Report date : yyyy,mm,dd

GMP Inspection Report

To: Chief Executive, Pharmaceuticals and Medical Devices Agency

Principal Inspector
Co-Inspector

1. Reference Number

2. Brief report of the inspection activities undertaken
   (1) Inspection dates
   (2) Name of the manufacturer inspected
   (3) Address of the manufacturer inspected
   (4) Name of the site inspected
   (5) Address of the site inspected
   (6) Category, number and date of Manufacturing License of the site inspected
   (7) Activities carried out by the site
      - Manufacture of Active Ingredient
      - Manufacture of Finished Medicinal Product
      - Manufacture of Intermediate or bulk
      - Subdivision, Packaging, Labeling
      - External Testing Institution
      - Batch Control and Batch release
      - Other ()
   (8) Scope of inspection
   (9) Name, title and contact information of the authorized person in the inspected site
   (10) Results of previous inspection

3. Content of Inspection
   (1) Purpose of inspection
   (2) Kind of inspection【Compliance inspection【On-site・Desktop】・Exploratory Inspection 】

(3) Details on inspection

A) Description of the site and the products inspected
B) Quality System
C) Equipment and facilities system
D) Products and Materials Holding System
E) Manufacturing System
F) Packaging and Labeling System
G) Laboratory Control System
H) Conformity with the Standard for Biological Ingredients
I) Discrepancy between NDA file and MF for API

4. reference information

5. Observations and Corrective actions

Issue date of observation:

Receipt date of corrective action plan/report:

Contents

(1) Critical deficiency
(2) Major deficiency
(3) Other deficiency

6. Synthetic judgment : yyyy,mm,dd

End