

## Confirmation of WHO Active Pharmaceutical Ingredient Prequalification (CPQ)

<b>Date:</b>	25 September 2020
<b>WHO prequalification number:</b>	WHOAPI-364a
<b>Active pharmaceutical ingredient (API):</b>	Pyrimethamine
<b>API specification number:</b>	STP/PMT/010-02 (version 02) (non-micronised)
<b>Re-test Period:</b>	36 months
<b>Storage conditions</b>	Do not store above 30°C, protect from moisture, protect from light

### API Manufacturers:

Anuh Pharma Ltd.  
Manufacturing Block: AB-3, AJM - 01, AJM - 02 & Blending Room  
E-17/3 & 17/4 & E-18, M.I.D.C, Tarapur Boisar, Dist.  
Thane-401506  
India

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

Not applicable.

This is to confirm that Pyrimethamine, 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](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 Pyrimethamine, 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.



## Confirmation of WHO Active Pharmaceutical Ingredient Prequalification (CPQ)

**Date:** 25 September 2020

**WHO prequalification number:** WHOAPI-364b

**Active pharmaceutical ingredient (API):** Pyrimethamine

**API specification number:** STP/PMT/011-02 (version 02) (micronised)

**Re-test Period:** 12 months

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

**API Manufacturers:**

Anuh Pharma Ltd.  
E-17/3 & 17/4 & E-18, M.I.D.C, Tarapur Boisar, Dist.  
Thane-401506  
India

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

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This is to confirm that Pyrimethamine, 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:

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The decision to prequalify Pyrimethamine, 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.

The prequalification status of this API and associated details can be verified from the WHO List of Prequalified API web page: [http://www.who.int/prequal/info\\_applicants/API\\_PQ-List.htm](http://www.who.int/prequal/info_applicants/API_PQ-List.htm). They are not detailed in this document as they are subject to change over time.

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