

Recommendations of the SEC (Dentistry) made in its 05th meeting held on 14.09.2021 at CDSCO HQ, New Delhi:

S.No	File Name & Drug Name, Strength	Firm Name	Recommendations
FDC Division			
1.	FDC/MA/19/000115 Streptococcus salivarius UBSS-01 1.0Billion cfu+Lactobacillus salivarius UBLS-22 0.5Billion cfu+Lactobacillus acidophilus UBLA-34 0.5 Billion cfu+ Lactobacillus rhamnosus UBLR-58 0.5 Billion cfu + Lactobacillus paracasei UBLPc-35 0.5 Billion cfu+Lactobacillus plantarum UBLP-40 0.5 Billioncfu+Lactobacillus reuteri UBLRu-87 0.2 Billion cfu Enkor Instamelt Sachet	M/s. Unique Biotech Ltd.	In light of the earlier recommendation of the SEC meeting dated 10.12.2019, the firm presented their proposal before the committee. After detailed deliberation the committee recommended that the firm should initially provide adequate justification for the rationale of the proposed FDC along with scientific evidences in support of their claim. Once the firm justifies the rationale of the FDC for the proposed indication, the firm will be required to conduct the Phase III Clinical trial before considering the manufacturing and marketing approval.
2.	FDC/CT/20/000016 Doxycycline Hyclate 10% w/w + Metformin Hydrochloride 1% w/w gel	M/s. Dr. Reddy's Laboratories Ltd.	The firm presented their proposal along with revised Phase-II Protocol before the committee. After detailed deliberation, the committee recommended that the firm should conduct study as per the Phase-II Protocol which was approved earlier by the committee.