

PROTOCOL No.:

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



PROTOCOL No.:

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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)			



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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 & Inprocess observations.



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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 Report:

DEPARTMENTS	RESPONSIBILITIES		
	Preparation, Authorization, Approval and Compilation of the		
0 124 1	Performance Qualification.		
Quality Assurance	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.		
	Review of qualification Report for correctness, completeness and		
Engineering	technical excellence		
Engineering	Responsible for trouble shooting (if occurred during execution).		
	Maintenance & preventive maintenance as per schedule.		



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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.



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7.0	TESTS	ΔND	CHECKS	•
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7.1	Verification	of Documents:
/ • I	v ci ilicationi	or pocuments.

Record the observations for documents in the below mentioned table

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

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



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7.2	Report Of Perfor	mance 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"	1.									
	Ferrous	2.									
		3.									
2.	Sample "B" Non	1.									
	Ferrous	2.									
		3.									
3.	Sample "C" SS	1.									
		2.									
		3.									
4.	Sample "D" Dummy	1.									
		2.									
		3.									
											.1

	Dummy	2. 3.							
(Prod	ked By uction) Date:		(Qı		ssurance)				
Infer	ence:		 	 					
						(1	teviewed Manager ign/Date	•	



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7.3 REPORT OF PERFORMANCE EVALUATION USING FORMULATION FIRST BATCH:

Droduct Man	201				
Product Nan	ne:		1		
Batch No.:			Batch S	ize:	
Mfg. Date:			Exp. Da	ite:	
Set Sensitivit	ty:				
					Observed By
S. No.	Product	Rejected Q	uantity	Passed Quantity	(Production)
	Quantity	· ·	•		(Sign/Date)
Checked By				Ver	fied By
(Production)					ality Assurance)
					/Date:
G				<u> </u>	
Inference:					
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				Revi	ewed By
				(Mai	nager QA)
				Sign	Date:



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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"	1.										
	Ferrous	2.										
		3.										
2.	Sample "B" Non	1.										
	Ferrous	2.										
		3.										
3.	Sample "C" SS	1.										
		2.										
		3. 1.										
		1.										
4.	Product	2.										
		3.										

Checked By (Production) Sign/Date:	Verified By (Quality Assurance) Sign/Date:
Inference:	
	Reviewed By (Manager QA) Sign/Date:



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SECOND BA	АТСН:				
Product Nan	ne:				
Batch No.:			Batch S	ize:	
Mfg. Date:			Exp. Da	ite:	
Set Sensitivi	ty:				
S. No.	Product Quantity	Rejected Q	uantity	Passed Quantity	Observed By (Production) (Sign/Date)
Checked By (Production Sign/Date: Inference:				(Qua	fied By ality Assurance) n/Date:
		• • • • • • • • • • • • • • • • • • • •	•••••		
				(Man	ewed By nager QA) Date:



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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"	1.										
	Ferrous	2. 3.										
2.	Sample "B" Non	1.										
	Ferrous	2.										
		3.										
3.	Sample "C" SS	1.										
	C 55	2.										
		3. 1.										
4.	Product	1.										
		2.										
		3.										

		3.										
		5.										
(Prod	Checked By (Production) Sign/Date: Sign/Date: Verified By (Quality Assurance) Sign/Date:											
Infere	ence:											
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THIRD BAT	гсн:							
Product Nar	me:							
Batch No.:		Batch S	Size:					
Mfg. Date:		Exp. Da	Exp. Date:					
Set Sensitivi	ty:	I						
S. No.	Product Quantity	Rejected Quantity	Passed Quantity	Observed By (Production)				
	Quantity			(Sign/Date)				
Checked By			Ver	ified By				
(Production)				ality Assurance)				
	•••••			/Date:				
Inference:								
		•••••						
			(Mai	ewed By nager QA) n/Date:				
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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	2.											
		3.											
3.	Sample "C" SS	1. 2.											
		3.											
4.	Product	2.											
		3.											

(Prod	ked By uction) Date:							(erified By Quality A Sign/Date:	ssurance)	
Infere	ence:										
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•••••				•••••	•••••	•••••	• • • • • • • • • • • • • • • • • • • •	• • • • • • • • •	•••••	• • • • • • • • • • • • • • • • • • • •	••••
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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:		
		Reviewed By (Manager QA) Sign/Date:



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9.0	DOCUN	MENTS	TO	BE A	TTA	CHED:
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- Operation And Maintenance Manual
- Copy of SOP's
- Any Other Relevant Documents

10.0	NON COMPLIANCE:
11.0	DEVIATION FROM PREDEFINED SPECIFICATION, IF ANY:
12.0	CHANGE CONTROL:



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



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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)			