

PHARMA DEVILS QUALITY ASSURANCE DEPARTMENT

STANDARD OPERATING PROCEDURE				
Department: Quality Assurance SOP No.:				
Title: Trend Preparation for QMS Documents	Effective Date:			
Supersedes: Nil	Review Date:			
Issue Date:	Page No.:			

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.



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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.

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	Done By
				Date	
00	Not Applicable	Not Applicable	New SOP		



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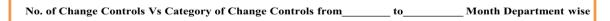
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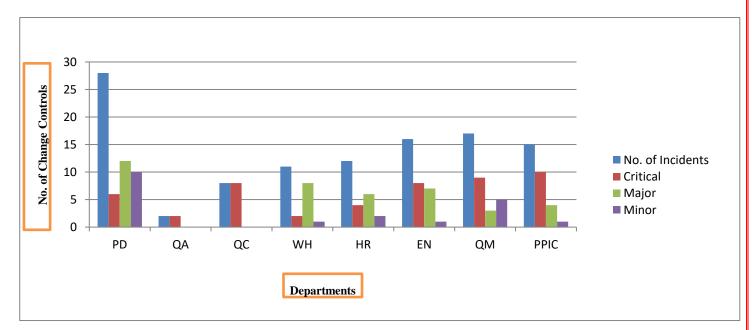
ANNEXURE-I

TREND CHARTS FOR CHANGE CONTROL

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

Year:		Mon	Ionth: Frequency: Quarterly		
S.No.	Department	Total No. of Change	Number of Change Controls Category wis		Category wise
		Controls	Minor	Major	Critical
1.					
2.					
3.					





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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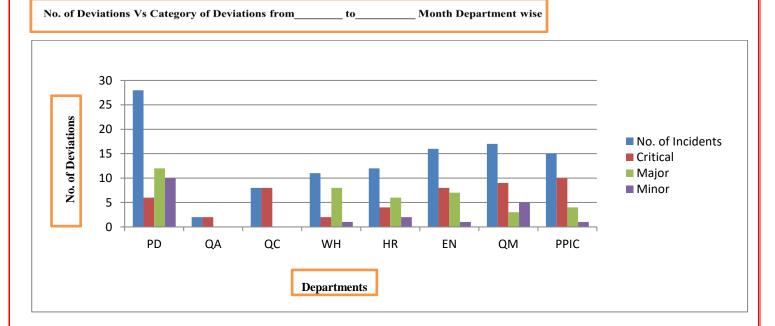
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ANNEXURE-II

TREND CHARTS FOR DEVIATION

Trend between No. of Deviations & Category of Deviations:

Year:		Month:		Frequency: Quarterly		
S.No.	Department	Total No. of	Number of Deviations Category wise		y wise	
		Deviations	Minor	Major	Critical	
1.						
2.						
3.						



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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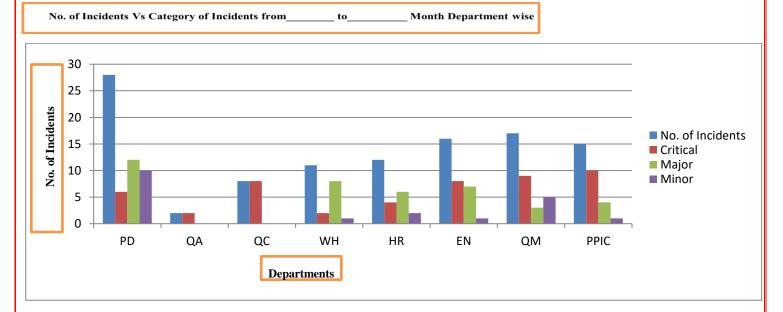
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ANNEXURE-III

TREND CHARTS FOR INCIDENT

Trend between No. of Incidents & Category of Incidents:

Year:		Month:	Frequency: Quarterly		
S.No.	Department	Total No. of	Number of Incidents Category wise		v wise
		Incidents	Minor	Major	Critical



Review Comments:

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

Reviewed By Manager QA (Sign & Date) **Approved By:** Head QA (Sign & Date