Organization and Main Tasks

Planning and Coordination Division

Planning and Organization Section

Unit for Planning and Organization Planning and coordination of assay task and test products of veterinary medicinal products (VMPs)

Unit for Technical Coordination....Collecting data and technical training of assays on VMPs

Evaluation and Organization Section

Unit for Biological Products....Technical review of application for manufacturing/marketing approval and application for registering drug substances of biological products

Unit for General Drugs....Technical review of application for manufacturing/marketing approval and application for registering drug substances of (VMPs) (excluding biological products and antibiotics)

Unit for Antimicrobial Products....Technical review of application for manufacturing/marketing approval and application for registering drug substances of antimicrobial products

Technical Guidance Section

Unit for Technical Review....Reevaluation and equivalence tests on VMPs
Unit for Research and Guidance....Research based on various criteria and submission of clinical studies on VMPs

Quality Assurance Section

Unit for Quality Assurance....Evaluation of assay results of VMPs **Unit for Management of Reference Standards**....Evaluation of assay results of reference standards on VMPs, assays of VMPs and inspection of biosafety

Senior Officer for VMPs Investigation

....Review of technical matters on assays of VMPs

Senior Officer for Veterinary Medical Devices Investigation

.... Review of technical matters for inspections of medical devices

Senior Officer for VMPs

.... Collection/organization of data of reevaluation/international assay criteria for veterinary drugs

Senior Officer for Biosafety

.... Planning and organization of technical matters on biosafety

Organization and Main Tasks

Administration Division

Unit for Administration
Unit for Personnel Affairs

Unit for Management/Welfare

Administration, manager for personnel affairs and management/welfare in general

Accounts Division

Unit for Budgets and Accounts

Unit for Accounting Unit for Supplies

Unit for National Property

Budgets, accounts and management of the government buildings

Assay Division I

(Staff)

Section Leader Senior Researcher

Chief Researcher Chief Inspector

Inspector Skilled staff (Sections and Main tasks)

- (i) Viral Assay Section I
- Assays of virus formulations for mammals
- (ii) Viral Assay Section II
- Assays of virus formulations for chickens
- (iii) Bacterial Assay Section
- Assays of bacteria formulations
- (iv) Immunology and Pathological Assay Section
- Overall management of pathological assays and standard references for assays of biological products and Regenerative, Cellular therapy and Gene therapy products

Assay Division II

(Staff)

Section Leader Senior Researcher

Chief Researcher Chief Inspector

Inspector Skilled staff (Sections and Main tasks)

- (i) Quality Assay Section
- Quality assays of VMPs
- (ii) Safety Test Section I

.... Biological safety tests, assays for drug-resistant microbial strains and management of reference standards for assays of antibiotics and strains

- (iii) Safety Test Section II
- Assays for residues of VMPs