

**Recommendations of the SEC (Haematology) made in its 10<sup>th</sup>/24 meeting held on 10.09.2024 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>GCT Division</b>			
1.	CT/31/24 Online Submission (34586)  Human cell line recombinant Factor VIII	M/s. Allucent (India) Private Limited	The firm didn't turn up for presentation.
2.	CT/103/24 Online Submission (45003)  Romiplostim	M/s. Enzene Biosciences Ltd.	The firm presented phase 1 clinical study protocol no. ENZROMI/24/267, version 00, dated 20 August 2024.  After detailed deliberation, the committee opined that, the investigational product is approved in India in 2021 and study is also proposed to be conducted in India, the firm should submit the recommendations from other international regulatory authorities for conducting the proposed Phase I trial in India only.
3.	CT/108/24 Online Submission (45065)  Mavorixafor	M/s. Novotech Clinical Research India Private Limited	The firm didn't turn up for presentation.
<b>SND Division</b>			
4.	SND/CT/22/000127  Ferrous Ascorbate Suspension 30mg/5ml (Additional Dosage Form)	M/s. Zuventus Healthcare Limited	In light of earlier SEC recommendation dated 19.03.2024, firm presented safety and efficacy data in children for Ferrous Ascorbate suspension 30mg/5ml indicated for the treatment of iron deficiency anaemia along with request for waiver of clinical trial study and BE study before the committee.  The Committee noted that various FDC suspension formulations of Ferrous Ascorbate is already approved by CDSCO as well as available in the market.  After detailed deliberation, the Committee recommended for grant of permission to manufacture and market of Ferrous Ascorbate suspension 30mg/5ml with BE & CT waiver based on the data

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			presented by the firm subject to submission of CMC data.
<b>New Drug Division</b>			
5.	ND/MA/23/000175  Ferric Maltol Capsules 30 mg	M/s. Pure & Cure Healthcare Pvt. Ltd.	<p>The firm presented the proposal for grant of permission to manufacture and market of Ferric Maltol Capsules 30 mg along with bioequivalence study protocol (No. VRL-23-004, Ver-1.0, dated: 01.09.2023 and Phase III clinical trial waiver justification before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct bio-equivalence study as per the protocol presented.</p> <p>And the result of the bio-equivalence study should be presented before the committee for further consideration.</p>