PERFORMANCE QUALIFICATION PROTOCOL FOR METAL DETECTOR

EQUIPMENT ID No.	
LOCATION	**Compression**
DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	**NIL**

 PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR METAL DETECTOR	PROTOCOL No.:

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 PHARMA DEVILS	PERFORMANCE QUALIFICATION PROTOCOL FOR METAL DETECTOR	PROTOCOL No.:

1.0 PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			
HEAD (QUALITY CONTROL)			
HEAD (ENGINEERING)			

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

2.0 OBJECTIVE:

- To provide documented evidence that the Equipment is performing consistently, repeatedly and reproducibly within its established operating range and the results of all the test parameters meet the pre-defined acceptance criteria.
- To confirm the suitability of the Standard Operating Procedures for all routine activities associated with the system.

3.0 SCOPE:

- The Protocol covers all aspects of Performance Qualification for the **Metal Detector** (**Make: ……)** installed in the Compression.
- The Metal Detector is a standalone unit with plug in type electrical connections for operation and is on castor wheel. Hence, may be moved as per requirement to other area of operation which shall not change the performance of equipment.
- This Protocol will define the methods and documentation used to qualify the Metal Detector for PQ.

4.0 RESPONSIBILITY:

The Validation Group, comprising of a representative from each of the following departments, shall be responsible for the overall compliance of this Protocol cum Report:

DEPARTMENTS	RESPONSIBILITIES
Quality Assurance	• Preparation, Authorization, Approval and Compilation of the Performance Qualification. • Co-ordination with Quality Control, Production and Engineering to carryout Performance Qualification Activity. • Monitoring of Performance Qualification.
Production	• Review of Protocol. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Review of Protocol.
Engineering	• Reviewing of qualification protocol for correctness, completeness and technical excellence • Responsible for trouble shooting (if occurred during execution). • Maintenance & preventive maintenance as per schedule.

5.0 EQUIPMENT DETAILS:

Equipment Name	Metal Detector
Equipment	…….
Manufacturer's Name	Unique Equipment Metal Detection System.
Model	
Sr. No.	
Supplier's Name	Unique Equipment Metal Detection System.
Location of Installation	Compression

6.0 SYSTEM DESCRIPTION:

Metal Detector detects unwanted or stray metal in moving bulk material, sheet or web material, or package or bagged material. They can also be used to detect the presence of metal item, which is intended to be in a non metallic package.

Metal Detector is installed around a conveyor or chute so that material or packages to be inspected will pass through the detector aperture. The detector creates a high frequency electromagnetic field through which all conveyed material and packages must pass. Presences of foreign metallic particles cause a reaction in this field.

The Search Coil consists of three coils surrounding the aperture. The centrally placed Transmitter Coil is driven by a powerful oscillator to generate a strong magnetic field. Spaced equally on each side of the transmitter is the Receiver Coils. These receiver coils acts as aerials, which collect the signal from the transmitter, producing a voltage across each coil. Without product or metal contamination passing through the aperture the voltage in each coil will be equal, because of the equal from the transmitter coil and with the introduction of a piece of metal into the aperture causes the induced voltages to be unequal. The coils are connected in such a manner that the signals are subtracted from one another to give a value of zero at their output. At this junction the system is said to be balanced.

Any conducting object moving through the aperture will interact with the generated magnetic field, so producing different voltages from each of the coils. The objects produce this effect as it alters the coupling between each receiver and the transmitter in turn as it passes through the aperture. Subtracting these voltages will no longer give an output of zero.

The reactor senses this reaction and the signal is amplified and processed further to actuate the relay contracts. The output may be used to stop a conveyor, sound an alarm, and actuate a marking or any other device or combination of devices.

7.0 REASON FOR QUALIFICATION:

- New equipment in Compression.
- After completion of the Operation Qualification of the Equipments, it is imperative to perform the Performance Qualification. The study will establish that the parameters are followed, critical variables are under control and the quality of the output is, as desired.

8.0 SITE OF STUDY:

- Compression.

9.0 FREQUENCY OF QUALIFICATION:

- Once in every two years time period.
- After any major breakdown or after major modification.
- After Change of Location.

10.0 PRE - QUALIFICATION REQUIREMENTS:

The below mentioned activities should be completed prior to commencing the performance qualification activity:

- Design Qualification.
- Installation Qualification.
- Operational Qualification.
- Calibration of all Critical Components of Equipment.
- Preparation of SOP for Operation & Cleaning of Metal Detector.
- Preparation of SOP for Preventive Maintenance of Metal Detector.

11.0 TESTS AND CHECKS:

11.1 Verification of Documents:

Verification for availability, completeness and approval status of all the required relevant documents shall be done and observations shall be recorded in the performance qualification report.

- Executed and approved Design Qualification document.
- Executed and approved Installation Qualification document.
- Executed and approved Operational Qualification document.
- SOP for Operation & Cleaning of Metal Detector.
- SOP for Preventive Maintenance Metal Detector.

Procedure:

- Verify the above mentioned documents for availability, completeness and approval status.
- If any deviation is observed the same has to be recorded giving reasons for deviation and approved.
- Supporting documents would form a part of the PQ Report.

Acceptance Criteria:

All the documents should be available, complete and approved by respective authorities.

11.2 To Confirms the Flap Operation of Metal Detector

Procedure:

- Switch ON the Metal Detector.
- The Metal Detector will be in initializing mode for a period of 10 Seconds.
- After Initialization, in stabilized state, there should be NULL indication on the Bar Graph. The display will show for the Product Code, Sensitivity and Counts.
- Pass the different samples through the Metal Detector and monitor the deflection of bar graph for any product signals. (Signals Generated by the products).
- The Product Signals can be reduced for some extent by adjusting the Phase Control. For this adjust the Phase Control settings in such a way that the bar graph should comparatively less signals to the products.
- Adjust the sensitivity level by setting the sensitivity control in such a way that the samples of Ferrous, Non Ferrous and Stainless Steel metals are detected and rejected by the metal detector.
- Note down the sensitivity level individually for different test samples one by one where the same is detected and rejected.
- Note down the sensitivity for different samples of products with test pieces and the results.

Acceptance Criteria:

- All the Product samples should be passed through the aperture.
- Ferrous, Non Ferrous and Stainless Steel metal samples should be reject when they pass through the aperture of Metal Detector.
- The Metal Detector Flap should not operate if only the product is passed through the aperture.

12.0 CHECKLIST OF ALL TESTS AND CHECKS:

A checklist shall be provided to ensure that all tests or checks required for this protocol have been executed. After execution observations shall be recorded in Performance Qualification Report.

The list includes:

- Verification of DQ, IQ & OQ & other documents.
- Verification of Performance using Drug Product.

13.0 REFERENCES:

The Principle Reference is the following:

- Validation Master Plan.
- Schedule-M – "Good Manufacturing Practices and Requirements of Premises, Plant and Equipment for Pharmaceutical Products."
- WHO Essential Drugs and Medicines Policy, QA of Pharmaceuticals, Vol-2 – Good Manufacturing Practices and Inspection.

The following references are used to give addition guidance:

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition /March 2001.
- EU Guide to Good Manufacturing Practice, Part 4, 1997.
- European Commission's working party on control of medicines and inspections document, Validation Master Plan, Design Qualification, Installation & Operational Qualification, Non Sterile Process Validation, Cleaning Validation, October 1999.

14.0 DOCUMENTS TO BE ATTACHED:

- Calibration Certificate.

15.0 NON COMPLIANCE:

- In case of any deviation observed during PQ, inform to Head QA for necessary action.
- Document the deviation detail in observed deviation section.
- The Head QA shall study the impact of deviation. If deviation is acceptable and it does not have an impact on operation as well as on performance of the machine, prepare final conclusion.

16.0 ABBREVIATIONS:

Sr.	:	Senior
Asst.	:	Assistant
No.	:	Number
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
cGMP	:	Current Good Manufacturing Practices
EU	:	European Union
QA	:	Quality Assurance
IQ	:	Installation Qualification
mm	:	Millimetre
Amp.	:	Ampere