



### Risk Assessment for Transport Validation

#### 1. Risk Assessment Tool– Failure Mode effect Analysis (FMEA)

##### Risk Identification

S.No.	Failure Mode {What can go wrong}	Potential cause of Failure	What are the Consequences	Justification
<b>Risk Identification</b>				
1.	<b>Failure of Instrument</b>	Over usage	Malfunctioning of Data logger	The over usage of data logger will reduce the efficiency of Data logger
		Temperature elevation	Malfunctioning of Data logger	Required temperature for data logger if it is exceeds it may damage the components of the data logger.
		Maintenance and calibration of data logger	Malfunctioning of data logger	If instrument is not maintained and calibrated at the required interval of time then it will result in malfunctioning that will have adverse impact at the time of downloading.



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S.No.	Failure Mode {What can go wrong}	Potential cause of Failure	What are the Consequences	Justification
<b>Risk Identification</b>				
02.	<b>Process</b>		Product validation Customer commitment Business impact Campaign failure	Study shall be carried out for batch of .... Mode of transportation Information shall be collected and recorded before starting the validation activity One container of product shall be identified from concerned batch to keep the electronic transit data logger inside the container Data logger placed over the top of outer bag & kept securely using cello tape to avoid damage To carry label outside A memo addresses to customer was placed along with data logger, requesting to return the data logger back to location.



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S.No.	Failure Mode {What can go wrong}	Potential cause of Failure	What are the Consequences	Justification
<b>Risk Identification</b>				
02	<b>Process (continue...)</b>	Awareness  Written Procedure	Deviation  Product Failure	Customer shall be enter the date & time when data logger removed from container  After receiving data logger. Data shall be down load from data logger & shall be evaluated based on acceptance criteria  Compare with initial quality data of selected batch observation shall be recorded.
03	<b>Training</b>	Non availability of standard procedure  People are not trained for the entire procedures		Untrained persons can make mistakes & errors because of unawareness about the results.



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**2. Risk Analysis:**

S.No.	Failure Mode {What can go wrong}	Potential cause of Failure	What are the Consequences	Existing Design Control	Severity	Probability	Detection	Risk Priority Number
					(S)	(P)	(D)	RPN=S x P x D
Risk Analysis								Risk valuation
01.	Failure of Instrument	Over usage	Malfunctioning of Data logger		4	6	2	RPN = 4X6X2 = 48
		Temperature elevation	Malfunctioning of Data logger					
		Maintenance and calibration of data logger	Malfunctioning of data logger	SOP				



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#### 3. Acceptance criteria

The Risk Priority Number shall be within the range  $0 < \text{RPN} < 125$

#### 4. Risk Control Strategy

S.No.	Risk Priority Number	Risk Decision	Risk control strategy
1.	$0 < \text{RPN} < 125$	Risk Acceptable	No control is required
2.	$125 < \text{RPN} < 500$	Risk Reduction	Additional Procedural Control
			Manual Control
			Documentary Evidence
3.	$500 < \text{RPN} < 1000$	Risk Reduction	Rugged Procedural control
			Additional Manual Control
			Auditing
			Engineering controls (if Possible)

#### 5. Summary and Conclusion

The risk associated with each Failure mode lies in between the range  $0 < \text{RPN} < 100$  after going through risk mitigation and reduction process

Hence it meets the acceptance criteria for risk acceptance

#### 6. References:

1. Risk Management Master Plan
2. ICH Q9

#### 7. Annexure:

Annexure No.	Annexure Title	Page No's
01	List of Reference Documents	02



**Risk Assessment for Transport Validation**

**Annexure – 01**

**List of Reference Documents**

<b>Facility :</b>	
<b>Location:</b>	
<b>No. of Pages:</b>	



**Risk Assessment for Transport Validation**

**List of reference documents**

S.No.	Document Title	Document No.