

Recommendations of the SEC (Antimicrobial & Antiviral) made in its 113th meeting held on 05.05.2022 at CDSCO (HQ), New Delhi:

S. No	File Name & Drug Name, Strength	Firm Name	Recommendations
New Drug Division			
1.	ND/MA/22/000051 Cy-Tb	M/s. Serum	<p>In light of the earlier SEC recommendation dated 06-04-2022, ICMR presented results of Phase III clinical trial titled “Assessment of comparative performance (efficacy and safety) of C-Tb with QuantiFERON-TB Gold Plus and 2 T.U. Tuberculin PPD RT23 SSI in Tube for detection of TB infection in general and key population”.</p> <p>Serum Institute of India (SII) presented various clinical trial data along with comparability data of the product manufactured at Serum Institute (Cy-TB) India and Statens Serum Institute (SSI), Denmark (C-TB) with respect to manufacturing details, analytical and release profile, product characterization stability study data and physicochemical characteristics including determination of primary and higher order structural analysis of the drug substance and drug product along with other physiochemical properties before the committee.</p> <p>During meeting, the committee noted the following:</p> <ul style="list-style-type: none"> • C-Tb has shown overall better sensitivity in general population and high risk population of TB patients as compared to PPD `while specificity was comparable in both groups. • Clinical trial was conducted by ICMR with Investigational product of Statens Serum Institute (SSI), Denmark, fill finished by Serum Institute of India (SII) using same technology from SSI, Denmark. <p>After detailed deliberation, the committee recommended for grant of permission to manufacture and market the product for detection of latent TB in the population of 18 yrs and above. The committee also</p>

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			opined that more clinical data should be generated in population less than 18 yrs of age for which separate protocol should be submitted to CDSCO for further review by the committee.