



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR META DETECTOR

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

DATE OF QUALIFICATION	
SUPERSEDES PROTOCOL No.	NIL



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR META DETECTOR

CONTENTS

S.No.	TITLE	PAGE No.
1.0	Pre-Approval	03
2.0	Objective	04
3.0	Scope	04
4.0	Responsibility	05
5.0	Brief Process Description	06
6.0	Equipment Specification	06
7.0	Critical Variables to be Met	07
8.0	Documents to be Attached	08
9.0	Review (Inclusive of Follow Up Action, If Any)	09
10.0	Any Changes Made Against the Formally Agreed Parameters	09
11.0	Recommendation	09
12.0	Abbreviations	10
13.0	Reviewed By	11



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR META 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)			



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR META DETECTOR

2.0 OBJECTIVE:

- To prepare the Design Qualification document for Metal Detector on basis of URS and information given by Supplier.
- To ensure that all Critical Aspects of Process/Product Requirement, cGMP and Safety have been considered in designing the equipment and is properly documented.

3.0 SCOPE:

- The Scope of this Qualification Document is limited to the Design Qualification of **Metal Detector**.
- The equipment shall be operated under the dust free environment and conditions as per the cGMP requirements.
- The drawings and P & ID's provided by Vendor shall be verified during Design Qualification.



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR META 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	<ul style="list-style-type: none">• Preparation, Review and Approval of the Design Qualification Protocol cum Report.• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.• Review of Design Qualification Protocol cum Report after Execution.• Co-ordination with Production and Engineering to carryout Design Qualification.• Monitoring of Design Qualification Activity.
Production	<ul style="list-style-type: none">• Review of the Design Qualification Protocol cum Report.• Assist in the verification of Critical Process Parameters, Drawings as per the Specification.• Review of Design Qualification Protocol cum Report after Execution.
Engineering	<ul style="list-style-type: none">• Review of the Design Qualification Protocol cum Report.• Assist in the Preparation of the Design Qualification Protocol cum Report.• To co-ordinate and support the Activity.• To assist in Verification of Critical Process Parameter, Drawings as per the Specification i.e.<ul style="list-style-type: none">➤ GA Drawing.➤ Specification of the sub-components/bought out items, their Make, Model, Quantity and backup records/ brochures.➤ Details of utilities.➤ Identification of Components for Calibration.➤ Material of Construction of all Components.➤ Brief Process Description.➤ Safety Features and Alarms.• Review of Design Qualification Protocol cum Report after Execution.



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR META DETECTOR

5.0 BRIEF EQUIPMENT 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 flux 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.

6.0 EQUIPMENT SPECIFICATION:

Equipment Specifications are based on User Requirement Specification prepared. The manufacturer of equipment ensures complies with User Requirement Specification.



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR META DETECTOR

7.0 CRITICAL VARIABLES TO BE MET:

7.1 PROCESS/PRODUCT PARAMETERS:

Critical Variables	Acceptance Criteria	Reference
Model No	Digitech-75	Design Requirement
Sr No.	Design Requirement
Application: Search Head	SS Structure	Process Requirement
Control section	This is placed inside the mounting base panel.	Process Requirement
Aperture	75 mm Width X 25 mm Height	Process Requirement
Sensitivity	0.30 mm Ferrous ,0.40 mm Non Ferrous & 0.50 mm S.S Metals & Above	Process Requirement
Input Voltage	230V AC , 1 PH, 50 Hz.	Process Requirement
Indication	Audio & Visual	Process Requirement

7.2 UTILITY REQUIREMENTS/LOCATION SUITABILITY:

Critical Variables	Acceptance Criteria	Reference
Utility connections should be available as per the manufacturer's specification.		
Electricity	230 V AC , 1 PH, 50 Hz. (To be assured by Engineering Department)	cGMP Requirement

7.3 TECHNICAL SPECIFICATIONS / KEY DESIGN FEATURES:

Critical Variables	Acceptance Criteria	Reference
Search Head	SS Structure (To be assured by Supplier).	Supplier (Unique equipment)
Control section	This is placed inside the mounting base panel.	Design Requirement
Aperture	75 mm Width x 25 mm Height	Design Requirement
Sensitivity	0.30 mm Ferrous, 0.40 mm Non Ferrous & 0.50 mm S.S Metals & Above	Design Requirement
Input Voltage	230V AC , 1PH, 50 Hz.	Design Requirement
Indication	Audio & Visual	Design Requirement



DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR META DETECTOR

7.4 MATERIAL OF CONSTRUCTION:

S.No.	Parts Name	Material Of Construction
1.	Search Head	SS 316
2.	Belt	Plastic coated (Non-Metallic)
3.	Skid plate	Polyethylene, Polypropylene
4.	Rollers	Non –metallic
5	Teflon chute	Teflon

7.5 SAFETY:

Critical Variables	Acceptance Criteria	Reference
Earthing	Properly earthing should be given to function	Process Requirement

7.6 VENDOR SELECTION:

Critical variables	Acceptance criteria	Reference
Selection of Vendor for supplying the “Metal detector”	Selection of Vendor is done on the basis of review of vendor. Criteria for review should include vendor background (general/financial), technical knowhow, quality standards, inspection of site, costing, feedback from market (customers already using the equipment)	Process Requirement

Reference: (1) The equipment shall confirm to the specifications and requirement.
(2) Operating and service manual for “Metal detector”.

8.0 DOCUMENTS TO BE ATTACHED:

- Technical details for Equipment Requirement with Engineering Drawings.
- Approved Design and Specifications.
- Minutes of meeting held with the supplier, if any.
- Purchase Order Copy.
- Any other relevant documents



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

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10.0 ANY CHANGES MADE AGAINST FORMALLY AGREED PARAMETERS:

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11.0 RECOMMENDATION:

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DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR META DETECTOR

12.0 ABBREVIATIONS:

cGMP	:	Current Good Manufacturing Practice
Ltd.	:	Limited
QA	:	Quality Assurance
P.O.	:	Purchase Order
Kg	:	Kilogram
NMT	:	Not More Than
RH	:	Relative Humidity
SS	:	Stainless Steel
MOC	:	Material of Construction
GA	:	General Arrangement
P & ID	:	Piping and Instrumentation Diagram
IPC	:	In process Container



PHARMA DEVILS
QUALITY ASSURANCE DEPARTMENT

DESIGN QUALIFICATION PROTOCOL CUM REPORT FOR META DETECTOR

13.0 REVIEWED BY:

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (ENGINEERING)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (PRODUCTION)			

DESIGNATION	NAME	SIGNATURE	DATE
HEAD (QUALITY ASSURANCE)			