

Recommendations of the SEC (COVID-19) made in its 251th meeting held on 07.12.2023 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	SARS-CoV-2 (Covid-19) Vaccine (Variant XBB.1.5) [Phase III CT] [BIO/CT/23/000118]	M/s. Biological E. Limited., Plot No. 1, Phase – II, Kolthur Village, Shameerpet, Medchal - Malkajgiri District, Telangana - 500078, India	<p>Permission in CT-23 was already granted to the firm for SARS-CoV-2 vaccine containing Receptor Binding Domain (RBD) of SARS-CoV-2 gene (CORBEVAX) in age group of ≥ 5 to <12 years, ≥ 12 years and ≥ 18 years old individuals.</p> <p>The firm presented the Phase –III Clinical trial protocol titled “ A prospective single-blind randomized Phase-III comparative study to evaluate immunogenicity and safety of Biological E’s XBB 1.5-RBD subunit Covid-19 vaccine in 5-80 years old Individual”.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Phase-III clinical trial as per the protocol presented by the firm.</p>