Steps before prequalification

I. BACKGROUND INFORMATION ON THE PROCEDURE

1. Submission of the dossier

The company S Kant Healthcare Ltd, Mumbai, India submitted in 2023 an application for [TB401 trade name][*] (TB401) to be assessed with the aim of including [TB401 trade name] in the list of prequalified medicinal products for the treatment and prevention of isoniazid-induced peripheral neuropathy in patients at risk of the condition.

[TB401 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.
June 2022	The manufacturer of the FPP was inspected for compliance with WHO requirements for GMP. The analytical facilities, relevant for the acceptability of the biowaiver were inspected for compliance with WHO requirements for GMP
March 2023	The safety and efficacy data were reviewed and found to comply with the relevant WHO requirements.
March and April 2023	The quality data were reviewed and further information was requested.
July 2023	The applicant's response letter was received.
July 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
September 2023	The applicant's response letter was received.
September and November 2023	During the meeting of the assessment team the additional quality data were reviewed and further information was requested.
November 2023	The applicant's response letter was received.
November 2023	The quality data were reviewed and found to comply with the relevant WHO requirements.
November 2023	Product dossier accepted (quality assurance)
20 November 2023	[TB401 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

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

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

Inspection status

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

The API site was accepted based on desk assessment.

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