World Health Organization

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Confirmation of WHO Active Pharmaceutical Ingredient Prequalification (CPQ)

Date: 10 June 2016

WHO prequalification number: WHOAPI-158

Active pharmaceutical ingredient (API): Pyrazinamide

API specification number: FPS/136-01 version 01

Re-test Period: 60 months

Storage conditions Do not store above 30°C, protect from light

API Manufacturers:

Anuh Pharma. Limited
Manufacturing Block - NP-l
E17/3 & 17/4 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 Team - Medicines Assessment 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.