

**Recommendations of the SEC (Endocrinology & Metabolism) made in its 05<sup>th</sup>/25 meeting held on 20.02.2025 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>FDC Division</b>			
1.	FDC/MA/25/000001 Alogliptin 12.5mg + Metformin hydrochloride 850mg Tablet	M/s Torrent Pharmaceuticals Ltd.	<p>The firm presented the proposal along with BE study report conducted for export purpose &amp; justification for Phase III CT waiver before the committee.</p> <p>After detailed deliberation, the committee noted that:</p> <ol style="list-style-type: none"> <li>1. The firm has not presented any scientific literature regarding essentiality and desirability of the proposed FDC (Alogliptin 12.5 (mg) + Metformin hydrochloride 850 (mg) Tablet).</li> <li>2. The firm didn't present any safety and efficacy data Generated in Indian Population for the proposed FDC.</li> <li>3. Firm has not presented any scientific literature/ data from peer reviewed journal regarding the unmet need of the proposed FDC.</li> <li>4. Firm has not presented any justification (PK and PD) for the particular combination (with literature support), specifically for the strengths of individual components used in the FDC.</li> </ol> <p>Accordingly, the firm should submit the above data to CDSCO for further review by the committee.</p>