



**OPERATIONAL QUALIFICATION  
PROTOCOL CUM REPORT  
FOR  
METAL DETECTOR**

<b>EQUIPMENT ID No.</b>	
<b>LOCATION</b>	<b>Compression</b>
<b>DATE OF QUALIFICATION</b>	
<b>SUPERSEDES PROTOCOL No.</b>	<b>NIL</b>



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR METAL DETECTOR**

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# PHARMA DEVILS

QUALITY ASSURANCE DEPARTMENT

## OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR METAL DETECTOR

### 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)			



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR METAL DETECTOR**

**2.0 OBJECTIVE:**

- To verify that the equipment operates in accordance with the design and user requirements as defined by set Acceptance Criteria and complies with relevant cGMP Requirements.
- To verify the Operational features of Metal Detector and to ensure that it produces desired Quality & rated output according to manufactures specifications.
- To verify all the Operational features from user point of view of the Equipment, Cleaning Procedure, Start up & Shut down Procedure and Safety Features.

**3.0 SCOPE:**

- The scope of this operational qualification protocol cum report is limited to qualification of Metal Detector to be installed.
- 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 perform OQ activity the Metal Detector for OQ. Successful completion of this Protocol will verify that Metal Detector meet all acceptance criteria and ready for Performance Qualification.



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**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:

<b>DEPARTMENTS</b>	<b>RESPONSIBILITIES</b>
<b>Quality Assurance</b>	<ul style="list-style-type: none"><li>• Preparation, Review, Approval and compilation of the Operational Qualification Protocol cum Report.</li><li>• Co-ordination with Production and Engineering to carryout Operational Qualification Activity.</li><li>• Monitoring of Operation Process.</li><li>• Post approval of Operational Qualification Protocol cum Report after Execution.</li></ul>
<b>Production</b>	<ul style="list-style-type: none"><li>• Review of Operational Qualification Protocol cum Report.</li><li>• To Co-ordinate and support for execution of Operational Qualification Study as per Protocol cum Report.</li><li>• Post Approval of Operational Qualification Protocol cum Report after Execution.</li></ul>
<b>Engineering</b>	<ul style="list-style-type: none"><li>• Review &amp; Pre Approval of Operational Qualification Protocol cum Report.</li><li>• Co-ordination, Execution and technical support in Operational Qualification Activity.</li><li>• Calibration of Process Instruments.</li><li>• Responsible for Trouble Shooting (if occurs during execution).</li><li>• Post Approval of Operational Qualification Protocol cum Report after Execution.</li></ul>



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR METAL DETECTOR**

**5.0 EQUIPMENT DETAILS:**

<b>Equipment Name</b>	Metal Detector
<b>Equipment</b>	
<b>Manufacturer's Name</b>	Unique Equipment Metal Detection System.
<b>Model No.</b>	
<b>Sr. No.</b>	
<b>Supplier's Name</b>	Unique Equipment Metal Detection System.
<b>Location of Installation</b>	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.



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR METAL DETECTOR**

**7.0 PRE – QUALIFICATION REQUIREMENTS:**

**7.1 Verification of Documents:**

- DQ Protocol cum Report.
- IQ Protocol cum Report.
- Draft SOP for Operation & Cleaning of Metal Detector.
- Draft SOP for Preventive Maintenance of Metal Detector.
- Electrical Circuits Diagram.
- Technical specification of equipment.

**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 OQ Protocol cum Report.

**7.1.2 Acceptance Criteria:**

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



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR METAL DETECTOR**

**8.0 CRITICAL VARIABLES TO BE MET:**

**8.1 Verification of documents:**

The results of any tests should meet the limits and acceptance criteria specified in the test documents.  
Any deviations or issues should be rectified and documented prior to OQ commencing.

S.No.	Document Name	Document / SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (Quality Assurance Officer/ Exe.) Sign/Date
1.	DQ Protocol Cum Report				
2.	IQ Protocol Cum Report				
3.	Draft SOP for operation & Cleaning of Metal Detector				
4.	Draft SOP for Preventive Maintenance of Metal Detector				

**Checked By (Production)**  
Sign/Date: .....

**Verified By (Quality Assurance)**  
Sign/Date: .....

**Inference:**

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





**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR METAL DETECTOR**

**8.2 Operational and Functional Checks:**

Operate the Metal Detector as per Manufacturer's Manual / SOP and Check for the following functions of the Equipment. The Equipment should function as desired.

Item	Acceptance criteria	Observation	Observed by (Engineering) (sign/date)
<b>ON the Main Power Switch</b>	Main power supply Should be indicate the in the metal detector.		
<b>Metal Detect</b>	Metal piece should be detected with in sensitivity range.		
<b>Metal Reject</b>	Should be indicating the rejection of the detected metal contamination by the aperture.		
<b>Rejection Error</b>	Should be glows when the detect and reject count does not match each other.		
<b>Phase Control</b>	Should be cause due to false triggering of the unit.		
<b>Electrical Loop</b>	Small electric current Should be create in the coil system		
<b>Flap operation</b>	Should be operated when ferrous, Non ferrous and Stainless Steel metals are through the aperture of the metal dedicator.		

**Checked By (Production)**  
**Sign/Date:** .....

**Verified By (Quality Assurance)**  
**Sign/Date:** .....

**Inference:**

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



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR METAL DETECTOR**

**8.1 Safety Testing/Interlocking:**

Safety checks	Acceptance criteria	Observation	Observed by (engineering) (sign/date)
Press 'OFF' Switch	Metal Detector Should be OFF.		
Body earth	Body earth connection fitted properly		
Electrical Wiring and Earthing	Must be inside the machine		
Motor Overload Relay or any short circuit	MCB should be trip if overloaded & Any short circuit		
Noise Level	Below 80 db		

**Checked By**  
**(Production)**  
**Sign/Date:** .....

**Verified By**  
**(Quality Assurance)**  
**Sign/Date:** .....

**Inference:**

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



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR METAL DETECTOR**

**8.2 Power Failure Verification:**

<b>Power failure checks</b>	<b>Acceptance criteria</b>	<b>Observation</b>	<b>Observed by (engineering) (sign/date)</b>
<b>Main Power Shut Down</b>	Equipment should be stopped in a safe and secure condition.		
<b>Restore electrical power to the system</b>	The system should not be automatically restart whenever start through PLC.		

**Checked By (Production)**  
**Sign/Date:** .....

**Verified By (Quality Assurance)**  
**Sign/Date:** .....

**Inference:**

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



## OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR METAL DETECTOR

### 8.3 Operation Test:

**Purpose:** To confirm the flap operation of Metal Detector.

**Procedure:**

- Switch ON the Metal Detector.
- In stabilized state, there should be NULL indication on the Bar Graph.
- Pass the different samples through the Metal Detector and monitor the deflection of bar graph for any product signals. (Signals Generated by the products) and note down the result.
- Confirm the Operation of solenoid valve by passing only the products and note down the result
- Confirm the operation of solenoid valve by passing both the product and the test samples and note down the result.

**Acceptance Criteria:**

- The flap should be in non operating mode if only the product is passed.
- The Flap should be operated when ferrous, Non ferrous and Stainless Steel metal are passed through the aperture of metal detector.

S. no.	Test Checks	Acceptance Criteria	Results
1.	<b>For Reject Timer (On delay)</b>	During operation of the machine, the reject timer shall be set at 40.	
2.	<b>For Reject Timer (Off delay)</b>	During operation of the machine, the reject timer shall be set at 40.	
3.	<b>For Sensitivity Level</b>	During operation of the machine, the sensitivity level shall be adjusted at 100.	
4.	<b>For Phase Level</b>	During operation of the machine, the Phase level shall be adjusted at 14.	



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR METAL DETECTOR**

**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 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.

**10.0 DOCUMENTS TO BE ATTACHED:**

- Operation And Maintenance Manual
- Copy of Draft SOP’s
- Any other Relevant Documents



**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR METAL DETECTOR**

**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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**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR METAL DETECTOR**

**14.0 CONCLUSION:**

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**15.0 RECOMMENDATION:**

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**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR METAL DETECTOR**

**16.0 ABBREVIATIONS:**

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
OQ	:	Operational Qualification
Pvt.	:	Private
Ltd.	:	Limited
SOP	:	Standard Operating Procedure
QA	:	Quality Assurance
mm	:	Millimeter
Hz	:	Hertz
V	:	Volt
No.	:	Number





**OPERATIONAL QUALIFICATION PROTOCOL CUM REPORT FOR METAL DETECTOR**

**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)			