MINISTRY OF HEALTH
PHARMACY AND POISONS BOARD

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Pharmacy & Poisons Board Hse
Along Lenana Road
P. O. Box 27663-00506
NAIROBI

When replying please quote our ref No:

PPB/INS/MAA/RPT/107/19

30th September 2019

To: The Quality Assurance Manager,

RE: MARKET AUTHORIZATION AUDIT CLOSURE

In reference to the audit that was performed on **6th -7th June 2019** by a team of GMP inspectors from the Pharmacy and Poisons Board at **M/s Bharat Serums and Vaccines Limited, Ambernath** at K-27, additional MIDC, Anand Nagar, Ambernath East, Thane 421501, Maharashtra, India, the site is considered **to be compliant** with PPB requirements and Current WHO Good Manufacturing Practice standards for Human dosage forms, categories and activities listed below:

Dosage form	Category	Activity
Sterile Preparations	**General Products:** SVP liquids, Lyophilized powder injectables, Implants	All manufacturing activities

This allows the Directorate of Product Evaluation and Registration to continue the evaluation of the submitted dossiers and accept new product dossiers submitted within the validity period of the site's compliance status.

Please note that acceptance of compliance with WHO GMP does not necessarily mean that any product under registration has been granted marketing authorization. You will be notified of the outcome of the assessment pending your marketing authorization/retention application in due course.

This compliance status shall be deemed to be valid until the **6th day of June 2022** unless it is invalidated under any of the following conditions;

1. The activities and/or categories certified herewith are changed.
2. The site is no longer considered to be in compliance with WHO cGMP.
3. The manufacturing site is changed.

The responsibility for the quality of the individual batches of the Pharmaceutical Products manufactured in this site and marketed in Kenya lie with the manufacturer. PPB reserves the right to inspect the manufacturing site at any time it deems necessary.

Please do not hesitate to send an email to **gmp@pharmacyboardkenya.org** should you require any further information regarding the closing of this inspection and report.

Yours sincerely,

Dr. Jacinta Waslke,
DIRECTOR, INSPECTORATE, SURVEILLANCE AND ENFORCEMENT