

Recommendations of the SEC (Haematology) made in its 09th/25 meeting held on 16.09.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/25/000115 Tranexamic acid spray 10% w/v	M/s. Shilpa Medicare Limited	<p>The firm has presented the proposal for grant of permission to manufacture and marketing of Tranexamic acid spray 10% w/v indicated to reduce or prevent hemorrhage during Class I and Class II injury (additional indication).</p> <p>Firm informed that, they have obtained the initial permission for Tranexamic acid spray 10% w/v on 19.09.2022 for indication to reduce or prevent hemorrhage and reduce the need of replacement therapy during accidental and domestic injury.</p> <p>Firm presented the post marketing data to support the applied additional indication before the committee.</p> <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and marketing of Tranexamic acid spray 10% w/v indicated to reduce or prevent hemorrhage as Topical irrigation (Class I injury) only. Other applied indications are not recommended due to lack of supporting clinical data.</p>