World Health Organization

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Confirmation of WHO Active Pharmaceutical Ingredient Prequalification (CPQ)

Date:	02 March 2022
WHO prequalification number:	WHOAPI-158
Active pharmaceutical ingredient (API):	Pyrazinamide
API specification number:	STP/WHOPZ/003-02
Re-test Period:	60 months
Storage conditions	Do not store above 30°C, protect from light

API Manufacturers:

Anuh Pharma Limited
E17/3 & 17/4 & E-18 MIDC
Tarapur, Biosar Thane – 401506
Maharashtra,
India

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

Not applicable.

This is to confirm that Pyrazinamide, 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 Team web page: **http://www.who.int/prequal/info_applicants/API_info_applicants.htm**.

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 Pyrazinamide, 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.