INSTALLATION QUALIFICATION

PROTOCOL CUM REPORT

FOR

METAL DETECTOR

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

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR METAL DETECTOR	PROTOCOL No.:

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1.0 PRE – APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR METAL DETECTOR	PROTOCOL No.:

2.0 OBJECTIVE:

- To provide documented evidence for the Installation Qualification of Metal Detector.
- To confirm that the equipment and its components are installed as per the Specifications mentioned in the design qualification document and other requirements given by supplier.

3.0 SCOPE:

- . The scope of this installation qualification protocol cum report is limited to qualification of **Metal Detector** to be 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 document provides all the relevant information related to specification, installation checks and acceptance criteria to be required to perform installation qualification activity of Metal Detector.

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, Review, Approval and Compilation of the Installation Qualification Protocol cum Report. • Co-ordination with Production and Engineering to carryout Installation Qualification. • Monitoring of Installation Qualification Activity. • Post approval of Installation Qualification Protocol cum Report after execution.
Production	• Review & Pre Approval of Installation Qualification Protocol cum Report. • To Co-ordinate and support for Execution of Installation Qualification study as per Protocol cum Report. • Post Approval of Installation Qualification Protocol cum Report after Execution.
Engineering	• Review & Pre Approval of Installation Qualification Protocol cum Report. • Co-ordination, Execution and technical support in Metal Detector Installation Qualification Activity. • Calibration of Process Instruments. • Responsible for Trouble Shooting (if occurs during execution). • Post Approval of Installation Qualification Protocol cum Report after Execution.

5.0 EQUIPMENT DETAILS:

Equipment Name	Metal Detector
Equipment	
Manufacturer's Name	Unique Equipment Metal Detection System.
Model No.	Digitech-75
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 PRE – QUALIFICATION REQUIREMENTS:

7.1 Verification of Documents:

- Executed and approved Design Qualification Document.
- Piping and Instrumentation Diagram (P & ID).
- Electrical Circuits Diagram.
- Technical Specification of Equipment.
- Calibration Certificate of Components.
- Certificate of Material of Construction of Components.

7.1.1 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. Deviation should be approved by Authorized person.
- Approved Drawings and supporting documents would form a part of the IQ Protocol cum Report.

7.1.2 Acceptance Criteria:

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

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8.0 CRITICAL VARIABLES TO BE MET:

8.1 General Checks and Location Suitability:

Installation Checks	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
Mounting of Equipment	Should Be Properly Mounted		
Leveling	Should be properly balanced and leveled		
Edges of parts	Metal parts should be properly grind without any sharp edges		
Welding of Joints	Welding of joints should be without any welding burrs		
Place of Installation	Compression		
Room Condition	Temp. - NMT 25°C RH - NMT 55%		
Illumination in area	NLT 300 Lux.		
Working space around the equipment	Should be sufficient for easy operation, cleaning, sanitation and maintenance		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……..……

8.2 Utilities Required:

Parameters	Acceptance Criteria	Observation	Observed By (Engineering) (Sign/Date)
Electricity	230 V AC, 1 PH, 50 Hz.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

PHARMA DEVILS	INSTALLATION QUALIFICATION PROTOCOL CUM REPORT FOR METAL DETECTOR	PROTOCOL No.:

8.3 Installation Checks:

S.No.	Specification	Observation	Observed By (Engineering) (Sign/Date)
1.	Check the Proper mechanical installation of Metal detector.		
2.	All the contact parts are Cleaned.		
3.	Check the proper electrical installation of Metal detector.		
4.	To Check that equipment is balanced.		
5.	Check the equipment is free from any defects.		
6.	Check the finishing of product contact parts.		
7.	Check that major components are protected from shock and there is no physical damage.		
8.	Equipment Identification name plate is visible		
9.	Check that all piping and electrical connection have been done according to the drawing.		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

8.4 Safety:

Checks	Acceptance Criteria	Observation	Observed By Engineering (Sign/Date)
Well embedded equipment	For cGMP site layout		
Electrical connection	Electrical should be as per approved drawings.		
Base plate of Machine	Should be perfectly horizontal		
Control Panel	Should be in apprised position		
Earthing	Properly earthing should be given to function		

Checked By
(Production)
Sign/Date: ……

Verified By
(Quality Assurance)
Sign/Date: ……

Inference:

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Reviewed By
(Manager QA)
Sign/Date: ……

9.0 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 for addition guidance:

- FDA/ISPE Baseline Pharmaceutical Engineering Guide-Volume 5:- Commissioning and Qualification Guide, First Edition / March 2001.
- Code of Federal Regulations (CFR), Title 21, Part 210, Current Good Manufacturing Practice (cGMP) in Manufacturing, Processing, Packing, or Holding of Drugs, Beta. April 1, 1998.
- Code of Federal Regulations (CFR), Title 21, Part 211, Current Good Manufacturing Practice (cGMP)
- 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.
- GMP Guide, Validation of Automated Systems in Pharmaceutical Manufacture, Version 4.0, December 2001.

10.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Certificate of MOC.
- Calibration certificates.
- Operation and Maintenance Manual.

11.0 DEVIATION FROM PREDEFINED SPECIFICATION IF, ANY:

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12.0 CHANGE CONTROL, IF ANY:

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13.0 REVIEW (INCLUSIVE OF FOLLOW UP ACTION, IF ANY):

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14.0 CONCLUSION:

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15.0 RECOMMENDATION:

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16.0 ABBREVIATIONS:

cGMP	:	current Good Manufacturing Practices
WHO	:	World Health Organization
FDA	:	Food and Drug Administration
CFR	:	Code of Federal Regulations
Kg	:	Kilogram
mm	:	Millimeter
AC	:	Alternating Current
NMT	:	Not More Than
RH	:	Relative Humidity
SS	:	Stainless Steel
MOC	:	Material of Construction
No.	:	Number
EU	:	European Union
QA	:	Quality Assurance
IQ	:	Installation Qualification
DQ	:	Design Qualification

17.0 POST APPROVAL:

INITIATED BY:

DESIGNATION	NAME	SIGNATURE	DATE
OFFICER/EXECUTIVE (QUALITY ASSURANCE)			

REVIEWED BY:

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

APPROVED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			