Bharat Serums and Vaccines Limited (BSV), Plot No.K-27, Anand Nagar, Additional M.I.D.C, Ambarnath (East) 421 501, India

We would like to express our thanks for the cooperation and hospitality you extended to us during the inspection of your plant on June 08/ 2016.

The purpose of the inspection was to determine the compliance of the manufacturing plant with the principles of Good Manufacturing Practice (GMP) as a complement to market authorization.

The level of occupancy of the company's Human Biological manufacturing facilities and operations with the principle of GMP for pharmaceutical products in general is considered to be acceptable. Accordingly, the authority would like to inform you that your plant is accepted to register its products from the above-mentioned manufacturing lines (Human Biological). Deficiencies which were observed during the inspection time as indicated in the above comments needs to be corrected and reported.

C.C:
+ Entre Impact & Export PLC
+ Addis Ababa
+ Inspection & Licensing Deputy Director General
+ Medicine Facility Inspection Directorate

With Best Regards,

Gezahegn Endale

[Signature]

Addis Ababa

[Stamp]