

Recommendations of the SEC (Haematology) made in its 13th meeting held on 10.12.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/72/21 35993 Online Submission (35993) Imetelstat sodium	M/s Parexel	The firm presented protocol amendment 3/IND-3 dated 19 September 2024 protocol no. GRNI63LMYF3001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/143/22 Online Submission (36054) VAY736 (Inalumab)	M/s Novartis	The firm presented protocol amendment version 05 dated 28 August 2024 protocol no. CVAY736Q12301. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
3.	CT/104/22 36089 Online Submission (36089) NNC 0365-3769 (Mim8)	M/s Novo nordisk	The firm didn't turn up for presentation.
FDC Division			
4.	FDC/MA/23/000218 Ferrous Fumarate (eq. to 49.5 mg elemental Iron) 150mg IP + L-Histidine HCL.H2O 4mg BP + L-Lysine HCL 25mg IP + Glycine 10mg IP + Thiamine Mononitrate (Vitamin B1) 5mg IP + Riboflavin (Vitamin B2) 3mg IP + Pyridoxine HCL (Vitamin B6) 1.5mg IP + Cyanocobalamin (Vitamin B12) 2g IP + Folic Acid (Vitamin B9) 500g IP + Ascorbic Acid (Vitamin C) 40mg IP + Zinc Sulphate 50mg IP capsule	M/s Albert David Limited	The firm didn't turn up for presentation.

