

Recommendations of the SEC (Haematology) made in its 02nd/24 meeting held on 08.02.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
Biological Division			
1.	BIO/CT04/FF/2023/3832 2 Romiplostim 250mcg for Injection	M/s. Levim biotech	In light of the earlier SEC recommendation dated 09.11.2023 & 10.11.2023, the firm presented the revised clinical trial protocol titled "A prospective, randomized, double-blind, multi-centre, parallel arm, comparative clinical study to determine the efficacy and safety of Romiplostim Biosimilar manufactured by Levim Biotech with Nplate manufactured by Amgen in patients with chronic immune thrombocytopenia (ITP)" vide protocol LBL-CT-20-003, Version 3.0 dated 21 Dec 2023. After detailed deliberation, the committee recommended to conduct the clinical trial study as per the revised protocol presented by the firm.
2.	X-11026/160/2023-BD Crizanlizumab	M/s. Novartis	The firm did not turn up for presentation.
FDC Division			
3.	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 presented their proposal before the committee. After detailed deliberation, committee opined the following: <ol style="list-style-type: none"> 1. The firm did not present the rationality of the combination and its significant benefits. 2. The firm did not present any published literature in support of therapeutic dose and proposed indication of the proposed FDC. 3. The firm did not present justification for need of addition of Zinc. Accordingly, the firm should submit above data for further review by the committee.

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4.	FDC/MA/22/000258 Transdermal Liposomal Lotion Product containing API of Ferrous Bis Glycinate (Elemental Iron), Vitamin B12, Vitamin D3, Folic Acid	M/s. Murli Krishna Pharma Pvt. Ltd.	<p>In light of earlier SEC recommendation dated 29.11.2023 and 30.11.2023, the firm presented their proposal along with revised Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee recommended for conducting the Phase III CT study.</p> <p>The PK study report should be presented for review by SEC before initiation of the Phase III clinical trial.</p>