

Recommendations of the SEC (Haematology) made in its 06th/24 meeting held on 21.05.2024 at CDSCO (HQ), New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/38/23 Online Submission (32184) Serpipidil PC	M/s. InVentiv	<p>The firm presented protocol amendment version 4.0 dated 18.10.2023, addendum 1.0 dated 20.03.2024 to increase the number of subjects from 19 to 40 in India protocol No. AP-0102.</p> <p>After detailed deliberation, the committee recommended for approval of protocol amendment and addendum to increase the number of subjects from 19 to 40 in India as presented by the firm with advise to include one or two more geographically distributed sites in the study subject to the condition that subsequent patients with hemophilia B without inhibitor shall only be enrolled into the study.</p>
2.	CT/02/22 Online Submission (32122) Fitusiran	M/s.Sanofi	<p>The firm presented protocol amendment 03 version 1 dated 20.10.2023 and protocol amendment 04 version 1 dated 24.11.2023 protocol No. EFC1546.</p> <p>After detailed deliberation, the committee recommended for approval of protocol amendment as presented by the firm subject to the condition that interim analysis report every 24 weeks shall be submitted to CDSCO.</p>