

የመድኃኒት የጠፍ P 7007 11: ክብካቤ አስተዳደርና ቁጥጥር 91 140 003

FOOD, MEDICINE AND HEALTHCARE **ADMINISTRATION AND CONTROL AUTHORITY OF** ETHIOPIA

Bharat Serums and Vaccines Limited (BSV), Plot No.K-27, Anand Nagar, Additional M.I.D.C, Ambernath (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 06-08/ 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 compliance of the company's Human Biological manufacturing facilities and operations with the principle of CEMP 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 /Elaman Biological/. Deficiencies which were observed during the inspection time as indicated in the attachment needs to be corrected and reported.

CC

+ Euro Import & Export PLC Addis Alaba

4 Inspection and Licensing Deputy Director General

 Modicing Facility Inspection Directorate EFMELACA

With Best Regards,

Gezahegn Endale Medicine Facility Inspection Directorate Director