Australian Government
Department of Health
Therapeutic Goods Administration

Manufacturing
Quality
Branch

Inspection Plan – Medicines & APIs

Manufacturer name: **Manufacturer address:** **Inspection type:** **Inspection date/s:** **Inspector/s:** **Inspection standard:**	PIC/S Guide to GMP for Medicinal Products PE009 (2018) - Part I or Part II + applicable Annexes

Time	Inspector	Activity / element
Day 1:		
9:00-9:30		**Opening meeting** ❒ Introductions ❒ TGA updates ❒ Inspection Standard ❒ Inspection plan ❒ Review Application ❒ Complaint/Feedback process ❒ Buildings in scope of Inspection ❒ Attendance record ❒ Inspection Process ❒ Inspection scope ❒ Breaks and use of facilities ❒ Recent changes. Proposed changes. ❒ A3 Maps/Drawings/Batch records ❒ Weekly Production Schedule ❒ Company overview - description of manufacturing and product range
Pharmaceutical Quality System		
		❒ Review of effectiveness of CAPA actions from previous inspection ❒ Product Quality Reviews ❒ Change control ❒ Complaints ❒ Document control ❒ Batch Release Process ❒ Approved Supplier Program ❒ Outsourced Activities ❒ Recall activities ❒ Deviation/NCR/CAPA ❒ Internal Audits ❒ Quality Risk Management ❒ Management Reviews ❒ Supplier Audits ❒ Quality Manual
		Personnel ❒ Organisation chart ❒ Job description for key personnel ❒ Training and assessment ❒ Consultants

Time	Inspector	Activity / element
		Materials Control
		❒ GMP Contract agreements ❒ Control of storage areas ❒ Temperature/humidity monitoring ❒ Cold Chain/DG's/Flammables/Freezers ❒ Status Control-Identification/Traceability ❒ Raw Materials/Bulk Materials ❒ Rejects Control ❒ Cleaning/Housekeeping ❒ Waste Disposal ❒ Dispatch/Handling/Traceability ❒ Supplier Evaluation ❒ Inventory Management System ❒ Finished Goods ❒ Returned goods ❒ Retention/Reference Samples **Starting Materials** ❒Receipt, Quarantine/Inspection/Testing ❒Control of utensils ❒Approval for use ❒Picking/Dispensing ❒Control of pre-printed packaging ❒ Sampling area/Plans ❒ Retention Samples ❒ Cleaning/Housekeeping ❒ Control of Components ❒ Sampling/Approval of packaging/components
17.00		**Optional daily debrief**
Day 2:		
		Production System
9:00		**Dispensing Areas** ❒ Materials Flow ❒ Room grading ❒ Control of utensils ❒ Cleaning/Housekeeping ❒ Gowning/Access ❒ Equipment logs ❒ Retention Samples ❒ Containment/Contamination control **Production - Formulation Areas** ❒ Materials Flow ❒ Room grading ❒ Water supply ❒ Preparation of solutions ❒ Bulk storage/monitoring ❒ IPQC testing ❒ Transfer of Bulk solutions to filling ❒ Gowning/Access ❒ Equipment logs ❒ Equipment CIP/SIP ❒ Mixing/Blending ❒ Environmental Monitoring ❒ Batch record formats/entries **Production - Manufacture/Filling** ❒ Process flow ❒ Batch record formats/entries ❒ Temp/Humidity/Pressure differentials ❒ Area condition/finishes ❒ Transfer airlocks/procedures ❒ Filling Equipment set-up/area ❒ Filling operations ❒ In-process checks/sampling ❒ Process Validation ❒ Dress codes/gowning areas/personal hygiene ❒ Cleaning procedures/records ❒ Contamination control – air/layout ❒ Equipment CIP/SIP ❒ Environmental Monitoring **Dosage Form Specific:** **Production – Labelling/Secondary Packaging** ❒ Process flow ❒ Batch record formats/entries ❒ Temp/Humidity/Pressure differentials ❒ Area condition/finishes ❒ Labelling/Coding ❒ Reconciliation of components ❒ Check weighers/VISY ❒ Dress codes/gowning areas/personal hygiene ❒ Cleaning procedures/records ❒ Room grading ❒ Packaging Equipment ❒ IPQC checks & records ❒ Line clearance ❒ Rejected units

Time	Inspector	Activity / element
		❒ Return of unused components ❒ Batch & Product displayed **IPC Laboratory** ❒ Equipment calibrated/maintained ❒ Procedures/Records ❒ Completion of Batch records ❒ Cleaning procedures/records ❒ Contamination control – air/layout
		Facilities and Equipment
		Utilities and services ❒ Preventive Maintenance ❒ Calibration ❒ Pest Control ❒ Waste Disposal
		HVAC ❒ Area Classifications ❒ P&ID's ❒ Specifications/Design/Construction ❒ Filtration supply/return/exhaust ❒ Pressures/Containment strategy ❒ Room certification/airflow visualisation ❒ Monitoring/Control/Testing/Trends ❒ Handling of alarms and trending ❒ Operation/Checks/Cleaning ❒ Validation system/BMS/Alarms ❒ Power failure ❒ Equipment calibration and maintenance
		Water Systems ❒ Use ❒ P&ID's ❒ Specifications/Design/Construction ❒ Sanitisation ❒ Monitoring/Control/Testing/Trends ❒ Operation/Checks/Cleaning ❒ Validation ❒ Equipment calibration and maintenance
		Compressed air/gasses/vacuum (Natural Gas/O_2/N_2) ❒ Use (N_2 overlay, burners) ❒ P&ID's ❒ Specifications/Design/Construction ❒ Sterilisation/Sanitisation ❒ Monitoring/Control/Testing ❒ Operation/Checks/Cleaning ❒ Validation ❒ Equipment calibration and maintenance
		Validation/Qualification
		Validation: ❒ VMP (Schedule) ❒ Document formats ❒ Equipment List ❒ Revalidation ❒ Equipment Qualification ❒ Operator Qualification ❒ Facility cleaning validation ❒ Cleaning Validation/HBEL ❒ Computerised systems ❒ Temperature controlled areas ❒ Process validation and ongoing process verification ❒ Transportation
17.00		**Optional daily debrief**
Day 3:		
		Quality Control
9.00		**Chemistry Laboratory** ❒ Sample Preparation/Dispatch ❒ Stability ❒ Specifications and test methods ❒ Testing as per specification ❒ Test results (raw data) ❒ Method validation ❒ Reference standards ❒ Reagents/Volumetric Solutions ❒ Reference/retention samples ❒ Instruments/Equipment ❒ Equipment calibration/maintenance ❒ Equipment Qualification ❒ System suitability ❒ Water testing ❒ Personnel training

Time	Inspector	Activity / element
		❒ Contract testing ❒ Certificates of Analysis ❒ *Sub-vis Particulate Testing* ❒ OOS/OOT Procedures ❒ Release of results ❒ DI
		Microbiology Laboratory ❒ Sample Preparation/Dispatch ❒ Culture collection ❒ Specifications and test methods ❒ Test results (raw data/computerised systems) ❒ Equipment Qualification ❒ OOS/OOT Procedures ❒ Water testing ❒ Bioburden analysis ❒ DI ❒ Sample Preparation/Dispatch ❒ Contract testing ❒ Certificates of Analysis ❒ Media Preparation/QC ❒ Test methods ❒ Method validation ❒ Equipment calibration/maintenance ❒ EM/PM (viables/non-viables) ❒ Antibiotic assays ❒ Incubator monitoring/mapping ❒ Personnel training ❒ Release of results
		Batch Record Review and Batch Release ❒ Line clearance ❒ Reconciliation ❒ Environmental monitoring ❒ Batch Release SOP ❒ Marketing Auth/Regulatory compliance ❒Traceability of materials ❒ Completeness/accuracy ❒ IPQC results ❒ Transport ❒ PQR/Ongoing Stability/RFFP documents
15.30		**Prepare for closing meeting**
16.00		**Closing meeting**
17.00		**Depart site**

The times indicated are for guidance only and can be modified to suit.