

Recommendations of the SEC (Dermatology & Allergy) made in its 01th/26 meeting held on 08.01.2026 at CDSCO HQ New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
BA/BE Division			
1.	BABE/CT05/FF/2025/52831 Deuruxolitinib Extended Release Capsules 20 mg	M/s. Sun Pharmaceutical Industries Limited.	Firm presented the BA/BE study Protocol No. DEU09425, Version No. 1.0 Protocol Date 28-AUG-2025 Amendment No. 1.0 and Date 03-OCT-2025 for export purpose only before the committee. After detailed deliberation, the committee recommended for grant of permission to conduct the BABE study for export purpose only with a condition to include additional safety monitoring and follow-up of the participants up to 6 months post study.
SND Division			
2.	SND/MA/25/000160 Levocetirizine Dihydrochloride Oral Drops 5 mg/mL	M/s. Dr. Reddy's Laboratories Limited	Firm presented proposal for manufacturing and marketing of Levocetirizine Dihydrochloride Oral Drops 5 mg/mL for the applied indication along with justification for BE and CT waiver before the committee. The firm informed that Levocetirizine Dihydrochloride Oral Syrup 2.5 mg/ 5 mL is approved since 2011 in children of 6 months of age & above and the proposed posology of the applied formulation is same as that of the approved dosage form. After detailed deliberation, the committee opined to submit the following data. 1. Pediatric Safety data on Paraben preservatives in 6 months of age and above. 2. More safety data of Levocetirizine Dihydrochloride Oral Syrup in children from 6 months of age and above. Accordingly, firm should submit the above mentioned data/information to CDSCO for further review by the committee.