

Recommendations of the SEC (Investigational New Drugs) made in its 09th /25 meeting held on 08.10.2025 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
IND Division			
1.	IND-11012(17)/2/2025-eoffice Nafithromycin 400 mg Tablet (Removal of condition)	M/s. Wockhardt Ltd	<p>In light of earlier SEC recommendation dated 30.04.2025, firm has presented additional data for removal of condition "For supply only to Medical College/Tertiary Care/District Hospital" stipulated in the permission issued in Form CT-23 & on the label of Nafithromycin Tablet 400 mg (MIQNAF), before the committee.</p> <p>After detailed deliberation, committee has recommended to submit following details/data to take further action in the matter;</p> <ul style="list-style-type: none"> (i) History of existing macrolide antibiotic's drug resistance, particularly time taken to develop resistance with such antimicrobials in Indian context. (ii) Copy of agreement with ICMR for surveillance of AMR for the drug Nafithromycin Tablets. (iii) Measures taken to ensure the sale of drug Nafithromycin Tablet through only valid prescription i.e. by Pulmonologist. (iv) Whether any mechanism implemented to ensure prescription of drug through e-prescription system only if so, the details thereof, if not, the challenges associated with it. (v) Current status of implementation of trace and track system and whether it ensures complete batch reconciliation. <p>Accordingly, firm should submit above requisite data to CDSCO for further evaluation by the SEC.</p>