

**Recommendations of the SEC (Antimicrobial & Antiviral) made in its 03<sup>rd</sup>/24 meeting held on 13.03.2024 at CDSCO (HQ), New Delhi:**

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
<b>FDC Division</b>			
1.	FDC/MA/22/000354  Combikit of Atazanavir 300mg and Ritonavir 100mg Tablet & Emtricitabine 200mg and Tenofovir Alafenamide 10mg Tablet	M/s. Emcure Pharmaceuticals Limited	<p>The firm was granted permission for the proposed Combikit in Form CT-23 dated 04.08.2023 with the condition to conduct Active PMS study. However the firm presented the justification for Active PMS waiver before the committee.</p> <p>After detailed deliberation, the committee did not consider the request of Active PMS waiver and recommended to conduct Active PMS study for proposed Combikit.</p> <p>Accordingly, the firm should submit the Active PMS protocol to CDSCO for further review.</p>
2.	FDC/MA/22/000407  Combikit of Darunavir 800mg and Ritonavir 100mg Tablet + Dolutegravir 50 mg Tablet	M/s. Emcure Pharmaceuticals Limited	<p>In light of the earlier SEC recommendation dated 25.04.2023, the firm presented their proposal along with justification for Active PMS waiver before the committee.</p> <p>After detailed deliberation, the committee did not consider the request of Active PMS waiver and recommended to conduct Active PMS study for proposed Combikit.</p> <p>Accordingly, the firm should submit the Active PMS protocol to CDSCO for further review.</p>
3.	FDC/MA/24/000059  Faropenem Sodium Hydrate JP eq. to Faropenem 50mg/100mg + Potassium Clavulanate Diluted IP eq. to Clavulanic Acid 31.25mg/62.5mg per 5mL suspension	M/s. Akums Drugs and Pharmaceuticals Ltd.	<p>The firm did not turn up for the presentation.</p>