

Recommendations of the SEC (Dermatology & Allergy) made in its 04th/25 meeting held on on 22.04.2025 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/23/000155 Tofacitinib Ointment 2% w/w	M/s Precise Biopharma Pvt. Ltd	<p>Firm presented Active Post Marketing Surveillance (PMS) Study protocol of Tofacitinib Ointment 2% w/w vide Protocol ID: CT/2023/75, version: 00, before the committee as per the condition of manufacturing & marketing permission granted to the firm in Form CT-23 dated 17.11.2023.</p> <p>After detailed deliberation, the committee recommended for grant of permission to conduct the Active PMS study subject to the condition that:</p> <ol style="list-style-type: none"> 1) Firm should include test of IgE and absolute eosinophil count at the time of screening and the end of the study. 2) Firm should include thyroid profile test at the time of screening. <p>Accordingly, firm should submit revised protocol to CDSCO.</p>