Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company S Kant Healthcare Ltd. Dr. Annie Besant Road, Worli, Mumbai – 400018, India. submitted in 2024 an application for [TB413 trade name]* (TB413) to be assessed with the aim of including [TB413 trade name] in the list of prequalified medicinal products treatment of peripheral neuropathy induced by tuberculosis medicines.

[TB413 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.

2. Steps taken in the evaluation of the product

September 2020	A desk review for evaluation of compliance of the manufacturer of the API for GMP was conducted and it met WHO requirements.
September 2024	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
September and November 2024	During the meetings of the assessment team the quality data were reviewed and further information was requested.
January 2025	The applicant's response letter was received.
January 2025	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
February 2025	The applicant's response letter was received.
February 2025	The quality data were reviewed and found to comply with the relevant WHO requirements
February 2025	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP.
February 2025	Product dossier accepted (quality assurance)
13 March 2025	[TB413 trade name] was included in the list of prequalified medicinal products.

II. GENERAL CONDITIONS FOR THE PREQUALIFICATION

1. Manufacturer and Inspection status

Manufacturer of the finished product and responsible for batch release

S Kant Healthcare Ltd.
Plot No. 1802-1805, G.I.D.C. Phase III,
Vapi-396 195,
Gujarat, India

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

Inspection status

The FPP site inspected was found to be in compliance with WHO requirements for GMP.

API supported by a CEP. Inspection of the manufacturing site waived based on previous satisfactory inspection by a stringent regulatory authority.

Not inspected for GCP/GLP since a biowaiver applies.

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/medicines/prequalified/finished-pharmaceutical-products