World Health Organization

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Confirmation of WHO Active Pharmaceutical Ingredient Prequalification (CPQ)

Date:	17 February 2025
WHO prequalification number:	WHOAPI-418
Active pharmaceutical ingredient (API):	Isoniazid
API specification number:	FPS/WHOIZ/094 - Version 00
Re-test Period:	60 months
Storage conditions	Do not store above 30°C. Protect from moisture. Protect from light.

API Manufacturers:

Anuh Pharma Ltd
Manufacturing Block NP -1, Blending Room
E-17/3, 17/4 & E-18, M.I.D.C, Tarapur Boisar
Dist. Palghar-401506,
India

API Intermediate manufacturers: *(in addition to the API manufacturers above)*

N/A

This is to confirm that Isoniazid - Temp, manufactured by Anuh Pharma Ltd, has been prequalified by the World Health Organization (WHO). Further information on the API prequalification procedure can be located on the Prequalification Unit - Medicines Assessment web page: **https://extranet.who.int/prequal/medicines**.

API prequalification provides an assurance that the supplied API is of good quality. The comprehensive evaluation procedure has two components: assessment of the API master file (APIMF) to verify compliance with WHO norms and standards, and assessment of the sites of API manufacture to verify compliance with WHO GMP requirements.

The decision to prequalify Isoniazid, manufactured by Anuh Pharma Ltd, is particular to the specific details assessed during evaluation, such as sites of manufacture, method of manufacture, control of the API and retest period.