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1.0 PURPOSE:

To lay down the procedure for preparation of Specification and Method of Analysis and assigning of AR Numbering System in Quality control.

2.0 SCOPE:

This SOP is applicable to the Procedure followed for the Preparation of Specification and Method of Analysis and A R Numbering System in Quality control department at Discovery.

3.0 RESPONSIBILITY:

- 3.1 Analyst-QC is responsible to follow this SOP.
- 3.2 Head-QC/Designee is responsible for ensuring implementation of this SOP.
- 3.3 Head-QA/Designee is responsible for monitoring overall compliance of this SOP.


4.0 DEFINITIONS:

Specification: A list of tests, references to analytical procedures and appropriate acceptance criteria
Record:

5.0 PROCEDURE :

- 5.1 To provide clear instructions to personnel for performing a particular operation in a systematic, consistent and safe manner.
- 5.2 To comply with the pharmacopeia or in-house requirements.
- 5.3 If finished product two or more specification and testing procedure(s) are to be prepared separately then the isolation, shall be addressed in the reference column available in product details.
- 5.4 Each Specification & testing procedure shall have the following:
 - 5.4.1 Header
 - 5.4.2 Footer
 - 5.4.3 Body of the STP

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name	A.Navya	S.Prasad	Ch.Mahendar Reddy
Department	Quality Control	Quality Control	Quality Assurance

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5.5 Specification and Testing Procedure shall contain following details:

S. No.	Parameter	Standards
1	Paper	White Paper
2	Paper size	A 4
4	Header	Company logo on left side.
5	Heading	As Specification & Testing procedure in bold capitals, font size 12 in times new roman font.
6	Title	Title of the Specification Product Name typed in bold capital letters with font size 12 in Times New roman font.
7	STP number, supersede, effective date, next review date, page number, department and category,	Font size 12 in Times new roman font.
8	Sub Headings	Bold and Font size 12 in Times New roman font.
9	Footer	Name, Department, Sign and date for prepared by, Reviewed by & Approved by for all pages with Times New Roman font and size 12.
10	Paragraph line spacing	1.5 lines

5.6 Body of the Specification & Testing procedure shall contain the following:

5.6.1 Specification


5.6.2 Product details

5.6.3 Testing procedure

5.7 **Product details:**

5.7.1 For finished products (dispatch batch / final API) the product details shall contain the parameters like Chemical name, reference, structure, molecular weight, molecular formula, total composite sample quantity, CAS Number, storage conditions and packaging details.

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5.7.2 For intermediate the product details shall contain molecular formula, molecular weight, storage conditions, sample quantity for analysis. For raw materials along with the above parameters type of material (i.e. General /Key starting material) also shall be mentioned.

5.7.3 For packing material, in-process cleaning samples no need to maintain product details.

5.8 **Specification:**

Specification shall contain Serial number, Test parameter and Specification limit.

5.9 **Testing procedure:**

The testing procedures shall describe clearly about the apparatus required to carry out the test, the quantities of samples and reagents, preparation of test and standard solutions, mathematical calculation of the test and where to record the results of the test.

5.10 **Work sheet / Analytical raw data (Format):**

The formats which are maintained with respect to the STP are to be listed in this section. Format prepared by, reviewed by, approved by, sign & date with date shall be printed back side of the format.

5.11 **Change history:**

Revision history shall be addressed through revision number, effective date, details of changes and ref change control number.


5.12 **STP Header and Footer:**

5.12.1 STP Header and footer should be as shown in below header respectively.


5.12.2 In header all columns shall be printed.

5.12.3 In footer, except sign and date all remaining columns shall be printed.

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Sign & Date			
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5.13 Header:

 1	SPECIFICATION & TESTING PROCEDURE ²			
	STP No.: ³		Effective Date: ⁶	
	Supersedes : ⁴		Next Review Date: ⁷	
	Department: ⁵		Page: ⁸	
TITLE: ⁹				Category: ¹⁰

5.14 Footer:

	Prepared by	Reviewed by	Approved by
Sign & Date			
Name			
Department			

5.15 Cell 1: Company Logo given in header at left side top of STP.


5.16 Cell 2: The name of the document i.e. ‘Specification & Testing Procedure’, It shall be printed at center of the cell.

5.17 Cell 3: STP Number, which a unique number is given to each STP Product Wise.

5.17.1 Whenever STP is revised through change control procedure. Version numbers will be 01, 02, and 03 and so on. New STP will have the version number as “00”. Training shall be given for all the concerned personnel in between Approval and Effective dates. If any person is not available within the above dates he/she shall be trained before followed revised STP / new STP.

5.18 Cell 4: Supersede is the reference of earlier effective Specification & Testing procedure number with its revision number and it shall be written under this heading. For any new STP shall be written as ‘NIL’ in supersede column.

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- 5.19 Cell 5: Department is the name of the originating department of specification & testing procedure. It shall be written in sentence case letters with font size 12 in times new roman.
- 5.20 Cell 6: Effective date is the date from which the particular specification & testing procedure shall be effective for implementation. The effective date for a STP Shall pre-printed. Allowing training and other requisites to be completed before effective date.
- 5.21 Cell 7: Review date is the date on which the STP should be revised once in three years or tolerance, \pm two months tolerance is acceptable to revise the STP. If required revised the STP through CMF before review date.
- 5.22 All the date(s) i.e. Effective Date and Review Date in the STP shall be printed as DD/MM/YYYY / DD.MM.YYYY / DD-MM-YYYY / DD/MM/YY / DD.MM.YY / DD-MM-YY.
- DD represents the date, MM represents the month, YY or YYYY represents the calendar year.
Ex.: 31.12.2016
- 5.23 Cell 8: It is the Page Number of the respective page along with total number of pages in the document it shall be given in X of Y format, where X is page number Y is total number of pages of the specification & testing procedure.
- 5.24 Cell 9: Title for name of the product /material for which STP is prepared all characters shall be in bold capital letters with font size 12 in times new roman.
- 5.25 Cell 10: Category represents the respective product/material category like, In-Process, Intermediate, Finished, RM and PM etc.

5.26 Raw data format preparation procedure:

- 5.26.1 In the body matter of the analytical raw data reference STP No., Batch number (B. No), AR No and Released on details should be mentioned.

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5.26.2 Above details are not required for Water, In-process and Cleaning Sample raw data.


5.26.3 Each and every analysis in the analytical raw data should have provision for analyzed by signatures along with date. End of the analytical raw data, checked by should be mentioned.

5.26.4 Analytical Raw Data for Finished, Intermediate and Cleaning sample first page header shall be follows header-1, remaining all pages follows header-2.

5.26.4.1 Header – 1

 Discovery	FINISHED PRODUCT / INTERMEDIATE/ RAW MATERIAL / PACKING MATERIAL/WATER ANALYTICAL RAW DATA		
Name of the Material			
STP Ref. No.			
AR. No.		Batch No.	


5.26.4.2 Header – 2:


 Discovery	FINISHED PRODUCT / INTERMEDIATE/ RAW MATERIAL / PACKING MATERIAL/WATER ANALYTICAL RAW DATA		
Name of the Material			
Batch No.			

5.26.5 For In-process analytical raw data first page shall be as shown in header-1 and remaining pages shall be shown in header – 2.


5.26.5.1 Header-1:

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	IN-PROCESS / CLEANING SAMPLE ANALYTICAL RAW DATA
Name of the Material	
STP Ref. No.	
Batch No.	


5.26.5.2 Header – 2:

	IN-PROCESS / CLEANING SAMPLE ANALYTICAL RAW DATA
Name of the Material	
Batch No.	

5.27 Procedure for sample Inward and Assigning of AR Number:

- 5.27.1 Each and every sample that is being received or sampled by Quality Control department shall be assigned a unique identification number and is defined as “Analytical Report Number” i.e. A.R.No.
- 5.27.2 Analytical report numbering system varies with the type of the material.
- 5.27.3 There are different types of materials that are being brought to Quality Control department. Materials like Raw materials, packing materials, In-process samples, Intermediates, Finished products, Water samples, Holding samples, Recovery solvents etc.
- 5.27.4 When the sample/analytical test requisition is received by user department, Quality Control personnel shall be update the details in respective inwards register.
- 5.27.5 After generating the ‘Analytical Report Number’ in the inward register, the same number shall be entered in the ‘Analytical Test Requisition’ sheet.

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5.27.6 Quality Control should maintain separate inward registers for each type of the material.

5.27.7 Based on the type of the material, the samples shall be assigned a unique A.R. No., which shall be entered in their respective inward registers.

5.27.8 Inward registers shall be maintained monthly for In-process samples and raw material intermediate samples other remaining samples registers are shall be maintained annually or accordingly.

5.27.9 A new inward register shall be issued for each type of material from Quality Assurance department at the starting of the New Year.

5.27.10 After completion, the respective inward registers shall be handed over to the Quality Assurance department.

5.28 Analytical Report Numbering System:

5.28.1 Numbering System (System-1)

A.R. Number : XXZZNNNN

XX indicates : Material code (as per table)

ZZ indicates : Last two digits of the calendar year (16 for the year 2016)


NNNN indicates : Sequential serial number starts from '0001' (from 1st January to 31st December)

The above-mentioned Analytical report numbering system shall be assigned for the following list of samples. (Table-1)

Ex: RM160001 indicates the first Raw material sample received in January, 2016.

S.No.	Type of the Material	Code
1.	Raw Material	RM
2.	Packing Material	PM

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S.No.	Type of the Material	Code
3.	Re-testing	RT
4.	Vendor samples	VS
5.	Raw Water	RW
6.	Potable Water	PW

5.28.2 AR Numbering System (System-2):

For ‘Product samples’: XXX/IPYYNNNN, for Recovery solvent as: XXX/RSPPP/YNNNN

XXX indicates: product code with stage (separate in process record shall be maintained for stage wise)

IP indicates: in process

PPP indicates: Solvent code (for recovery solvents only)

YY indicates: Last two digits of the calendar year (16 for the year 2016)

NNNN indicates: Sequential serial number starts from ‘0001’ (from 1st January to 31st December)


Eg-1: EZB-1/IP160001 indicates the first in-process sample in January, 2016

Eg-2: EZB-1/RSMET/160001 first recovery solvent in the product EZB.

5.28.3 The above-mentioned Analytical report numbering system shall be assigned for the following list of samples. (Table-2).

S.No.	Type of the Material	Code
1.	In process samples	IP
2.	Cleaning samples	CS
3.	Intermediate samples	IM
4.	Finished Product	FP
5.	Recovery Solvents	RS

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S.No.	Type of the Material	Code
6.	Stability samples	SS
7.	Holding time study	HT
8.	R&D Samples	RD

5.29 Specification and Test Procedure numbering system:

5.29.1 For Raw materials & Packing materials:

PPP/XX/NNN-RR Where,

PPP indicates: STP

XX indicates: Category of samples. (i.e. RM for raw materials & PM for packing materials).

NNN indicates: Serial number of the specification (starting from 001).

RR indicates: Revision number of the specification.

Examples: STP /RM/001-00 & STP /PM/001-00

5.29.2 For In-process, Cleaning and Intermediate:

STP/XX/ ZZZZ/NNN-RR

Where,

STP indicates: STP (Specification and Test Procedure)

XX indicates: Category of STP (i.e., IP for in process and IM for intermediate)

ZZZZ indicates: Product code along with Stage (for EZB)

NNN indicates: Serial number of the specification (start from 001)

RR indicates: Revision number of the specification


Examples: STP/IM/EZB-1/001-00 (Intermediate)

STP/IP/EZB-1/001-00 (In-process)

STP/CS/EZB-1/001-00 (Cleaning)

5.29.3 For Finished Product samples:

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STP/XX/ZZZ/NNN-RR Where,

STP indicates: STP (Specification and Test Procedure)

XX indicates: Category of STP (I.e. FP for finished products)

ZZZ indicates: Product code

NNN indicates: Serial number of the specification (start from 001)

RR indicates: Revision number of the specification.

Example: STP /FP/EZB/001-00 (For finished product)

5.29.4 For water samples:

STP/XX/NNN-RR Where,

STP indicates: (STP) Specification and Method of Analysis

XX indicates: Category of water sample as mentioned below
(PW for Potable water & RW for raw water)

NNN indicates: Serial number of the specification (start from 001)

RR indicates: Revision number of the specification.

Examples: STP /PW/001-00 Or STP /RW/001-00

5.30 RAW DATA NUMBERING SYSTEM:

5.30.1 For In-process, Intermediate and Cleaning samples raw data:

ARD/XXX/NNN/IP/FM01-RR & ARD/XXX/NNN/IM/FM01-RR

ARD/XXX/NNN/CS/F01-RR

ARD indicates: Analytical raw data

XXX indicates: Product code along with stage

NNN indicates: Serial number of the STP


IP indicates: In-process

IM indicates: Intermediate

CS indicates: Cleaning sample

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FM01 indicates: Format

001 indicates: STP Serial number

RR indicates: Revision number of the raw data.

Example: ARD/EZB-1/001/IP/FM01-00 & ARD/EZB-1/001/IM/FM01-00

ARD/EZB-1/001/CS/F01-00

5.30.2 For Finished product raw data:

ARD/XXX/NNN/FP/FM01-RR

ARD indicates: Analytical raw data

XXX indicates: Product code along with stage

NNN indicates: Serial number of the STP

FP indicates: Finished product

FM01 indicates: Format

RR indicates: Revision number of the raw data.

Example: ARD/EZB-2/001/FP/F01-00

5.30.3 For Raw material and Packing material raw data:

ARD/NNN/RM/FM01-RR & ARD/NNN/PM/FM01-RR Where,

ARD indicates: Analytical raw data

NNN indicates: Raw material/packing material serial number

RM indicates: Raw material

PM indicates: Packing material

FM01 indicates: Format number


RR indicates: Revision number of the raw data.

Example: ARD/001/RM/F01-00 & ARD/001/PM/F01-00

5.30.4 For Water raw data:

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ARD/AAXX/F01-RR Where,

ARD indicates: Analytical raw data

AA indicates: Category of samples (DM for De-Mineralized water, RW for raw water, SW for softener water, and BW for blow down water)

XX indicates: Serial number of STP

F01 indicates: Format number

RR indicates: Revision number of the raw data

Example: ARD/DM001/F01-00, ARD/SW001/F01-00, ARD/RW001/F01-00

6.0 FORMATS / ANNEXURE(S):

NIL

7.0 CHANGE HISTORY:

Revision No.	Effective Date	Details of Revision	Ref. CCF No.
00	01.08.2009	New Initiation SOP.	---
01	01.01.2014	1. SOP change with more clear & clarity.	---
02	01.01.2017	1. SOP format changed make to in line with SOP-QA-001-04 2. ATR numbering system changed 3. STP Head & footer format changed. 4. Altogether procedure has been changed for better clarity.	QC-CRF-025/16

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Department	Quality Control	Quality Control	Quality Assurance

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