

Recommendations of the SEC (Antimicrobial & Antiparasitic) made in its 01st/26 meeting held on 08.01.2026 at CDSCO HQ New Delhi:

S. No.	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/25/000127 Posaconazole Gastro-Resistant Tablets 300 mg	M/s AET Laboratories Private Limited	<p>The firm presented proposal for grant of permission to manufacture and market Posaconazole Gastro Resistant Tablets 300 mg along with BE study report under fasting & fed condition for the Proposed indication before the Committee.</p> <p>The Committee noted that Posaconazole Gastro Resistant Tablets 300 mg already approved by CDSCO on 25.07.2022. Further, the committee noted that BE study demonstrated bioequivalence under fed conditions and test product is more bioavailable in the fasting condition than the reference product and same can be accepted inline with published public assessment reports of Posaconazole gastro resistant tablets.</p> <p>After detailed deliberation, the Committee recommended for grant of permission to manufacture and market Posaconazole Gastro-Resistant Tablets 300 mg for the Proposed indication.</p>