

Recommendations of the COVID-19 SEC made in its 107th meeting held on 03.09.2020 under accelerated approval process at CDSCO HQ New Delhi:

Agenda No	File Name & Drug Name, Strength	Firm Name	Recommendation
Biological Division			
1.	BIO/CT/20/000077 Whole Virion Inactivated Corona Virus Vaccine, [BBV152] (Phase I/II clinical trial)	M/s Bharat Biotech International Ltd., Hyderabad	The firm presented proposed amendments to the Phase II part of clinical trial protocol (Version 5.0 dated 02.09.2020) along with animal challenge study data. After detailed deliberation, the committee recommended for the conduct of Phase II part of the clinical trial with 380 participants subject to the condition that time for screening the participants should be revised to 4 days.