



# DECODING PHARMA

QUALITY ASSURANCE DEPARTMENT

## STANDARD OPERATING PROCEDURE

<b>Department:</b> Quality Assurance	<b>SOP No.:</b>
<b>Title:</b> Trend Preparation for QMS Documents	<b>Effective Date:</b>
<b>Supersedes:</b> Nil	<b>Review Date:</b>
<b>Issue Date:</b>	<b>Page No.:</b>

### 1.0 OBJECTIVE:

To lay down the Procedure for Preparation of QMS trends.

### 2.0 SCOPE:

This SOP is applicable for Preparation of trends related to QMS documents like change control, incident & deviation to be followed at .....

### 3.0 RESPONSIBILITY:

**QA (Officer/ Executive):** Preparation, Distribution, Revision, Retrieval and Destruction of this SOP.  
Preparation of trends related to QMS documents.

### 4.0 ACCOUNTABILITY:

**Head QA:** Approval, ensure Training and Implementation of this SOP. Approval of trend data prepared for QMS documents and give review comments.

### 5.0 DEFINITIONS:

- 5.1 Deviation:** It is a departure from Approved Procedure, Specifications or Protocols.
- 5.2 Incident:** An event which may or may not affect the product quality but is a violation of cGMP.
- 5.3 Change Control:** It is a systematic approach to managing all changes made to a product or system, to ensure that changes are carry out in a controlled and organized manner. Changes can be related to facility, documentation, system, equipment, instrument, procedure, layouts and products etc.

### 6.0 PROCEDURE:

- 6.1** QA Officer/Executive shall maintain the log of QMS documents like change control, deviation & incident as per their respective SOP's.
- 6.2** On the basis of log of QMS documents, QA Officer/Executive shall prepare the trend of QMS documents quarterly as per format presented in Annexure-I, II & III for trend charts.
- 6.3** After preparation of trend data, it shall be reviewed by Manager QA and approved by Head QA and Review Comments shall be given by Head QA.



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### 7.0 ABBREVIATIONS:

cGMP	Current Good Manufacturing Practices
Ltd.	Limited
No.	Number
Pvt.	Private
QA	Quality Assurance
SOP	Standard Operating Procedure

### 8.0 ANNEXURES:

ANNEXURE No.	TITLE OF ANNEXURE	FORMAT No.
Annexure-I	Trend Charts for Change Control	
Annexure-II	Trend Charts for Deviation	
Annexure-III	Trend Charts for Incident	

### 9.0 DISTRIBUTION:

- Master Copy                      Quality Assurance Department
- Controlled Copy No. 01        Quality Assurance Department.

### 10.0 REFERENCES:

In-House

### 11.0 REVISION HISTORY:

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



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### ANNEXURE-I

### TREND CHARTS FOR CHANGE CONTROL

Trend between No. of Change Controls & Category of Change Controls:

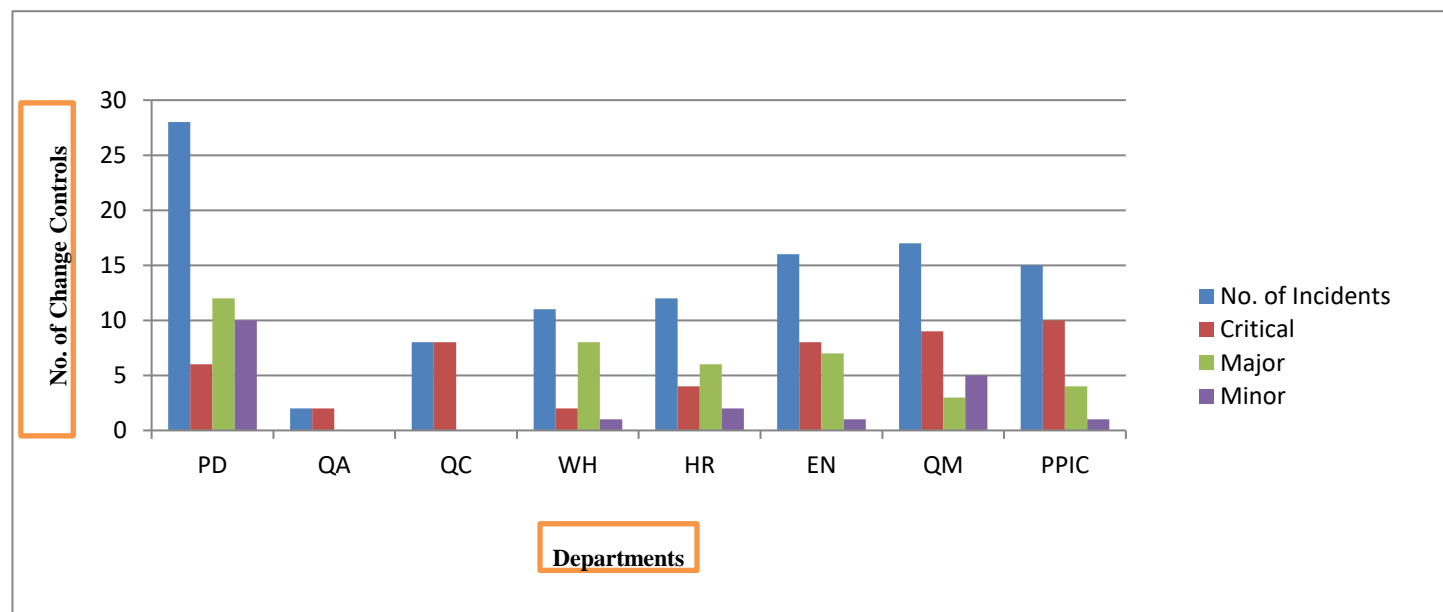
Year:

Month:

Frequency: Quarterly

S.No.	Department	Total No. of Change Controls	Number of Change Controls Category wise		
			Minor	Major	Critical
1.					
2.					
3.					

No. of Change Controls Vs Category of Change Controls from \_\_\_\_\_ to \_\_\_\_\_ Month Department wise



Review Comments:

Prepared By:  
Officer/Executive QA  
(Sign & Date)

Reviewed By  
Manager QA  
(Sign & Date)

Approved By:  
Head QA  
(Sign & Date)



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### ANNEXURE-II

### TREND CHARTS FOR DEVIATION

Trend between No. of Deviations & Category of Deviations:

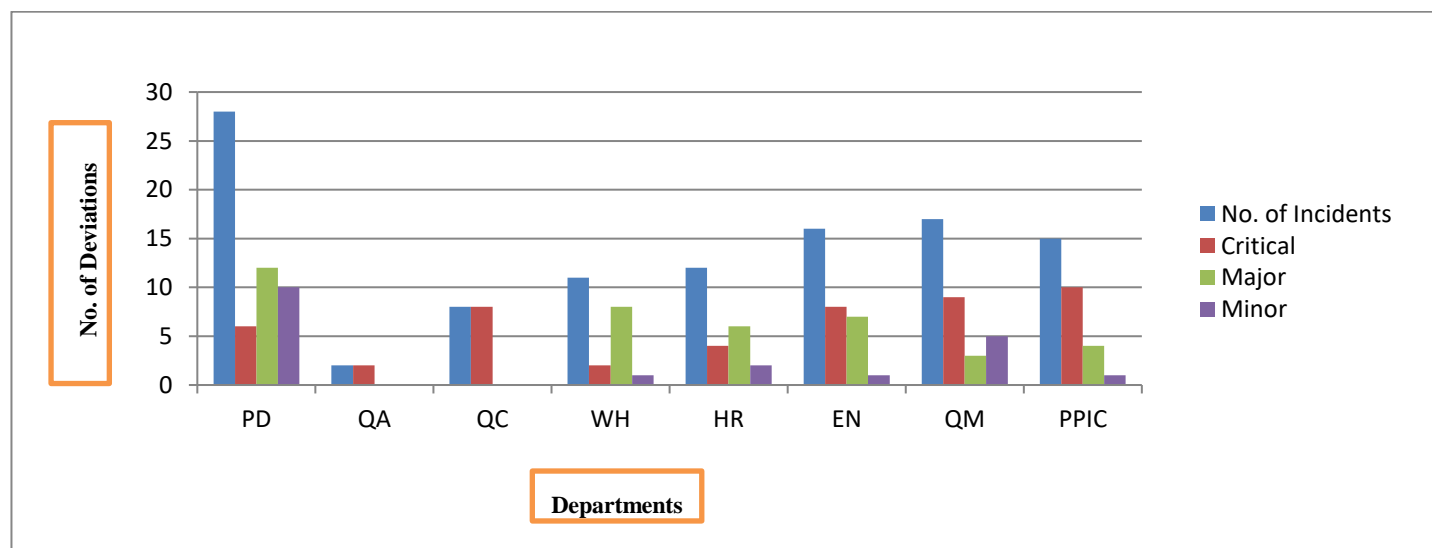
Year:

Month:

Frequency: Quarterly

S.No.	Department	Total No. of Deviations	Number of Deviations Category wise		
			Minor	Major	Critical
1.					
2.					
3.					

No. of Deviations Vs Category of Deviations from \_\_\_\_\_ to \_\_\_\_\_ Month Department wise



Review Comments:

Prepared By:  
Officer/Executive QA  
(Sign & Date)

Reviewed By  
Manager QA  
(Sign & Date)

Approved By:  
Head QA  
(Sign & Date)



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### ANNEXURE-III

### TREND CHARTS FOR INCIDENT

#### Trend between No. of Incidents & Category of Incidents:

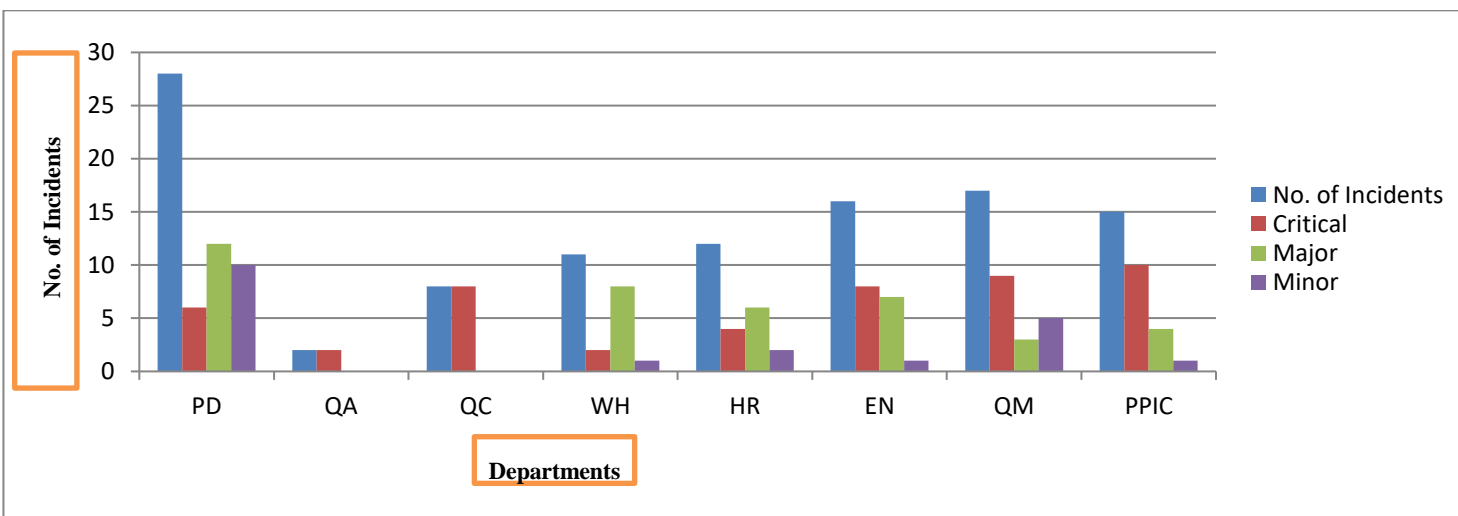
Year:

Month:

Frequency: Quarterly

S.No.	Department	Total No. of Incidents	Number of Incidents Category wise		
			Minor	Major	Critical
1.					
2.					
3.					

No. of Incidents Vs Category of Incidents from \_\_\_\_\_ to \_\_\_\_\_ Month Department wise



Review Comments:

Prepared By:  
Officer/Executive QA  
(Sign & Date)

Reviewed By  
Manager QA  
(Sign & Date)

Approved By:  
Head QA  
(Sign & Date)