I BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company Livzon (Group) Pharmaceutical Factory submitted in 2016 an application for [TB328 trade name][1] (TB328) to be assessed with the aim of including [TB328 trade name] in the list of prequalified medicinal products for the treatment of tuberculosis.

[TB328 trade name] was assessed according to the 'Procedure for Assessing the Acceptability, in Principle, of Pharmaceutical Products for Purchase by United Nations Agencies' by the team of WHO assessors. The assessors are senior experts, mainly from national authorities, invited by WHO to participate in the prequalification assessment process.

Licensing status:

[TB328 trade name] has not been licensed / registered in any country.

2. Steps taken in the evaluation of the product

March 2016	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
May 2016	During the meeting of the assessment team the quality data were reviewed and further information was requested.
August 2016	The applicant's response letter was received.
September 2016	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2016	The applicant's response letter was received.
January 2017	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
March 2017	The manufacturer of the API was inspected for compliance with WHO requirements for GMP.
May 2017	In between the meetings of the assessment team the applicant's response letter was received. The additional quality data were reviewed and further information was requested.
November 2017	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
March 2018	The applicant's response letter was received.
March 2018	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
May and August 2018	In between the meetings of the assessment team the applicant's response letter was received. The additional quality data were reviewed and further information was requested.
October 2018	The applicant's response letter was received.
October 2018	The additional quality data were reviewed and further information was requested.
January 2019	The applicant's response letter was received.
January 2019	The quality data were reviewed and found to comply with the relevant WHO requirements.
January 2019	Product dossier accepted (quality assurance)
06 February 2019	[TB328 trade name][1] was included in the list of prequalified medicinal products.

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

II GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer, Commitments and Inspection status

Manufacturer of the finished product and responsible for batch release:

Livzon (Group) Pharmaceutical Factory
No.38, Chuangye Road North,
Jinwan District, Zhuhai,
Guangdong, 519045, P. R. China

Commitments for Prequalification

None which has an impact on the benefit–risk profile of the medicinal product.

Inspection status

The sites inspected were found to be in compliance with WHO requirements for GMP.
Not inspected for GCP/GLP. No bioequivalence study was required due to the pharmaceutical formulation.

2. (Advice on) Conditions or restrictions regarding supply and use

Medicinal product subject to medical prescription.

Further information is available at:

https://extranet.who.int/prequal/