

WHO Prequalification Programme

WHO PUBLIC ASSESSMENT REPORT (WHOPAR)

SIILTIBCY (Cy-Tb)¹

International Nonproprietary Name (INN): rdESAT-6 and rCFP-10 (*Mycobacterium tuberculosis*-specific antigens)

Abstract

SIILTIBCY (Cy-Tb), manufactured at Serum Institute of India Private Limited, Pune, India, was submitted to be considered for prequalification in 2025 when the product was licensed / registered by the European Medicines Agency (EMA). It was subsequently accepted for inclusion in the WHO list of prequalified products for the WHO-recommended indication: a diagnostic aid for detection of *Mycobacterium tuberculosis* infection, including disease, in adults and children aged 28 days or older, on the 23 July 2025.

“WHO Procedure for Prequalification of BTPs or their corresponding SBPs”² defines specific evaluation mechanisms for products approved by regulatory authorities, which apply similar stringent standards for quality, safety and efficacy as those required by WHO.

The prequalification of this product by the WHO Prequalification of Medicines Programme is based on the approval by the EMA (<https://www.ema.europa.eu/en/homepage>) in line with the “WHO Guidelines on submission of documentation for the procedure for prequalification of biotherapeutic product or their corresponding similar biotherapeutic products approved by stringent regulatory authorities.”³

Hence, no assessment of the data underlying this approval has been undertaken within the WHO Prequalification Team: Medicines (PQTm). However, according to the above- mentioned guidelines, WHO requested additional data for the safe use of the product in regions relevant for prequalified products and this information is included in part 6b of this WHOPAR. In order to safeguard product quality throughout its intended shelf-life, WHO assessed the evidences to verify the adherence to the principles outlined in the most recent version of the WHO guidelines on the international packaging and shipping of vaccines⁴, also partially applicable to other biotherapeutic products, to demonstrate suitability of the packaging to regions outside of climatic zone II. WHO assessed the packaging procedures for international shipments, the validation protocols and reports of the shipping boxes used for supply of the prequalified product.

In addition, the adequacy of the procedures for handling quality complaints and recalls with the inclusion of restrictions on distribution or recalls of the product in regions relevant for prequalified products was evaluated by the assessment team.

Furthermore, in accordance with the relevant guidelines³, a WHO prequalification-specific addendum to the Risk Management Plan (RMP) was submitted and assessed by the team of assessors. With this addendum the Applicant outlined their approach to identifying the risks of the product and which measures will be applied to monitor and minimize such risks, taking into consideration potential differences in the health care setting that may change the benefit/risk profile defined within the SRA settings.

Country-specific adaptation and implementation of the RMP as detailed within the PQ- specific addendum to the RMP should be put in place by the Applicant.

¹ Trade names are not prequalified by WHO. This is the national medicines regulatory authority’s responsibility.

² https://extranet.who.int/prequal/sites/default/files/document_files/01_Prequelification_procedure_General.pdf

³ https://extranet.who.int/prequal/sites/default/files/document_files/03_Prequelification_general_AbridgedPathway.pdf

⁴ https://extranet.who.int/prequal/sites/default/files/document_files/WHO_IVB_05.23_eng.pdf

This WHOPAR refers to the information available at the approving stringent regulatory authority in terms of the assessment of the quality, efficacy and safety as well as steps taken after the prequalification.

WHOPAR part		Reference ⁵
Part 1	Summary for the Public	https://www.ema.europa.eu/en/documents/overview/siiltibcy-epar-medicine-overview_en.pdf
Part 3	Patient information Leaflet	https://www.ema.europa.eu/en/documents/product-information/siiltibcy-epar-product-information_en.pdf
Part 4	Summary of Product Characteristics	https://www.ema.europa.eu/en/documents/product-information/siiltibcy-epar-product-information_en.pdf
Part 5	Labelling	https://www.ema.europa.eu/en/documents/product-information/siiltibcy-epar-product-information_en.pdf
Part 6a	EPAR-Scientific Discussion	https://www.ema.europa.eu/en/documents/assessment-report/siiltibcy-epar-public-assessment-report_en.pdf
Part 8	Steps taken after the Authorization	https://www.ema.europa.eu/en/documents/procedural-steps-after/siiltibcy-epar-procedural-steps-taken-scientific-information-after-authorisation_en.pdf

Parts 2, 6b and 7 of the WHOPAR for [BT-DX001 trade name] are included here.

Summary of prequalification status for [BT-DX001 trade name]:

Initial acceptance	Date	Outcome
Status on PQ list	23 Jul 2025	listed
Dossier evaluation		
Verification	17 March 2025	MR
Quality	29 June 2025	MR
Pharmacovigilance	29 June 2025	MR
Inspection Status		
GMP (re-)inspection drug substance		NA
GMP (re-)inspection drug product		NA
GCP/GLP (re-)inspection		NA
API: active pharmaceutical ingredient FPP: finished pharmaceutical product GCP: good clinical practice [quality standard] GLP: good laboratory practice [quality standard] GMP: good manufacturing practice [quality standard] MR: meets requirements MR*: desk review (based on recent inspection reports) NA: not applicable, not available PQ: prequalification		

The table represents the status of relevant completed activities only.

If you require any additional information, please send the request to WHO PQ Team Lead Medicines Assessment.

⁵ <https://www.ema.europa.eu/en/homepage>