

Recommendations of the SEC (Dentistry) made in its 06th meeting held on 20.05.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
SND Division			
1.	SND/MA/21/000508 Metronidazole Extended Release Tablet 600mg	M/s. Abbott Healthcare	The firm presented the proposal for manufacturing and marketing of Metronidazole Extended Release Tablet 600mg for the proposed additional indication. After detailed deliberation, the committee recommended that the firm should present additional clinical and published data in support of the proposed additional indication before the committee for further consideration.
FDC Division			
2.	FDC/CT/20/000016 Doxycycline Hyclate + Metformin Hydrochloride (10%w/w + 1%w/w) Gel	M/s. Dr. Reddy's laboratories Ltd.	The firm presented their protocol amendment in Phase II clinical trial protocol before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.
GCT Division			
3.	CT/11/20 Online Submission (17010) Tranexamic Acid Mouthwash (50mg/ml)	M/s. Ethicare Clinical Trial Services	The firm presented their proposal for protocol amendment ECTS/19/004, version 03, dated 01-March-2022 before the committee. After detailed deliberation, the committee recommended for approval of the proposed protocol amendment.