



**POST RISK ASSESSEMENT FOR PASTE KETTLE**

**RISK ASSESSMENT  
REPORT BY FMEA**

<b>Product/System/Equipment</b>	<b>PASTE KETTLE (250 LTR )</b>
<b>Risk Assessment Report No.</b>	
<b>Report Date</b>	



## POST RISK ASSESSEMENT FOR PASTE KETTLE

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**POST RISK ASSESSEMENT FOR PASTE KETTLE**

**DOCUMENT APPROVAL:**

This risk analysis study for the preapproval of report by following:

Responsibility	Department	Name	Signature	Date
<b>Prepared by</b>	Quality assurance			
<b>Reviewed by</b>	Production			
	Quality control			
	Engineering			
	Store			
	Quality assurance			
<b>Approved by</b>	Head-QA			



## **POST RISK ASSESSEMENT FOR PASTE KETTLE**

### **1.0 Introduction**

The “PASTE KETTLE” is intended for Mixing and paste preparation with assurance of product safety. It consists of a jacketed & insulated bowl welded to cylindrical shell

### **2.0 Objective**

Objective of this report is to assess the risk associated with the equipment “PASTE KETTLE” in post assessment in the manufacturing facility of Cepha Oral Block of ....., in line with the guidance of the Risk Management manual of .....and ICH Q9.

### **3.0 Scope**

The scope of this document is limited to the design, installation, operation, performance and safety of equipment “PASTE KETTLE” and define its failure mode at post assessment in the manufacturing facility at .....

### **4.0 Risk assessment approach**

Risk assessment is carried out as per FMEA (Failure mode, effects analysis) method.

### **5.0 Responsibility**

Quality Assurance

Engineering

Production

Quality Control

Store

### **6.0 Reference Documents**

1. ICH Q9-Quality Risk Management
2. .... guidance on Risk assessment.



## POST RISK ASSESSEMENT FOR PASTE KETTLE

### Background

.....is intended to start manufacturing of solid oral facility at ..... Risk assessment is a part of corporate quality assurance. Post Quality Risk assessment of "PASTE KETTLE" is done to check the system is capable of providing quality product throughout the life cycle of the drug product.

### 7.0 RISK RANKING PARAMETERS\_

#### 7.1 Rating parameters for Severity

Effect	Scale	Description
No effect	1	No effect on output
Very slight	2	Customer not annoyed
Slight	3	Slight
Minor	4	Minor effect on performance
Moderate	5	Moderate effect on performance
Significant	6	Partial failure but operable
Major	7	Product performance severely affected, but some operability and safe
Extreme	8	Very dissatisfied, product inoperable but safe
Serious	9	Potentially hazardous effect, time-dependent failure
Hazardous	10	Hazardous effect, safety related sudden failure

#### 7.2 Rating parameters for Occurrence

Occurrence	Scale	Description
Almost never	1	Failure unlikely; history shows no failures
Remote	2	Rare number of historical failure
Very Slight	3	Very few failures likely
Slight	4	Few failures likely
Low	5	Occasional number of failures likely
Medium	6	Medium number of failures likely
Moderately High	7	Moderately high number of failures likely



## POST RISK ASSESSEMENT FOR PASTE KETTLE

Occurrence	Scale	Description
High	8	High number of failures likely
Very High	9	Very high number of failures likely
Almost certain	10	Failure almost certain

### 7.3 Rating parameters for Detection control

Detection	Scale	Description
Almost certain	1	Proven detection methods with high reliability
Very High	2	Proven detection methods available
High	3	Detection tools have high chance of detecting methods
Moderately High	4	Almost certain not to detect failure
Medium	5	Detection tools have moderate chance of detecting defect
Low	6	Detection tools have a low chance of detecting failure
Slight	7	Detection tools may not detect failure
Very Slight	8	Detection tools will probably not detect failure
Remote	9	Detection tools most likely will not detect failure
Impossible	10	Failure not detected

**Note:** Individual contributory factor for each potential failure mode shall be rated. Other scale parameters may also be selected based on the process.

### 8.0 ACCEPTANCE CRITERIA FOR RISK ASSESSMENT BY FMEA

Acceptance criteria for FMEA are as follows:

S.No.	RPN Rating	RPN Category	Action Status
1.	$\geq 76$	Critical	CAPA Required
2.	51 to 75	Major	CAPA Required
3.	26 to 50	Moderate	CAPA Required
4.	Up to 25	Minor	Not applicable



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## QUALITY RISK ASSESSEMENT AND MITIGATION PLAN

### 9.0 POST-RISK ASSESSMENT AS PER FMEA:

Name of facility/Utility/Equipment/Process/Operation: PASTE KETTLE

S.No.	Potential Failure Mode	Potential effect (s) of failure	Severity (S)	Potential cause/ Mechanism of failure	Occurrence (O)	Current Control	Detection (D)	RPN (S x O x D)	Recommended action	Responsibility and TCD	Action Results				
											Action taken	Severity	Occurrence	Detection	New RPN
1	Design Qualification document received is inadequate.	Equipment may not function as desired.	4	No or inadequate clarity (Knowledge) in preparation of URS.	3	URS is prepared by experienced personnel with the help of engineering, QA & department Head.  Well experienced Personnel from QA, Engineering & user department verified DQ against URS.	2	24	Current control measures are adequate	NA	NA	NA	NA	NA	NA
		c-GMP requirement will not met	7		3		1	21		NA	NA	NA	NA	NA	NA
		Safety measures with respect to operator and environment will not be clear.	4		3		2	24		NA	NA	NA	NA	NA	NA
		Major components list will be missed out.	6		2		2	24		NA	NA	NA	NA	NA	NA
	Design Qualification document received is inadequate	Requirement of utilities (power and Steam ) will not be clear.	3	No or inadequate clarity (Knowledge) in preparation of URS.	4	URS is prepared by experienced personnel with the help of engineering , QA & department Head.	2	24	Current control measures are adequate	NA	NA	NA	NA	NA	NA



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## POST RISK ASSESSEMENT FOR PASTE KETTLE

S.No.	Potential Failure Mode	Potential effect (s) of failure	Severity (S)	Potential cause/ Mechanism of failure	Occurrence (O)	Current Control	Detection (D)		Recommended action	Responsibility and TCD	Action Results					
							RPN (S x O x D)	Action taken			Severity	Occurrence	Detection	New RPN		
		Functional design specification will not be available.	4		3	Well experienced Personnel from QA, Engineering & user department verified DQ against URS.	2	24		NA	NA	NA	NA	NA	NA	
		Generally assembling diagram will not be clear	4		4		1	16		NA	NA	NA	NA	NA	NA	NA
		Instrument list connected with equipment will be missing	4		3		2	24		NA	NA	NA	NA	NA	NA	NA





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											Action taken	Severity	Occurrence	Detection	New RPN
2	Design Qualification document is not checked and verified properly.	Document verification related to design verification, c-GMP requirement, Instrument & control verification, components verification, utility verification & safety verification will not be appropriate.	4	Inadequate knowledge or inadequate training to all concerned.	3	Well experienced Personnel from QA, Engineering & user department will verify DQ against URS.	2	24	Current control measures are adequate	NA	NA	NA	NA	NA	NA
3	Installation Qualification document is inadequate	Inadequate Installation of equipment	7	Inadequate information in IQ.	3	Interpretation of URS along with DQ. SOP is in place for verification of IQ document.	1	21	Current control measures are adequate	NA	NA	NA	NA	NA	NA
		Identification of major components will be missing	6	Inadequate information in IQ.	2	Interpretation of URS along with DQ. SOP is in place for verification of IQ	2	24	Current control measures are adequate	NA	NA	NA	NA	NA	NA



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											Action taken	Severity	Occurrence	Detection	New RPN
		No or inadequate clarity on equipment / documents required for completion of IQ.	3		3	document.	2	18		NA	NA	NA	NA	NA	NA
4	Calibrated Measuring equipment not available at site.( multimeter, spirit level, Tachometer)	Installation will be improper, Equipment will not perform as intended	6	Inadequate training	4	Qualification team will ensure Physically for the availability of equipment before execution of IQ.	1	24	Current control measures are adequate	NA	NA	NA	NA	NA	NA
5	Reference document not available at site during IQ. ( F DS, GA and electrical drawing, installation & Operational manual, Material chart with test certificate & Manual.)	Installation will be improper, Equipment will not perform as intended	6	Inadequate knowledge for verification of reference documents on receipt.	4	Qualification team will ensure Physically for the availability of document before execution of IQ.	1	24	Current control measures are adequate	NA	NA	NA	NA	NA	NA



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											Action taken	Severity	Occurrence	Detection	New RPN
6	MOC verification not done during IQ ( For contact and non contact parts )	Product may gets contaminated	7	MOC Test certificate not provided by vendor.  Molybdenum Kit Not available	4	Procedure is in place for verification during IQ.	2	56	Molybdenum kit to be procured	Engin eering,					
7	Equipment name plate not available during IQ	Equipment will not be identified.	4	Equipment name plate not provided by vendor	3	Procedure is in place for verification during IQ.	2	24	Controlled measures are in place	NA	NA	NA	NA	NA	NA
8	Instrumentation & calibration check not performed.	IQ will not be performed	5	Inadequate Knowledge or training to concern personnel	3	Procedure is in place for verification during IQ.	1	15	Controlled measures are in place	NA	NA	NA	NA	NA	NA
9	Operational document is inadequate	inadequate Operation of equipment	6	Inadequate information in OQ	4	SOP is in place for verification of OQ Protocol.	1	24	Controlled measures are in place	NA	NA	NA	NA	NA	NA
10	IQ not completed prior to OQ	OQ Cannot be proceed	6	Incomplete documentation.  Installation not completed	4	SOP is in place to perform OQ after successful completion of IQ	1	24	Controlled measures are in place	NA	NA	NA	NA	NA	NA



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											Action taken	Severity	Occurrence	Detection	New RPN
11	Prequalification requirement not checked during OQ. (Tools are not removed from the equipment.)	Accident may happen	10	Inadequate knowledge or safety measures are not followed	2	Activity will be performed by Trained personnel.	1	20	Controlled measures are in place	NA	NA	NA	NA	NA	NA
	Emergency "STOP" button not released.	Equipment will not run	6	Inadequate knowledge	4	Procedures are in place for verification during OQ.	1	24	Controlled measures are in place	NA	NA	NA	NA	NA	NA
	External equipment is not disconnected.	Accident may happen	10	Inadequate knowledge or safety measures are not followed	2	Activity will be performed by trained personnel.  Procedure are in place for verification during OQ	1	20	Controlled measures are in place	NA	NA	NA	NA	NA	NA
12	Main motor not functioning.	Equipment will not run	7	Inadequate knowledge/training for operating the equipment.  Required input supply of suitable frequency of motor not provided	3	Procedure are in place for verification during OQ	1	21	Controlled measures are in place	NA	NA	NA	NA	NA	NA



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											Action taken	Severity	Occurrence	Detection	New RPN
13	Equipment operation verification not done. (Hand wheel performance, , Noise level).	Equipment will not perform as intended	10	Inadequate knowledge/training for operating the equipment.	2	Procedure are in place for verification during OQ	1	20	Controlled measures are in place	NA	NA	NA	NA	NA	NA
14	Adequate safety features for men and material not provided with the equipment	Accident may happen	10	Inadequate knowledge	2	Procedure are in place for verification during IQ & OQ	1	20	Controlled measures are in place	NA	NA	NA	NA	NA	NA
	Flame proof motors,& earthing not provided	Accident may happen	10	Inadequate knowledge	2	Procedure are in place for verification during IQ & OQ	1	20	Controlled measures are in place	NA	NA	NA	NA	NA	NA
	Equipment control functions verification test not done.	Equipment will not function as desired.	7	Inadequate knowledge/training for operating the equipment.	3	Procedure are in place for verification during OQ	1	21	Controlled measures are in place	NA	NA	NA	NA	NA	NA
15	Equipment is not assembled after cleaning, preventive maintenance, break down, calibration	Accident may happen. Equipment not functioned as expected	10	Inadequate knowledge/training for operating the equipment	2	Procedure is in place for proper assembling after properly cleaning, preventive maintenance, calibration	1	20	Control measures are in place.	NA	NA	NA	NA	NA	NA



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											Action taken	Severity	Occurrence	Detection	New RPN
16	Major changes done without any documentation	Performances of equipment will not guaranteed.  Product quality may get affected	6	Inadequate knowledge/training	3	Change control Sop is in place	1	18	Control measures are in place.	NA	NA	NA	NA	NA	NA
17	Product designing is not done considering current equipment design and capacity	Performances of equipment will not guaranteed.  Product quality may get affected	6	No or inadequate clarity about equipment design and capacity	3	Performance qualification will be carried out on equipment considering Max. capacity as per design	1	18	Control measures are in place.	NA	NA	NA	NA	NA	NA
18	Equipment is not cleaned properly	Product will contaminated	8	Cleaning procedure is not followed correctly	2	Line clearance & cleaning procedure is in place	1	16	Control measures are in place.	NA	NA	NA	NA	NA	NA
20	Improper /No Insulation of the steam line	Accident may happen to Man	8	Inadequate knowledge	3	Visual verification before OQ	3	72	Insulation to the steam line to be carried out	Engin eering & produc tion					





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### 10.0 RISK CONTROL MEASURES

**Investigation/findings:** *(an extra sheet can be used if space is insufficient)*

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**Corrective Action:** *(an extra sheet can be used if space is insufficient)*

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**(Sign/Date)**







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## POST RISK ASSESSEMENT FOR PASTE KETTLE

### 12.0 FINAL REPORT APPROVAL:

The final report shall be signed after identifying all the risks and critical control parameters. All the reports or documents have been attached to the respective report (if applicable).

Signature in the block below indicates that all the control measures taken are documented and have been reviewed and found to be acceptable.

Department	Name	Designation	Signature	Date
Quality assurance				
Production				
Quality control				
Engineering				
Store				
Head-QA				