

Recommendations of the SEC (Haematology) made in its 07th/25 meeting held on 10.06.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
BA/BE Division			
1.	BABE/CT05/FF/2024/46508 Iron (III) Hydroxide Polymaltose 100 mg Hard Gelatin Capsules.	M/s Genecht Research Pvt. Ltd.	Firm presented the BA/BE study Protocol No. GRCT-23-001, Version-04, Dated 30-May-2025 before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BABE study for export purpose only.
Blood Product Division			
2.	X-11026/CTNOC/CT-06/BSV/01/2025-BD (E-office: BD PRO-11015(11)/3/2025-eoffice; E-19871) Human Normal Immunoglobulin for Intravenous Use, IVIG (Human) 5% Solution.	M/s. Bharat Serums and Vaccines Limited, 3rd Floor, Liberty Tower, Plot No. K-10, Behind Reliable Plaza, Kalwa Industrial Estate, Airoli, Navi Mumbai 400708	The firm has presented the revised protocol (revised as per the recommendations given by the committee during the SEC meeting held on 11.02.2025) for the proposal to conduct phase III Clinical trial titled: “An Open-Label, Multicenter, Phase III Clinical Study in India to Evaluate the Efficacy and Safety of Human Normal Immunoglobulin for Intravenous use (IVIG) in Chronic Immune Thrombocytopenia (ITP)” vide Protocol No. BSV_IVIG_ITP_2023_02 Version: 4.0 dated 17.04.2025. After detailed deliberation, the committee has recommended for the grant of permission to conduct Phase III Clinical Trial as per revised protocol No. BSV_IVIG_ITP_2023_02 Version: 4.0 dated 17.04.2025.