

Recommendations of the SEC (Investigational New Drugs) made in its 12th meeting held on 27.12.2024 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/24/000072 Pioglitazone Hydrochloride IP eq. to Pioglitazone 15mg/15mg + Ezetimibe IP 10mg/5mg Tablets	M/s Mankind Pharma Ltd.	<p>In light of the earlier SEC recommendations dated 14.05.2024 and 20.06.2024, firm presented the proposal before the IND committee.</p> <p>After detailed deliberation, the committee noted that-</p> <ol style="list-style-type: none"> 1. Firm did not present the data in respect to proposed claim of the FDC as well as not addressed the issues which were pointed out in earlier SEC recommendations. 2. Firm did not submit justification on desirability and essentiality of the proposed FDC. 3. Firm could not justify the use of the FDC over the single drugs. 4. Firm presented patent related document which is not pertain to the proposed FDC. 5. Firm presented the in-vivo animal studies data in same dose which is also proposed for human dose, it is not appropriate. <p>In view of above, committee did not recommend the approval of the proposed FDC.</p>