

Recommendations of the SEC (Endocrinology & Metabolism) made in its 19th/25 meeting held on 11.09.2025 at CDSCO (HQ), New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/23/000362 Empagliflozin 10 mg/25 mg + Vildagliptin IP (SR) 100 mg/100 mg tablet	M/s. Exemed Pharmaceuticals	<p>In light of earlier SEC recommendation dated 24.01.2024, the firm presented the proposal along with BE study report and Phase III clinical trial protocol before the committee.</p> <p>After detailed deliberation, the committee did not recommend the Phase III clinical trial, noting that while Empagliflozin can be used in patients with varying degrees of renal impairment, Vildagliptin is contraindicated in such cases, thereby rendering the clinical utility of the combination questionable.</p> <p>In view of above, the committee did not consider the proposed FDC.</p>