DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Root Cause Analysis	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

1.0 OBJECTIVE:

To lay down a Procedure for Root Cause Analysis.

2.0 SCOPE:

This SOP shall be applicable to Root Cause Analysis for all Department of …….

3.0 RESPONSIBILITY:

3.1 QA (Officer/Executive): Preparation, Distribution, Revision, Retrieval and Destruction of this SOP. Issuance of RCA form and maintain the RCA log Initiation of the Root Cause Analysis.

3.2 QA Manager: Review, Training and effective implementation of this SOP to all concerned Departments.

3.3 Respective Departments: Initiation of the Root Cause Analysis.
(Officer/ Executive)

3.4 Respective Departments: Training and effective implementation of this SOP.
(Manager)

4.0 ACCOUNTABILITY:

4.1 Head QA: Approval, Authorization, ensure Training and Implementation of this SOP Selection of RCA Team for Plant specific Department. To ensure retrieval of this SOP.

4.2 Respective Departments Head: To ensure Training and Implementation of this SOP.

5.0 DEFINITION:

5.1 Root Cause Analysis (RCA): Root cause analysis (RCA) is a problem solving technique for identifying the root causes of problems or adverse events.

5.2 Root Cause Analysis is the method or Technique to identify actual cause (s) underlying the said deviation, Incident, Market Complaint, OOS/OOT results or GMP non conformance.

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Root Cause Analysis	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

6.0 PROCEDURE:

6.1 ISSUANCE OF RCA FORM:

6.1.1 Initiating department shall raise the request to QA for RCA Form in the Format as per Format **SOP**, Titled **"Request Form for Issuance of SOP/Format"** of SOP, Titled **"SOP for SOP"**.

6.1.2 QA shall assign a RCA No. in the format of **"Root Cause Analysis Log"** as shown in **Annexure-I** and same shall be assigned in the **"Root Cause Analysis Form"** as shown in **Annexure-II**.

6.2 INITIATION OF RCA:

6.2.1 Manager QA along with Respective Department Head shall initiate RCA process as part of Investigation of Deviation, Incident, Market Complaints, OOS/OOT results or GMP non conformance.

6.2.2 Numbering System of Root Cause Analysis (RCA):

6.2.2.1 Root Cause Analysis No. shall be assigned by QA as **RCA/YY/NNN**

Where,

RCA **:**Denotes Root Cause Analysis

/ **:** separator

YY **:**Last two digits of the Current Calendar Year

/ **:** separator

NNN **:** Serial Number of the RCA Form in current Calendar Year.

6.2.3 Same Root Cause Analysis No. shall be recorded on each format i.e. **Root Cause Analysis by Fish Bone Analysis** shown in **Annexure-IV** and **Root Cause Analysis by 5- Why`s** shown in **Annexure-VI**.

6.3 ROOT CAUSE ANALYSIS (RCA) TEAM:

6.3.1 Selection of Team for Root Cause Analysis for individual Root Cause Analysis shall be done by Head QA on the basis of Qualification, Experience, Expertise, Technical Skills, understanding and Logical Analysis of process and system.

6.3.2 Name of RCA team members shall be recorded in format as **"Root Cause Analysis Form"** as shown in **Annexure-II**.

6.4 ROOT CAUSE ANALYSIS (RCA) TOOLS:

6.4.1 Head QA shall select the Root Cause Analysis (RCA) tool with consultation with RCA Team.

1. Brain Storming
2. Cause and Effect Diagrams (also called an Ishikawa diagram or fish bone diagram).
3. Five Why's
4. Pareto Charts
5. Flow Chart

6.5 BRAIN STORMING:

6.5.1 Brainstorming is an effective tool to identify contributing factors by asking, "What might have happened that would increase the likelihood for the event to occur".

6.5.2 Brain storming a kind of free from all the ideas and shall be done in a structured way. Don't dismiss anyone's ideas during brainstorming.

6.5.3 Brain Storming shall be performed in format as given in **Annexure-III**, Titled **"Root Cause Analysis by Brain Storming"**.

6.5.3.1 Fish Bone Diagram (Ishikawa Fish Bone/ Herringbone or Cause –and-effect diagram):

6.5.3.2 Fish bone diagram is an analysis tool to provide systematic way of understanding effects and the causes that create those effects.

6.5.3.3 Design of the diagram looks like the skeleton of a fish where the product / process is the main spine, the effect is the actual nonconformance, and the secondary spines are the different factors or causes that could have affected or "caused" the deviation (i.e., Method, Machine, Materials, Man, Measurement, Milieu etc.).

6.5.3.4 Each cause or reason for imperfection is a source of variation. Causes are usually grouped into major categories to identify these sources of variation. The categories typically include:

6.5.3.4.1 Methods: How the process is performed and the specific requirements for doing it, such as policies, procedures, rules, regulations and laws.

6.5.3.4.2 Machines: Any equipment, computers, tools, etc. required to accomplish the job.

6.5.3.4.3 Materials: Raw materials, Packaging Materials, In-process Materials etc. used to produce the final product.

6.5.3.4.4 Man: Personnel involved with the process.

6.5.3.4.5 Measurements: Data obtained from the process that is used to evaluate its Quality.

6.5.3.4.6 Milieu (Environment): The conditions, such as location, temperature, and humidity in which the process operates.

6.5.3.5 Creation of Fish Bone Diagram:

6.5.3.5.1 Write the problem in the right side box (Appear as head of Fish Skeleton) in format as given in **Annexure-IV** (Format can also be prepared on larger Paper size as per requirement).

6.5.3.5.2 Label each bone of the fish with probable causes (6 M's) Methods, Machines, Materials, Manpower, Measurement and Milieu.

6.5.3.5.3 Continue asking, "Why is this happening?" to find out Sub factor and write down on tertiary spines.

6.5.3.5.4 Continue until you no longer get useful information as you ask, "Why is that happening?" and record by drawing quaternary spines.

6.5.3.5.5 Analyze the results of the fishbone after team members agree that an adequate amount of detail has been provided under each major category. Do this by looking for those items that appear in more than one category. These become the 'most likely causes".

6.5.3.5.6 For those items identified as the "most likely causes", the team should reach consensus on listing those items in priority order with the first item being the most probable" cause.

6.5.3.5.7 Example of causes/Reasons of non-conformance that may be identified by fish bone diagram are as follows (but not limited to):

6.5.3.5.8 Methods (Process): Method may include no procedure, wrong, invalidated, poorly communicated procedure or practices are not same as written procedure.

6.5.3.5.9 Machine (or Equipment): Incorrect tool/machine parts selection, poor maintenance or design, defective equipment or tool, out of calibration, unqualified, inappropriate capacity, contaminated/unclean, not operated as per written procedure.

6.5.3.5.10 Material: Material may include defective material, wrong material, contaminated material, Mix-Up in material; Material from un-approved source, inappropriate sampling and testing etc.

6.5.3.5.11 Man: Unauthorized to operate, unskilled and untrained, insufficient number of manpower, not performing his/her assigned role.

6.5.3.5.12 Measurement: Measuring device not calibrated/ out of calibration, Procedure not followed as per written procedure, defective instrument.

6.5.3.5.13 Milieu (Environment): Temperature/humidity out of specified limit during processing/storage, Grade of area not maintained, insufficient/inappropriate light and process carried out in wrong area.

6.5.3.5.14 Sub cause shall be identified further by brainstorming to explore the potential root cause using the questions as given in **Annexure-V**, Titled **"Questionnaire for Sub Cause Identification"**. These questions are given for guidance and not limited, any more questions can be considered.

6.5.3.5.15 Each question shall be answered to find out any abnormal finding. Such abnormal finding may further analyzed using **5 Why's** analysis tool or any other suitable method to reach to Root Cause.

6.5.4 FIVE WHY`S ANALYSIS:

6.5.4.1 The **"5-Why's"** refers to a series of sequential questions (i.e. each response given is asked "why", normally from 3 up to 5 times or can be increased for a particular case). This exercise allows a thorough understanding of the underlying or root causes of the issue under consideration.

6.5.4.2 5Why analysis tool can be used alone or in conjunction with Fish bone diagram tool.

6.5.4.3 Root cause identification by using 5 Whys Analysis shall include the following steps:

6.5.4.4 The Problem shall be written in format as **"Root Cause Analysis by 5-Why's"**given in **Annexure-VI**.

6.5.4.5 Ask why the problem happened and write down the answer below the problem.

6.5.4.6 If the answer written in first instance doesn`t identify the root cause of the problem again question why, shall be repeated and the answer shall be written.

6.5.4.7 The question shall be asked 3-5 times (or more, if required) until the team reaches to the Root Cause of the Problem.

6.5.4.8 After Identification of Root Cause (s), CAPA shall be initiated as per SOP, Titled **"Corrective Action and Preventive Action (CAPA)"**.

6.5.5 PARETO CHARTS:

6.5.5.1 Pareto Charts are the Vertical bar chart that illustrates relative importance of the factors or causes that contributes to a particular problem or situation.

6.5.5.2 Pareto Charts illustrates problem factors or causes in order of severity according to frequency or cost (impact, risk) of occurrence.

6.5.5.3 Also called 80:20 rule or 80/20 rule or the Pareto principle. Only a few (20%) of the problem causes or factors will account for most (80%) of the problem or opportunity.

Examples: Number of errors by batch record type, Status of pending record revisions by department. Number of pending work requests by approval phase Order the bars from highest to lowest.

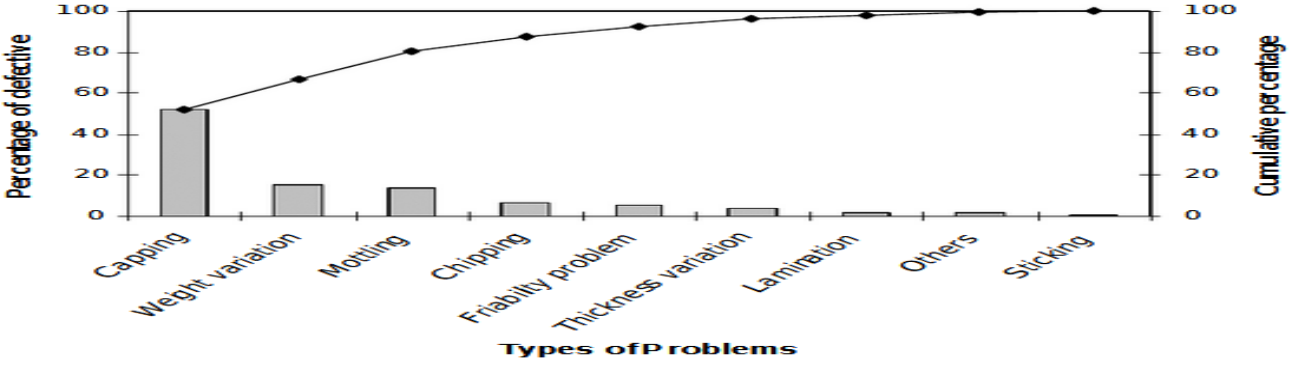


Fig 1. Pareto chart for processing and compression

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Root Cause Analysis	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

6.5.6 FLOW CHARTS:

6.5.6.1 **Flowcharts** are used in designing and documenting simple processes or programs. Like other types of diagrams, they help visualize what is going on and thereby help understand a process, and perhaps also find flaws, bottlenecks, and other less-obvious features within it.

6.5.6.2 There are many different types of flowcharts, and each type has its own repertoire of boxes and notational conventions. The two most common types of boxes in a flowchart are:

- A processing step, usually called *activity*, and denoted as a rectangular box
- A decision, usually denoted as a diamond.

6.5.6.3 A flowchart is described as "cross-functional" which is divided into different that visually distinguishes job sharing and responsibilities for sub-processes of a business process. It may be arranged either horizontally or vertically.

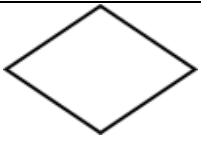
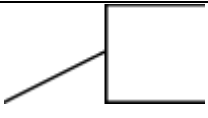
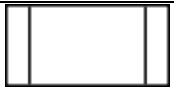
6.5.6.4 This is describing the control of different organizational units. A symbol appearing in a particular "lane" is within the control of that organizational unit.

6.5.6.5 This technique allows the author to locate the responsibility for performing an action or making a decision correctly, showing the responsibility of each organizational unit for different parts of a single process.

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Root Cause Analysis	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANSI/ISO Shape	Name	Description
	Flow line (Arrowhead)	Shows the program's order of operation. A line coming from one symbol and ending at another. Arrowheads are added if the flow is not the standard top-to-bottom, left-to right.
	Terminal	Beginning or ending of a program or sub-process. Represented as a stadium, oval or rounded (fillet) rectangle. They usually contain the word "Start" or "End", or another phrase signaling the start or end of a process, such as "submit inquiry" or "receive product".
	Process	Set of operations that change value, form, or location of data. Represented as a rectangle.
	Decision	Conditional operation determining which of two paths the program will take. The operation is commonly a yes/no question or true/false test. Represented as a diamond (rhombus).
	Input / Output	Input and output of data, as in entering data or displaying results. Represented as a parallelogram.
	Annotation (Comment)	Additional information about a step the program. Represented as an open rectangle with a dashed or solid line connecting it to the corresponding symbol in the flowchart.
	Predefined Process	Named process which is defined elsewhere. Represented as a rectangle with double-struck vertical edges.
	On-page Connector	Pairs of labeled connectors replace long or confusing lines on a flowchart page. Represented by a small circle with a letter inside.
	Off-page Connector	A labeled connector for use when the target is on another page. Represented as a home plate-shaped pentagon.

6.6 FILING OF RCA FORM:

6.6.1 After Root Cause Analysis, RCA Form of Departments shall be filed in QA and recorded in **"Root Cause Analysis Log"** as shown in **Annexure-I**.

6.6.2 Xerox copy of Root Cause Analysis form shall be enclosed with respective Deviation/ Incident Report/ Market Complaint /OOS/OOT / other Report (GMP non-conformance) Xerox copy of Implemented CAPA Form.

7.0 ABBREVIATIONS:

CAPA	Corrective Action and Preventive Action
IPR	Intellectual Property Rights
Ltd.	Limited
No.	Number
QA	Quality Assurance
RCA	Root Cause Analysis
S. No.	Serial Number
SOP	Standard Operating Procedure

8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Root Cause Analysis Log	
Annexure-II	Root Cause Analysis Form	
Annexure-III	Root Cause Analysis by Brain Storming	
Annexure-IV	Root Cause Analysis by Fish Bone Analysis	
Annexure-V	Questionnaire for Sub Cause Identification	
Annexure-VI	Root Cause Analysis by 5- Why's	

9.0 DISTRIBUTION:

- Master Copy Quality Assurance Department
- Controlled Copy No. 01 Quality Assurance Department.
- Controlled Copy No. 02 Quality Control Department.
- Controlled Copy No. 03 Production Department.
- Controlled Copy No. 04 Human Resource Department (HR).
- Controlled Copy No. 05Engineering Department.
- Controlled Copy No. 06 Warehouse Department (Store).
- Controlled Copy No. 07 Information Technology Department

10.0 REFERENCES:

- ICH Q9 Quality Risk Management**,** November 2005
- Root Cause Analysis for Drug makers; 2013

11.0 REVISIONHISTORY:

Revision No.	Change Control No.	Details of Changes	Reason of Changes	Effective Date	Done By
00	Not Applicable	Not Applicable	New SOP		

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Root Cause Analysis	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE–I
ROOT CAUSE ANALYSIS LOG

Year:

S. No.	Date of Issuance of RCA Form	RCA No.	Concerned Department	RCA Logged By QA (Sign & Date)	Reference Deviation / Incident / Market Complaint / OOS/OOT	Ref. No.	Details	RCA Date of Closure	Reference CAPA No.	RCA Closed By (Sign & Date)	Remarks

Note: Text in Header Row is only for representation and Text direction (Orientation) in Log shall be in horizontal position (Left to Right).

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Root Cause Analysis	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE–II
ROOT CAUSE ANALYSIS FORM

Root Cause Analysis No.: **Date:**
Reference (Deviation/ Incident/Market Complaint/OOS/OOT/Non-Conformance) No.:
Problem Description:

_____

_____

_____

RCA Team			
S.No.	**Name**	**Designation**	**Department**

Head QA:

(Sign & Date)

Selection of RCA Tool: Fish Bone Diagram/ 5-Why`s / Both				
S.No.	**Name**	**Designation**	**Department**	**Signature**

Head QA

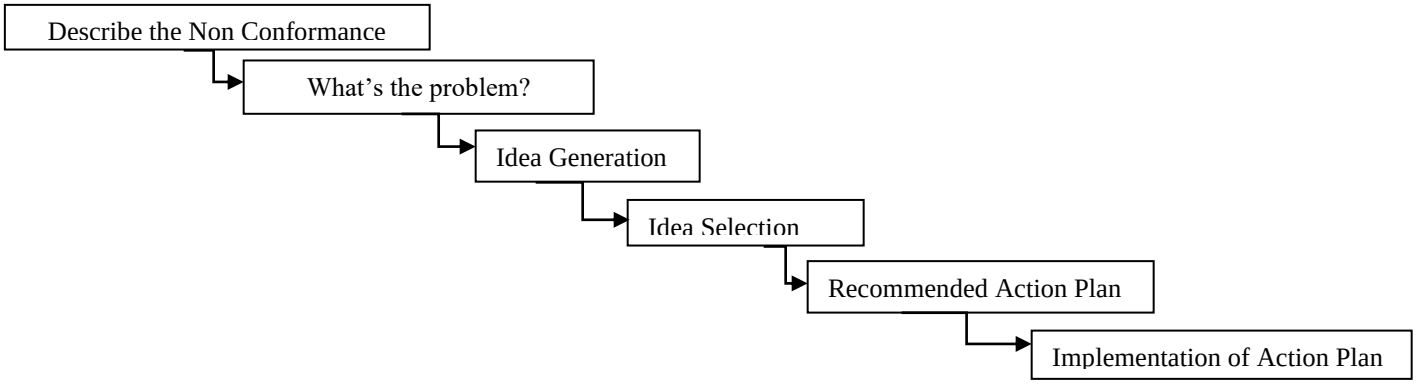
(Sign & Date)

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Root Cause Analysis	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE–III
ROOT CAUSE ANALYSIS BY BRAIN STORMING

Root Cause Analysis No.: **Date:**
RCA Team:

Reference (Deviation/Market Complaint/OOS/OOT/Non-Conformance) No.:



Details of Brain Storming Session:

S.No.	Idea Details	Idea Champion	Idea Selection	Recommended Action Plant	Responsibility	TCD	Remark

Sign & Date (RCA Team) **Sign & Date (RCA Team)** **Sign & Date (Department Head)** **Sign & Date (Manager QA)**

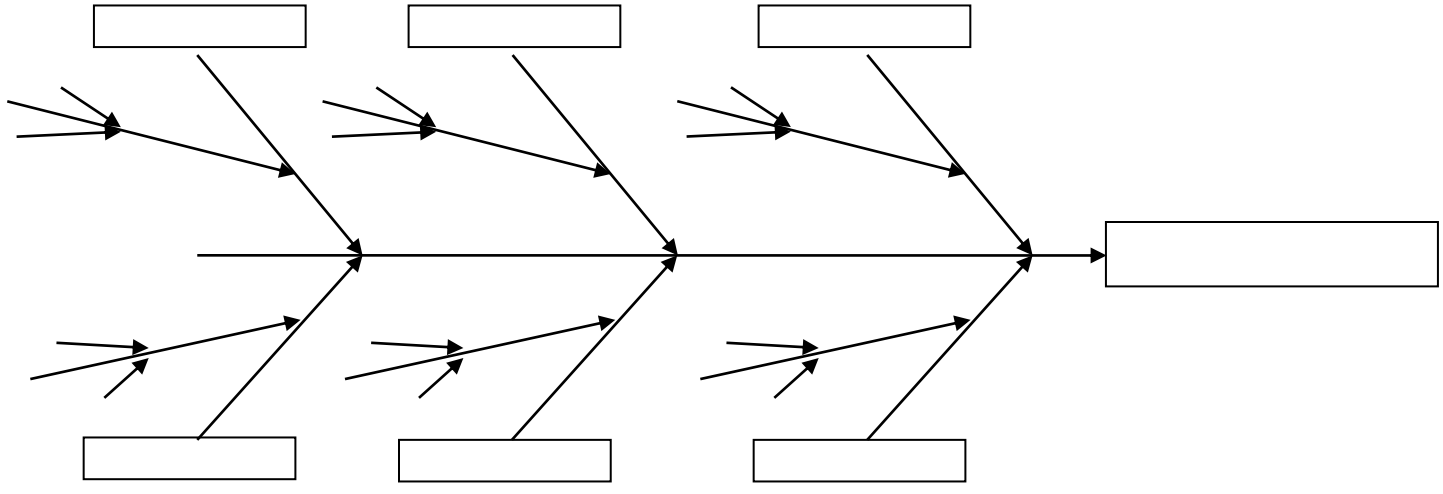
Reference CAPA No.: Required ☐ **Not Required** ☐
If required mention CAPA No.:
Review Comments by Head QA:
Name: **Sign:** **Date:**

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Root Cause Analysis	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE–IV
ROOT CAUSE ANALYSIS BY FISH BONE ANALYSIS

Root Cause Analysis No.: **Date:**

Reference (Deviation/ Incident/Market Complaint/OOS/OOT/ Non-Conformance) No.:



CONCLUSION:

RCA Team **RCA Team** **RCA Team** **Head QA**
(Sign & Date) **(Sign & Date)** **(Sign & Date)** **(Sign & Date)**

Recommendation:

Reference CAPA No.:

Head QA
(Sign & Date)

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Root Cause Analysis	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE–V

QUESTIONNAIRE FOR SUB CAUSE IDENTIFICATION

Principle Cause: Method (Process)
Root Cause Analysis No.: **Date:**
Reference (Deviation/ Incident/Market Complaint/OOS/OOT/Non-Conformance) No.:

S.No.	Question	Yes	No	NA	Remarks
1.	Was the written procedure available in respective Area?				
2.	Was the written procedure approved and of current version?				
3.	Was the procedure followed?				
4.	Was any step of operation done wrongly?				
5.	Was the sequence of operation followed properly?				
6.	Was the each step of operation carried out for specified time & within specified specifications?				
7.	**Any Other Question (If any, Please Specify)**				

Note: Put "√" mark in applicable column
Conclusion: Following Sub Causes identified from above Analysis.
1.
2.
3.
Principal Cause: Machine
Root Cause Analysis No.: **Date:**
Reference (Deviation/ Incident/Market Complaint/OOS/OOT/Non-Conformance) No.:

S.No.	Question	Yes	No	NA	Remarks
1.	Was the Machine/Equipment qualified?				
2.	Was correct change Parts/Tools used?				
3.	Was the Machine/Equipment Calibrated?				
4.	Was the Machine/Equipment of appropriate Capacity?				
5.	Was the Machine/Equipment Cleaned before start of operation?				
6.	Was line clearance taken before start of Operation?				
7.	Was the Machine/Equipment labeled properly?				
8.	Was the correct program selected in PLC of Machine/Equipment?				
9.	Was the Machine/Equipment operated as per written procedure?				
10.	Was the Machine/Equipment used within operating Range				
11.	Whether Machine parameters were set as per approved procedure?				
12.	Was any breakdown observed during the process?				

13.	Is there any wear & tear observed?				
14.	**Any Other Question (If any, Please Specify)**				

Note: Put "√" mark in applicable column

Conclusion: Following Sub Causes identified from above Analysis.

1.
2.
3.

Principal Cause: Material

Root Cause Analysis No.: **Date:**

Reference (Deviation/Incident/Market Complaint/OOS/OOT/Non-Conformance) No.:

S.No.	Question	Yes	No	NA
1.	Were right materials of right A.R. No. & grade used in manufacturing?			
2.	Were the used materials approved?			
3.	Was the line clearance taken before starting of Dispensing?			
4.	Were the environmental conditions of dispensing area meet with specifications?			
5.	Was the dispensing performed as per written procedure?			
6.	Was the exact quantities dispensed as per BOM/BMR/BPR?			
7.	Was any incident observed during dispensing operation?			
8.	Was the cleaned dispensing tools used in dispensing?			
9.	Was the dispensed material properly packed?			
10.	Was the dispensed material properly labeled?			
11.	Were the materials verified on production floor?			
12.	Was any spillage observed during manufacturing?			
13.	Was there any observation regarding to any of materials during Manufacturing/handling?			
14.	**Any Other Question (If any, Please Specify)**			

Note: Put "√" mark in applicable column

Conclusion: Following Sub Causes identified from above Analysis.

1.
2.
3.

Principal Cause: Man

Root Cause Analysis No.: **Date:**

Reference (Deviation/ Incident/Market Complaint/OOS/OOT/Non-Conformance) No.:

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE

Department: Quality Assurance	**SOP No.:**
Title: Root Cause Analysis	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

S.No.	Question	Yes	No	Not Applicable
1.	Is the person qualified enough to perform the assigned work?			
2.	Is the person having enough experience to perform the assigned work?			
3.	Was the person trained to perform the assigned work?			
4.	Was the personnel followed proper gowning during operation?			
5.	Were the personnel in good health & hygiene condition?			
6.	Was any of person wear wrist watch, jewelry, bangles, rings etc. during operation?			
7.	Was the sufficient number of personnel available to perform the activity?			
8.	Were the Procedure & specification interpreted properly?			
9.	**Any Other Question (If any, Please Specify)**			

Note: Put "√" mark in applicable column

Conclusion: Following Sub Causes identified from above Analysis.

1.
2.
3.

Principal Cause: Measurement

Root Cause Analysis No.: **Date:**

Reference (Deviation/ Incident/Market Complaint/OOS/OOT/ Non-Conformance) No.:

S.No.	Question	Yes	No	No Applicable
1.	Was the measuring device in calibrated state?			
2.	Was the measuring device cleaned?			
3.	Was the measuring device repaired before the use?			
4.	Is the display of measuring device working properly?			
5.	Is there any defect in Measuring device?			
6.	Was the written operating procedure available?			
7.	Was the written procedure followed for measurement?			
8.	Was any problem observed during measurement?			
9.	**Any Other Question (If any, Please Specify)**			

Note: Put "√" mark in applicable column

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Root Cause Analysis	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Conclusion: Following Sub Causes identified from above Analysis.

1.
2.
3.

Principal Cause: Milieu (Environment)

Root Cause Analysis No.: **Date:**

Reference (Deviation/ Incident/Market Complaint/OOS/OOT/ Non-Conformance) No.:

S.No.	Question	Yes	No	Not Applicable
1.	Was the Process/Operation carried out in designated area?			
2.	Was the Area qualified?			
3.	Was the process area clean at the time of start of Process/Operation?			
4.	Was the area sanitized at defined frequency?			
5.	Was the temperature & Relative Humidity within specified limit?			
6.	Is the intensity of light in the Area proper?			
7.	Was the operation carried out under specified light condition (i.e. Monochromatic Light)?			
8.	Was there any observation related to Temperature & Relative Humidity during Process/Operation?			
9.	Was there any breakdown in HVAC during Process/Operation?			
10.	Is the area in good state of condition?			
11.	Is the door of the area properly closed?			
12.	Is the door interlock of the Area work properly?			
13.	Door interlock of Material entry pass- box/Hatch work properly?			
14.	Is the area free from rusted/ unclean articles (Tools/Machine Parts etc.)?			
15.	**Any Other Question (If any, Please Specify)**			

Note: Put "√" mark in applicable column

Conclusion: Following Sub Causes identified from above Analysis.

1.
2.

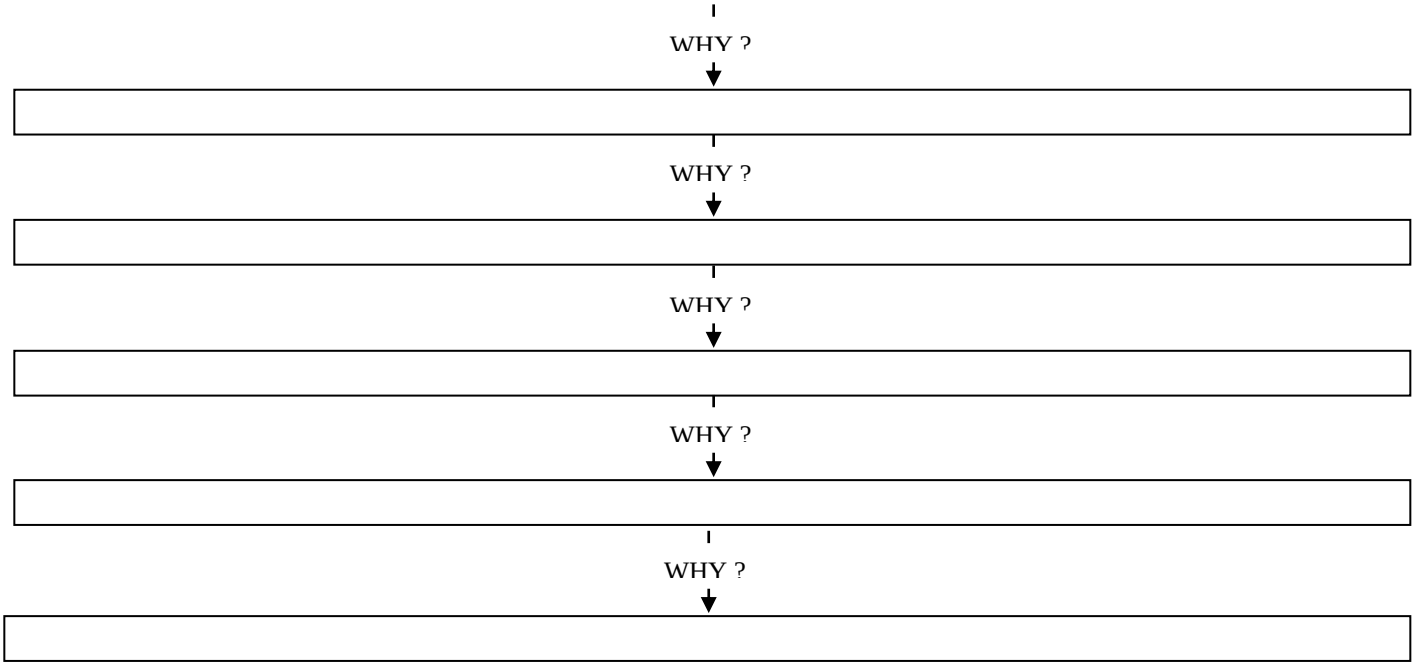
STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Root Cause Analysis	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

ANNEXURE – VI
ROOT CAUSE ANALYSIS BY 5-WHY`s

Root Cause Analysis No.: **Date:**

Reference (Deviation/Incident/Market Complaint/OOS/OOT/Non-Conformance) No.:
Problem Description:

_____
_____
_____



CONCLUSION / IDENTIFIED ROOT CAUSE (S):

–

RCA Team (Sign & Date)	**RCA Team (Sign & Date)**	**RCA Team (Sign & Date)**	**Head QA (Sign & Date)**

DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE	
Department: Quality Assurance	**SOP No.:**
Title: Root Cause Analysis	**Effective Date:**
Supersedes: Nil	**Review Date:**
Issue Date:	**Page No.:**

Recommendation:

_____

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_____

_____

_____

Reference CAPA No.:

Head QA
(Sign & Date)