20/000038 Biocompatible calcined nano-scale Gold IH 2 mg + Biocompatible calcined nano-scale Copper IH 5 mg + Biocompatible calcined nano-scale Zinc IH 10 mg-	M/s Rasayani	In light of the recommendations of SEC meeting held on 07.05.2020, firm presented safety and efficacy data generated with individual components of the drug etc. before the committee. After detailed deliberation, the committee recommended that the firm should follow the drug development pathway. Accordingly, the firm should submit the phase I clinical trial proposal with justification for dose, duration of treatment etc. for review by the committee.
GCT Division			
6.	CT/73/20-DCG(I) Ruxolitinib 5 mg	M/s Novartis	The applicant presented their proposal for conduct of Phase-III Global clinical trial After detailed deliberation the

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			committee recommended that the firm should submit the following for further review by the committee. 1) Clarification on protocol title Vis-à-vis inclusion criteria. 2) Define inclusion & exclusion criteria clearly along with efficacy measurement especially in respect of cytokine storm.