

Recommendations of the SEC (Dentistry) made in its 7th meeting held on 28.12.2022 at CDSCO (HQ)
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S.No.	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/21/00508 Metronidazole Extended release tablets 600mg	M/s. Abbott Healthcare Pvt. Ltd.	<p>In light of earlier recommendation of SEC (Dentistry) meeting dated 20.05.2022, the firm presented the proposal of manufacture and marketing of Metronidazole Extended Release Tablets 600mg for proposed additional indication along with additional clinical and published data in support of additional indication before the committee.</p> <p>After detailed deliberation the committee opined that firm did not present any comparative clinical data of proposed drug product i.e. Metronidazole Extended Release Tablets 600mg (Proposed dose: 2 x 600mg OD) with Metronidazole conventional Tablets 400mg (TS) w.r.t proposed additional indication.</p> <p>Hence, the committee recommended that the firm should submit comparative clinical data of Metronidazole Extended Release Tablets 600mg (Proposed dose: 2 x 600mg OD) with Metronidazole conventional Tablets 400mg (TS) w.r.t proposed additional indication for further consideration.</p>