World Health Organization

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Confirmation of WHO Active Pharmaceutical Ingredient Prequalification (CPQ)

Date:	12 July 2017
WHO prequalification number:	WHOAPI-234
Active pharmaceutical ingredient (API):	Sulfadoxine
API specification number:	FPS/130-03, Version 03
Re-test Period:	36 months
Storage conditions	Do not store above 30°C, protect from moisture, protect from light

API Manufacturers:

Anuh Pharma Ltd
Manufacturing Block AB–3
E-17/3&E17/4 M.I.D.C, Boisar
Tarapur, Taluka –Palghar, Dist: Thane-401 506
Maharashtra state
India

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

Not applicable.

This is to confirm that Sulfadoxine, 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 Sulfadoxine, 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.

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