INSPECTION AGENDA – EXTERNAL HOUSEHOLD REMEDY/EXTERNAL OTC

Inspection Activity
Opening Meeting ● Introduction from FDA Lead Inspector ● Discussion of Scope, Inspection Agenda and GMP Standard ● Timetable of activities ● Attendance Sheet ● Company Introduction and Overview **Design and Lay-out Review prior to Site Inspection** ● (Warehouse, Production Areas, Utilities, Quality Control Laboratory) **Site Inspection** ● Warehouse (Starting Materials and Finished Goods) ○ Receipt ○ Sampling ○ Storage area (quarantine, approved, reject, cold room) ○ Storage condition (temperature, humidity) ○ Approval for use / release to production ○ Dispatch ● Production Facilities ○ Building Maintenance and Structure ○ Dispensing ○ Gowning Areas / Changing Rooms ○ Bulk Manufacture (including in-process controls) ○ Cross contamination prevention measures ○ Equipment (status: cleaning, maintenance, calibration) ● Packaging Operations

- Control of labels and pre-printed packaging materials/ prevention of mix-up
- Line Clearance
- Coding
- Reconciliation
- Storage of finished goods

- Utilities and Engineering Services
- Air Handling Units (where applicable)
  - Design and Structure
  - Operation and Maintenance
  - Monitoring and testing
- Water System (where applicable)
  - Design and Structure
  - Operation and Maintenance
  - Monitoring and Testing
- Pest Control and Waste Disposal

- Quality Control Laboratory
  - Laboratory Design
  - Laboratory Staff Training and Assessment
  - Handling of QC Samples
  - Specifications and Testing Procedures including results
    - Raw material, packaging materials and finished product
  - Instrumentation Room (status: calibration, maintenance, logbooks)
  - Stability Program
  - Handling of Out-of-Specifications
  - Retention Samples
  - Micro laboratory (where applicable)
    - Media Preparation and controls
    - Reference Cultures
    - Testing (Products, Environmental Monitoring, Water)

- LAF or BSC (calibration and maintenance)

- **Documentation**
  - Pharmaceutical Quality System
    - Quality Risk Management
    - CAPA
    - Supplier Qualification
    - Product Dossier
    - Batch Release Procedure
  - Personnel
    - Organizational Chart
    - Job Description
    - Training and Assessment
    - Personnel Hygiene
    - Health Examination
  - Qualification and Validation
    - Process verification
  - Batch Manufacturing Records
    - BMR Review
    - Release for supply

- **Other Relevant Documents**
  - Product Complaint and Recall
  - Outsourced Activities
  - Self-Inspection

Report Writing
Discussion of audit findings