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
PT. SANBE FARMA Sterile Preparations Plant
Jl. Industri Cimareme No.8 Block A
Bandung Barat 40553, Bandung
Indonésie

15 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 Sterile Preparations Plant
Unit:	III
Line:	Corima ampoule line
Address:	PT. SANBE FARMA Sterile Preparations Plant Jl. Industri Cimareme No.8 Block A, Bandung Barat – 40553, Bandung – Indonesia
Date:	13-14 February and 16-17 February 2017

Thank you for your email dated 14 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 and packaging of small volume aseptically-processed sterile products.
- 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:

PQT Number	Product	Strength	Dosage Form	Applicant
RH050	Oxytocin	10IU/mL	Solution for injection	PT Sanbe Farma (Corp)

.../...

Please note that acceptance of compliance with WHO GMP does not necessarily mean that the product has been prequalified by WHO. You will be notified of the outcome of the assessment of your prequalification application in due course.

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,

Ms Xingyu Chen
Acting Group Lead, Inspection Services
Prequalification Team
Regulation of Medicines and other Health Technologies