PERFORMANCE QUALIFICATION REPORT FOR METAL DETECTOR

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

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

CONTENTS

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

1.0 REPORT 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 scope of this report is limited for qualification of Metal Detector 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 report provides all the relevant information of the performance qualification activity & In-process observations.

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 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 Report. • To co-ordinate and support Performance Qualification Activity.
Quality Control	• Review of Report.
Engineering	• Review of qualification Report 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	
Model No.	
Sr. No	
Supplier's Name	Unique Equipment Metal Detection System.
Location of Installation	Compression

6.0 PRE QUALIFICATION REQUIREMENT:

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 operating & Cleaning of Metal Detector.
- SOP for Preventive Maintenance Metal Detector.

7.0 TESTS AND CHECKS:

7.1 Verification of Documents:

Record the observations for documents in the below mentioned table

S.No.	Document Name	Document/SOP No.	Completed (Yes/No)	Checked By (Engineering) Sign/Date	Verified By (QA) Sign/Date
1.	Executed and approved Design Qualification document				
2.	Executed and approved Installation Qualification document				
3.	Executed and approved Operational Qualification document				
4.	PQ Protocol approved				
5.	SOP for operating & Cleaning of Metal Detector				
6.	SOP for Preventive Maintenance Metal Detector				

Inference:

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

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

7.2 Report Of Performance Evaluation Of Sensitivity Of Metal Detector:

Challenge Test: Initial Verification without Product at Different Sensitivity Level.

S. No.	Test Sample	Test Performed	Observation at Different Sensitivity levels								
		Sample passed through the aperture of the metal detector	0-25	26-50	51-75	76-100	101-125	126-150	151-175	176-200	201-250
1.	Sample "A" Ferrous	1.									
		2.									
		3.									
2.	Sample "B" Non Ferrous	1.									
		2.									
		3.									
3.	Sample "C" SS	1.									
		2.									
		3.									
4.	Sample "D" Dummy	1.									
		2.									
		3.									

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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

7.3 REPORT OF PERFORMANCE EVALUATION USING FORMULATION

FIRST BATCH:

Product Name:	
Batch No.:	**Batch Size:**
Mfg. Date:	**Exp. Date:**
Set Sensitivity:	

S. No.	Product Quantity	Rejected Quantity	Passed Quantity	Observed By (Production) (Sign/Date)

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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

S. No.	Test Sample	Test Performed	Observation at Different Sensitivity Levels								
		Sample passed through the aperture of the metal detector	0-25	26-50	51-75	76-100	101-125	126-150	151-175	176-200	201-250
1.	Sample "A" Ferrous	1.									
		2.									
		3.									
2.	Sample "B" Non Ferrous	1.									
		2.									
		3.									
3.	Sample "C" SS	1.									
		2.									
		3.									
4.	Product	1.									
		2.									
		3.									

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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

SECOND BATCH:

Product Name:	
Batch No.:	**Batch Size:**
Mfg. Date:	**Exp. Date:**
Set Sensitivity:	

S. No.	Product Quantity	Rejected Quantity	Passed Quantity	Observed By (Production) (Sign/Date)

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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

S. No.	Test Sample	Test Performed	Observation at Different Sensitivity Levels								
		Sample passed through the aperture of the metal detector	0-25	26-50	51-75	76-100	101-125	126-150	151-175	176-200	201-250
1.	Sample "A" Ferrous	1.									
		2.									
		3.									
2.	Sample "B" Non Ferrous	1.									
		2.									
		3.									
3.	Sample "C" SS	1.									
		2.									
		3.									
4.	Product	1.									
		2.									
		3.									

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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

THIRD BATCH:

Product Name:	
Batch No.:	**Batch Size:**
Mfg. Date:	**Exp. Date:**
Set Sensitivity:	

S. No.	Product Quantity	Rejected Quantity	Passed Quantity	Observed By (Production) (Sign/Date)

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

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

S. No.	Test Sample	Test Performed	Observation at Different Sensitivity Levels								
		Sample passed through the aperture of the metal detector	0-25	26-50	51-75	76-100	101-125	126-150	151-175	176-200	201-250
1.	Sample "A" Ferrous	1.									
		2.									
		3.									
2.	Sample "B" Non Ferrous	1.									
		2.									
		3.									
3.	Sample "C" SS	1.									
		2.									
		3.									
4.	Product	1.									
		2.									
		3.									

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

8.0 CHECKLIST OF ALL TESTS & CHECKS:

This checklist is provided to ensure that all tests or checks required for this protocol have been executed.

Tests or Checks	Executed (Yes/No)	Remarks
Verification of DQ, IQ & OQ & other documents		
Initial Verification of Performance without Product		
Verification of Performance using Drug product.		

Checked By
(Production)
Sign/Date: ……

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

Inference:

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

9.0 DOCUMENTS TO BE ATTACHED:

- Operation And Maintenance Manual
- Copy of SOP's
- Any Other Relevant Documents

10.0 NON COMPLIANCE:

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11.0 DEVIATION FROM PREDEFINED SPECIFICATION, IF ANY:

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12.0 CHANGE CONTROL:

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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:

QA	:	Quality Assurance
DQ	:	Design Qualification
IQ	:	Installation Qualification
OQ	:	Operational Qualification
PQ	:	Performance Qualification
SOP	:	Standard Operating Procedure
QA	:	Quality Assurance
No.	:	Number

17.0 REPORT POST – 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)			