

**Recommendations of the SEC (Antimicrobial & Antiviral) made in its 04<sup>th</sup>/25 meeting held on 08.04.2025 at CDSCO (HQ), New Delhi:**

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>FDC Division</b>			
1.	FDC/MA/24/000159  Nitrofurantoin SR 100 (mg) + Flavoxate Hydrochloride 200 (mg) Tablets	M/s Unicure India Ltd.	<p>In light of the earlier SEC recommendation dated 26.11.2024, the firm presented their proposal along with justification for the proposed FDC.</p> <p>After detailed deliberation, the committee noted that the firm did not present the adequate justification on rationality of proposed FDC.</p> <p>Further, the firm also did not present scientific literature from peer reviewed journal, significant clinical need &amp; synergistic effect in support of proposed FDC.</p> <p>In view of above, the committee did not recommend for the approval of the FDC.</p>