 Discovery Labs	<b>STANDARD OPERATING PROCEDURE</b>			
	SOP No.:	SOP-QA-023-02	Effective Date:	01.01.2018
	Supersedes:	QA-023-01	Next Review Date:	31.12.2020
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<b>TITLE: TREND ANALYSIS</b>				

## 1.0 PURPOSE:

To lay down a procedure for trend analysis of trend analysis of manufacturing process of various products being manufactured at Discovery Laboratories Pvt. Ltd.

DM water and process water and to provide a procedure for carrying out the investigations for out of Trend results as and when observed.

## 2.0 SCOPE:

This SOP is applicable to all Raw materials, various stages of Intermediates, API's, Stability studies, DM water and process water being produced at Discovery Laboratories Pvt. Ltd.

## 3.0 RESPONSIBILITY:

- 3.1 It is the responsibility of Quality Assurance department to carry out trend analysis as written in this SOP.
- 3.2 It is the responsibility of Quality Control to investigate the Out of trend result in Co-ordination with quality Assurance and production departments as per the procedure defined in this SOP.


## 4.0 DEFINITIONS:

Nil

## 5.0 PROCEDURE:

- 5.1 For all the Raw Materials, Intermediates finished Products, process water and water.
- 5.2 Compile the data of yield quality parameters that were mentioned in the Batch Production records and analytical test reports/ raw data books against the set of Specifications using Microsoft excel.
- 5.3 The data shall be reviewed by second person. If a define trend (getting, worse or better) is observed in the yield or analytical parameters, the causes for the same shall be investigated and the investigation details are to be reported.
- 5.4 Once the cause for the out of trend is determined, corrective action shall be proposed. Approved and implemented.

	<b>Prepared by</b>	<b>Reviewed by</b>	<b>Approved by</b>
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5.5 In case where the trend analysis shows significant shift in actual trend that has been established, a thorough review of the causes that contributes to the shift need to be carried out based on the conclusion drawn and corrective action taken.

5.6 If any batch results is found more or less than the defined limits shall be treated as “Out of trend” and need to initiate investigation for identifying the cause.

5.7 When all the results fall within the limits (UCL and LCL), the results are said to be in the state of Statistical ‘Quality control’.

**5.8 Procedure for investigation of Out Of Trend Results:**

OOT in quality parameter follow as per OOT SOP current Version QC-031.

**6.0 FORMATS / ANNEXURE(S):**

Nil

**7.0 CHANGE HISTORY:**

Revision No.	Effective Date	Details of Revision	Ref CCF No.
00	01.07.2009	New SOP is introduced.	--
01	15.06.2014	Formats are the part of SOP. Sp prepared separately and more clarity	--
02	01.01.2018	SOP format changed make to inline with SOP-QA-001-05.	CCF/GEN/ 17037

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