PROTOCOL FOR CRITICALITY EVALUATION OF INSTRUMENT & MEASURING DEVICE

Document Number	:	
Effective Date	:	

PROTOCOL FOR CRITICALITY EVALUATION OF INSTRUMENT MEASURING DEVICE

PROTOCOL APPROVAL:

Function	Signatories	Name of individual	Signature	Date
Prepared by	Executive-QA			
Checked by	Head-Production			
Checked by	Head-QC			
Checked by	Head-Warehouse			
Checked by	Head-Engineering			
Approved by	QA-Head			
Authorized by	Site Head			

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1.0 OBJECTIVE:

The objective of this study is to ensure the Criticality/Complexity of instrument & measuring devices.

2.0 SCOPE:

2.1 This protocol shall be applicable for the evaluation of instrument/measuring devices to ensure the Criticality/Complexity in term of various parameter as per Protocol.

2.2 The protocol shall specify the responsibilities for the activity related to ensure the Criticality/Complexity of instrument & measuring devices.

3.0 RESPONSIBILITIES:

The team shall comprise of the following team members and their responsibilities shall be as Specified below.

Operation	Site- Head
Quality Assurance	Head, Quality Assurance
	Executive, Quality Assurance
Warehouse	Head, Warehouse
	Officer, Warehouse
Quality Control	Head, Quality Control
	Executive, Quality Control
Production	Head, Production
	Sr. Executive Production
Engineering	Head, Engineering
	Executive Engineering

Production:

Officer/Executive Production shall monitor and ensure the Complexity & Criticality of instrument/measuring devices.

The Executive Production is responsible for review included in this protocol and verification of proper scale followed to ensure the Complexity & Criticality of instrument/measuring devices.

The Head production is responsible for ensuring that the conducted activity is inline as per predetermine evaluation process.

Quality Control:

Officer/Executive Quality Control shall monitor and ensure the Complexity & Criticality of

instrument/measuring devices

The Executive Quality Controls responsible for review included in this protocol and verification of proper scale followed to ensure the Complexity & Criticality of instrument/measuring devices

The Head Quality Control is responsible for ensuring that the conducted activity is inline as per predetermine evaluation process.

Warehouse:

Officer/Executive Warehouse shall monitor and ensure the Complexity & Criticality of instrument/measuring devices

The Executive warehouse responsible for review included in this protocol and verification of proper scale followed to ensure the Complexity & Criticality of instrument/measuring devices

The Head warehouse is responsible for ensuring that the conducted activity is inline as per predetermine evaluation process.

4.0 "Instrument/Measuring devices criticality evaluation" Methodology:

Below listed Scale shall be followed to ensure the Complexity & Criticality of instrument on the basis of their Utilization, Automation, and Impact on product, Availability of control measures for any discrepancy & Detectability. This evaluation shall be done in annexure-I by multiplying the rating assigned for each parameter. The total obtained by multiplication of various parameters rating shall be checked with the obtained criteria in section 5.0.

Factor A: Utilization:

Utilization	Rating	Reference Document used for evaluation of rating
Continuous	5	Operation & cleaning logbook
Daily	4	
Weekly	3	
Monthly	2	
Quaterly /half yearly/ Annualy	1	

Factor B: Automation:

Automation	Rating	Reference Document used for evaluation of rating
Completely Automated	1	Qualification documents
Significantly automated	2	
Partially automated	3	
Manual	4	

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Factor C: Impact on Product:

Impact on Product	Rating	Reference Document used for evaluation of rating
Impacting	4	Critical process variable of Qualification documents
Significant impact	3	
Likely impacting	2	
Non impacting	1	

Factor D: Availability of control measures for any discrepancy:

Availability	Rating	Reference Document used for evaluation of rating
Available	1	Available Supported Documents or SOP
Partially Available	2	
Not Available	3	

Factor E: Detectability:

Breakdown	Rating	Reference Document used for evaluation of rating
Low	3	Available Supported Documents or SOP
Moderate	2	
High	1	

5.0 Instrument criticality assigning based on the factor:

Instrument/measuring devices criticality shall be assign as per Multiplication of Factor for all equipment/instrument used at site.

Multiplication of Factor: = A x B x C x D x E

Criticality Criteria	Multiplication of Factor
Non Critical	1-179
Moderate	180-359
Critical	360-720

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6.0 DEVIATION:

S.No.	Deviation details	Justification(s) / Corrective action(s)	Remarks (Acceptable/ Not acceptable)
1.			

Comments: _____

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_____ _____

Checked By Sign Date

_____ _____

Reviewed By Sign Date:

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7.0 EXECUTIVE SUMMARY:

*Note: Use additional pages if required.

Checked By: Date:

Reviewed By: Date:

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8.0 REFERENCES:

8.1 Initial Qualification documents of Instrument & Measuring devices.

8.2 History card of Instrument.

8.3 Operation and cleaning logbook of specified instrument & Measuring Devices.

8.4 Maintenance and Breakdown logbook.