

Recommendations of the SEC (Haematology) made in its 09th/24 meeting held on 08.08.24 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/117/22 Online Submission (25505) Fitusiran (SAR439774)	M/s. Sanofi Health Care India Private Limited	The firm presented protocol amendment number 03, version 01 dated 30.01.2023 protocol No. EFC17574. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm.
2.	CT/87/24 Online Submission (43603) Luspatercept (ACE-536)	M/s. PPD Pharmaceutical Development India Private Limited	The firm presented Phase 2a clinical trial protocol No. ACE-536-B-THAL-004, version 3.1 dated 27.03.2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm
3.	CT/91/24 Online Submission (44329) Etavopivat	M/s. Novo Nordisk India Pvt. Ltd.	The firm presented Phase III clinical trial protocol No. NN7535-7807 version No.1.0 dated 18.04.2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm
4.	CT/18/19 Online Submission (33933) Fitusiran	M/s. PPD Pharmaceutical Development India Private Limited	The firm presented protocol amendment version 6.0 dated 02.05.2024 protocol No. LTE15174. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm
5.	CT/71/23 Online Submission (34054) VGA039 Monoclonal Antibody	M/s. In Ventiv International Pharma Services Pvt. Ltd.	The firm presented protocol amendment version 6.0 dated 05.05.2024 protocol No. VGA039-CP001. After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm
SND Division			
6.	SND/MA/23/000266 Iron (III) Hydroxide Polymaltose Syrup 125 mg/5 mL	M/s. Ajanta Pharma Limited	The firm intended to present the proposal/protocol which was different from the proposal submitted to CDSCO. Therefore, the firm is advised to submit the proposal to CDSCO before deliberation in the committee.
New Drugs Division			

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7.	ND/MA/23/000155 Ferric Maltol Capsules 30 mg	M/s. Precise Biopharma Pvt. Ltd.	<p>In light of earlier SEC recommendations dated 21.12.2023 & 22.12.2023, the firm presented the major organs histopathological slides of the repeated dose toxicity study before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the bioequivalence study as per the protocol.</p>