

**Recommendations of the SEC (Investigational New Drugs (IND) made in its 06<sup>th</sup>/25 meeting held on 08.07.2025 at CDSCO HQ New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>IND Division</b>			
1.	IND/CT04/FF/2025/49408  Nafithromycin 400 mg tablet.	M/s. Wockhardt Limited	<p>Firm has presented the proposal to conduct Phase IV trial entitled “A Phase IV, open label, multicentre, interventional study to assess the safety and efficacy of oral MIQNAF (Nafithromycin) as monotherapy in the treatment of adult patients with community-acquired bacterial pneumonia (CABP) vide Protocol number: W-4873-401, Version no. 01 dated 03.05.2025.</p> <p>After detailed deliberation, the committee recommended for the conduct of Phase IV trial as presented by the firm with the following condition;</p> <ol style="list-style-type: none"> <li>1. Interim report w. r. t. AE, SAE, SUSAR and TEAEs shall be submitted to CDSCO within 03 months after initiation of study.</li> </ol>