World Health Organization

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In reply please refer to: P5-447-3/IS/AGM/1

Your reference:

Mr Hafizh Darusalam Esas
Technical Operation Director
PT Sanbe Farma
Penicillin Plant
Jl. Leuwigajah No. 162 Cimahi
Indonésie

6 June 2017

Dear Mr Esas,

WHO Prequalification Team – Inspection Services
Closing of Inspection

I refer to the inspection that was performed by Mrs Iveta Streipa and Mr Ian Thrussell, the details of which are outlined below:

Site name:	PT Sanbe Farma
Unit:	II, Penicillin Plant production 2nd floor, secondary packaging 1st floor
Address:	Jl. Leuwigajah No. 162 Cimahi – Indonesia
Date:	20-21 February 2017

Thank you for your email dated 6 June 2017 and the corrective actions to the deficiencies listed in the inspection report. The actions taken, or proposed to be taken, to correct the deficiencies have been reviewed by the Prequalification Inspection Group.

In general, they are considered to be acceptable. Therefore, taking into account these responses, as well as the findings of the inspection, the Prequalification Inspection Group has recommended that the site can be considered to be compliant with the standards of Good Manufacturing Practices (GMP) published by the World Health Organization (WHO) for the scope activities listed below:

- Manufacture, blending / granulation, compression and packaging of solid unit dosage form - beta-lactam tablets.
- Analytical and microbiological testing of drug substance and other raw materials associated intermediates and finished product.

The inspection findings and your response allow us to recommend to the Prequalification Assessment Group that the site inspected may be named to be named as a manufacturing site in the dossier for the following product:

Product	*Dosage Form*	*Strength*
Amoxicillin (Amoxsan® 250)	Tablets	250mg

Please note that acceptance of compliance with WHO GMP does not necessarily mean that the product has been prequalified by WHO.

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Please do not hesitate to send an email to **prequalinspection@who.int** should you require any further information regarding the closing of this inspection.

Yours sincerely,

Mr Mustapha Chafai
Acting Group Lead, Inspection Services
Prequalification Team
Regulation of Medicines and other Health Technologies