

Recommendations of the SEC (Dermatology & Allergy) made in its 05th/25 meeting held on 21.05.2025 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
GCT Division			
1.	CT/47/25 Online Submission (49315) Abrocitinib (PF-04965842)	M/s Pfizer Limited	The firm presented phase III Clinical study protocol no.: B7451023 version no. Original Protocol dated 20- DEC-2024. After detailed deliberation, the committee recommended for grant of permission to conduct the trial as presented by the firm with following condition: 1. Use of any concomitant systemic corticosteroids & Topical Janus Kinase (JAK) inhibitor shall be excluded in the study. The outcome (study end) parameters also required in reduction of corticosteroids use.
SND Division			
2.	SND-16011(11)/239/2024-eoffice Hydroxyzine Hydrochloride Sustained Release Tablet 50mg	M/s Dr. Reddy's Laboratories Ltd.	The firm presented the proposal for grant of permission to conduct the observational study vide protocol ID.: DRL-IND-GGI-053-ATAR/2023, Version 01; Dated: 30 May 2024 to assess the effectiveness and tolerability of Hydroxyzine HCl 50 mg SR Tablet as an anti-pruritic, by gathering data from Indian subjects for the treatment of chronic pruritus before the committee. The committee noted that, there is no safety data of Hydroxyzine Hydrochloride Sustained Release Tablet 50mg for proposed duration of study. After detailed deliberation, the committee did not agree for conduct of observational study.