STANDARD OPERATING PROCEDURE	
Department: Quality Control	**SOP No.:**
Title: Analytical Raw Data Entry, Verification and Generation of Certificate of Analysis	**Effective Date:**
Supersedes: Nil	**Review Date:**
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1.0 OBJECTIVE:

To lay down a procedure for Analytical raw data entry & verification and generation of Certificate of analysis.

2.0 SCOPE:

This SOP is applicable to Analytical raw data entry & verification and generation of Certificate of analysis for finished products, raw materials, and packaging materials, microbial reports, stability reports and in process samples in quality control. This also applicable for market sample and Pre shipment samples and validation samples.

3.0 RESPONSIBILITY:

Officer/Executive – Quality Control and Quality Assurance

Head – Quality Control

4.0 PROCEDURE:

4.1 Entry of Raw data:

4.1.1 The analyst shall enter all the raw data pertained to the material/product in the raw data sheet issued to him.

4.1.2 The analyst shall enter all the data on line during the analysis.

4.1.3 The analyst shall ensure that only valid (within their assigned shelf life) reagents and solutions are being used for analysis.

4.1.4 Analyst shall attach all relevant chromatograms and printouts to the data sheet wherever applicable and the same shall be mentioned in the data sheet.

4.2 Verification of Data:

4.2.1 All the data shall be verified for each test by competent personnel/by the reviewer. There should no long time gap between execution of analysis and subsequent review.

4.2.2 Checking shall be done for all relevant data as mentioned in Annexure I, (but not limited to the list). Any relevant details other than listed, but are specific to the test, shall also be verified by the

checker.

4.2.3 The checker shall ensure that all the relevant attachments are available with the data sheet.

4.2.4 COA shall be checked by the executive or his designee of quality control against the raw data sheet and specifications and also review the chromatogram soft copy by the quality control reviewer.

4.2.5 After completion of QC personal checking COA, raw data sheet along with printouts and all relevant chromatograms shall be handed over to quality assurance for further review.

4.2.6 Section head/reviewer or his designee shall review the analytical raw data sheet, chromatograms, chromatography soft data and COA. After reviewing quality assurance person same shall be handover to quality control.

4.2.7 During review if any observation made by Section head/reviewer or his designee same shall be investigate jointly and corrected with proper corrective and preventive action.

4.2.8 The data sheet and the COA shall be finally approved by the head of quality control.

4.3 Generation of Certificate of analysis.

4.3.1 Certificate of analysis shall be prepared after the analysis is over and the respective raw data sheet is checked and reviewed.

4.3.2 The COA shall be prepared by computer generation or PQR module.

4.3.3 A copy of COA shall be given to QA department for reference. The COA along with data sheet and attachments shall be then filed accordingly.

4.3.4 Certificate of analysis for Raw material, Packing material, Finished product a, In process/validation and water shall be prepared as per Annexures II, III, IV, V and IX respectively.

4.3.5 Reports of microbiological department are generated as per individual relevant SOPs of the department.

4.3.6 The COA of Preshipment sample (raw material) shall be prepared as per Annexure-VI. The COA of market sample (finished product) shall be prepared as per Annexure-VII and the COA of market sample (finished product) for BE (Bio-equivalence) studies shall be prepared as per Annexure-VIII.

4.3.7 The copies of the COA for the requirement of other Department/ agencies/Regulatory affairs shall

be reproduced from the original report data and shall be checked and approved by concerned and shall be issued on current date.

4.3.8 For Retest material, the tests which are not performed, the results shall be reported from initial report for preparation of COA.

5.0 ANNEXURE (S):

Annexure – I : Check list for checking analytical raw data.

Annexure – II : Certificate Of Analysis (Raw Material)

Annexure – III : Certificate Of Analysis (Packing Material)

Annexure – IV : Certificate Of Analysis (Finished Product)

Annexure – V : Certificate Of Analysis (In-process Samples)

Annexure – VI : Certificate Of Analysis (Raw Material - Pre shipment samples)

Annexure – VII : Certificate Of Analysis (Market Sample)

Annexure – VIII: Certificate Of Analysis (Market Sample for BE Studies)

Annexure – IX: Certificate Of Analysis (Water).

6.0 REFERENCE (S):

Nil

7.0 ABBREVIATION (S) /DEFINITION (S):

QC - Quality Control

QA - Quality Assurance

COA – Certificate of analysis

PQR – Product Quality Review

GRN – Goods Received Note

BE - Bio Equivalence

LOD – Loss On Drying

TLC – Thin Layer Chromatography

PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

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REVISION CARD

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION	REFERENCE CHANGE CONTROL No.
1	00	---	---	New SOP	-

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ANNEXURE I
CHECK LIST FOR CHECKING THE ANALYTICAL RAW DATA

S.No.	Checking Parameter
1.	Batch details against inward register.
2.	Specification and Standard Test procedures are current.
3.	Instruments are within calibration due date/within grace period when the analysis has been carried out.
4.	Reagents/volumetric solutions validity (within assigned shelf life).
5.	Check logs book entry of instrument logs.
6.	Verification of contract lab reports and report Nos. (if any)
7.	Instruments Identification Number is mentioned.
8.	Chromatograms/spectrums /IR spectrum are checked and attached
9.	Working standards validity/purity is checked.
10.	Working standard/primary standard reference/ID No. is mentioned.
11.	System suitability checks.
12.	Chromatographic column no. checks.
13.	TLC plates or prints are checked by checker.
14.	Microbial reports are attached (wherever applicable).
15.	All relevant attachments are available (GRN, supplier's COA, etc).
16.	Calculation and dilution are checked.
17.	Specimen of under test, approved labels with batch details are attached
18.	Retest date is correctly assigned.
19.	Identification tests for containers are performed and relevant data are attached (Applicable for Raw Material).
20.	Data for LOD/Water and assay for group samples are done and relevant data are attached. (Applicable for Raw Material)
21.	Specimen sample (wherever applicable) is attached (Applicable for Packing material).
22.	Full web sheet is available (Applicable for Packing material).
23.	Roll labels are numbered correctly. (Applicable for Packing material)

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ANNEXURE II

CERTIFICATE OF ANALYSIS (RAW MATERIAL)

Name of the Material			
GRN No. & Date		**Item Code**	
Batch No.		**A. R. No.**	
Mfg. Date		**Exp. Date**	
Quantity Received		**Retest Date**	
Manufacturer		**Supplier**	
Date of Sampling		**Date of Release**	
SPC No.		**STP No.**	

S.No.	Test	Specification	Observation

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ANNEXURE III
CERTIFICATE OF ANALYSIS (PACKING MATERIAL)

Name of the Material			
GRN No. & Date		**Item Code**	
Batch No.		**A. R. No.**	
Manufacturer		**Supplier**	
Quantity Received		**Date of Sampling**	
SPC No.		**Date of Release**	

S.No.	Test	Specification	Observation

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ANNEXURE IV
CERTIFICATE OF ANALYSIS (FINISHED PRODUCTS)

Product		**A. R. No.**	
Batch No.		**Batch Size**	
Packing Batch No.		**Packing Batch size**	
Mfg. Date		**Exp. Date**	
Date of Analysis		**Date of Report**	
SPC No.		**STP No.**	

S.No.	Tests	Specification	Result

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ANNEXURE V

CERTIFICATE OF ANALYSIS (IN-PROCESS SAMPLES)

Product			
Batch No.		**A. R. No.**	
Batch Size		**Mfg. Date**	
Date of Analysis		**Exp. Date**	
Stage		**Date of Release**	
SPC No.		**STP No.**	

S.No.	Tests	Specification	Result

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ANNEXURE VI
CERTIFICATE OF ANALYSIS (RAW MATERIAL - PRE SHIPMENT SAMPLES)

Name of the Material			
GRN No. & Date		**Item Code**	
Batch No.		**A. R. No.**	
Mfg. Date		**Exp. Date**	
Quantity Received		**Retest Date**	
Manufacturer		**Supplier**	
Date of Sampling		**Date of Release**	
SPC No.		**STP No.**	

S.No.	Test	Specification	Observation

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ANNEXURE VII
CERTIFICATE OF ANALYSIS (MARKET SAMPLE)

Product			
Batch No.		**A. R. No.**	
Mfg. Date		**Batch Size**	
Exp. Date		**Pack**	
Date of Analysis		**Date of Report**	
SPC No.		**STP No.**	

S.No.	Tests	Specification	Result

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ANNEXURE VIII
CERTIFICATE OF ANALYSIS (MARKET SAMPLE FOR BE STUDIES)

Product			
Lot. No.		**A. R. No.**	
Mfg. Date		**Exp. Date**	
Mfg. by		**Pack**	
Date of analysis		**Date of Report**	
SPC No.		**STP No.**	

S.No.	Test	Specification	Observation

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ANNEXURE IX
CERTIFICATE OF ANALYSIS (WATER)

Types of Water			
Sampling Point		**A. R. No.**	
Date of analysis		**Date of Release**	
SPC No.		**STP No.**	

S.No.	Test	Specification	Observation