



STANDARD OPERATING PROCEDURE

| | |
|---|------------------------|
| Department: Quality Control | SOP No.: |
| Title: Allocation of Analytical Reference Number | Effective Date: |
| Supersedes: Nil | Review Date: |
| Issue Date: | Page No.: |

1.0 OBJECTIVE:

To lay down a procedure for Allocation of Analytical Reference Number.

2.0 SCOPE:

This SOP is applicable for Allocation of Analytical Reference Number in the Quality Control Laboratory.

3.0 RESPONSIBILITY:

Officer, Executive – Quality control

Head – Quality Control

4.0 PROCEDURE :

4.1 Analytical reference number shall be generated when the material / product received in the quality control for analysis.

4.2 For Raw Materials & Packaging materials:

4.2.1 All analytical reference number for raw materials and packaging materials shall have nine characters.

4.2.2 AR Number for Raw material & Packaging material report will consist of

R-serial Number/15 & P-serial Number/15

e.g. For Raw material

| | | | | |
|---|---|------|---|----|
| R | - | 0001 | / | 15 |
|---|---|------|---|----|

R Raw Materials

- Dash

0001 Serial number of the sample

/ Slash

15 Last two digit of the Year (15 for year 2015, 16 for year 2016... etc)



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e.g. For Packaging materials

| | | | | |
|---|---|------|---|----|
| P | - | 0001 | / | 15 |
|---|---|------|---|----|

P Packing Materials

- Dash

0001 Serial number of the sample

/ Slash

15 Last two digit of the Year (15 for year 2015, 16 for year 2016... etc)

4.3 For Finished product Tablets, Capsules, Ointment & In process sample :

4.3.1 All analytical reference number for finished product tablets and finished product Injection shall have ten characters.

4.3.2 AR Number for Finished product Tablet and granules, Finished product Ointment & Finish product capsule report will consist of FT-serial number / 15, FO-serial number / 15 & FC- serial number / 15.

e.g. For Finished product Tablets/granules

| | | | | |
|----|---|------|---|----|
| FT | - | 0001 | / | 15 |
|----|---|------|---|----|

FT Finished product tablets

- Dash

0001 Serial number of the sample

/ Slash

15 Last two digit of the Year (15 for year 2015, 16 for year 2016... etc) e.g. For Finished product Ointment

| | | | | |
|----|---|------|---|----|
| FO | - | 0001 | / | 15 |
|----|---|------|---|----|

FI Finished product Injection

- Dash

0001 Serial number of the sample

/ Slash

15 Last two digit of the Year (15 for year 2015, 16 for year 2016... etc)

e.g. For Finished product Capsule



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| | | | | |
|----|---|------|---|----|
| FC | - | 0001 | / | 15 |
|----|---|------|---|----|

FC Finished product Capsule

- Dash

0001 Serial number of the sample

/ Slash

15 Last two digit of the Year (15 for year 2015, 16 for year 2016... etc)

4.3.3 AR Number for Inprocess sample report will consist of IP-serial number / 15.

e.g. For Inprocess sample

| | | | | |
|----|---|------|---|----|
| IP | - | 0001 | / | 15 |
|----|---|------|---|----|

IP In process sample

- Dash

0001 Serial number of the sample

/ Slash

15 Last two digit of the Year (15 for year 2015, 16 for year 2016... etc)

4.4 For Validation Samples:

4.4.1 All analytical reference number for validation samples shall have eleven characters.

4.4.2 AR Number for validation samples report will consist of VAL-serial number/15.

e.g. For Validation sample

| | | | | |
|-----|---|------|---|----|
| VAL | - | 0001 | / | 15 |
|-----|---|------|---|----|

VAL Validation sample

- DASH

0001 Serial number of the sample

/ Slash

15 Last two digit of the Year (15 for year 2015, 16 for year 2016... etc)

4.5 For Raw water, Purified water & Water for Injection Samples & swab sample:



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4.5.1 AR Number for Water samples report will consist of following manner.

e.g. For Raw water, Purified water sample.

| | | | | |
|----|---|------|---|----|
| WS | - | 0001 | / | 15 |
|----|---|------|---|----|

WS Raw water sample, Purified water

- Dash

0001 Serial number of the sample

/ Slash

15 Last two digit of the Year (15 for year 2015, 16 for year 2016... etc) e.g. For swab samples (Wash water)

| | | | | |
|----|---|------|---|----|
| SW | - | 0001 | / | 15 |
|----|---|------|---|----|

SW Swab water sample

- Dash

0001 Serial number of the sample

/ Slash

15 Last two digit of the Year (15 for year 2015, 13 for year 2016... etc)

4.6 For ETP water treatment sample:

4.6.1 AR Number for ETP Water samples report will consist of following manner.

e.g.

| | | | | |
|-----|---|------|---|----|
| ETP | - | 0001 | / | 15 |
|-----|---|------|---|----|

ETP Effluent treated plant water

- Dash

0001 Serial number of the sample

/ Slash

15 Last two digit of the Year (15 for year 2015, 16 for year 2016... etc)

4.7 For Pre shipment or Free sample:

4.7.1 AR Number for preshipments sample report will consist of following manner.



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e.g.

| | | | | |
|----|---|------|---|----|
| PS | - | 0001 | / | 15 |
|----|---|------|---|----|

PS Preshipment or free samples

- Dash

0001 Serial number of the sample

/ Slash

15 Last two digit of the Year (15 for year 2015, 16 for year 2016... etc)

4.8 For Trial Batches:

4.8.1 AR Number for trial batches sample report will consist of following manner.

e.g.

| | | | | |
|----|---|-----|---|----|
| TR | - | 001 | / | 15 |
|----|---|-----|---|----|

TR Trial batches samples

- Dash

001 Serial number of the sample

/ Slash

15 Last two digit of the Year (15 for year 2015, 16 for year 2016... etc)

4.9 Analytical reference number for microbiological section shall be given in the following manner. FOR EXAMPLE:

4.9.1 Microbial limit test report : MLT/0001/12

4.9.2 Environmental, personnel, surface and drain monitoring in,
Non Sterile, Manufacturing and Testing area : ENV/0001/12

4.9.3 Miscellaneous test report : MIS/0001/12

4.9.4 Nitrogen gas Test report : N/0001/12

4.9.5 Compressed air Test Report : CA/0001/12

List of the tentative items described under the Miscellaneous items are enlisted below:

1. Culture dilution

2. Biological indicator qualification for Total viable count determination

3. Gowning qualification



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4. MLT/PET/DET/ method validation
5. Growth promotion test for newly procured lot of media
6. LAF qualification
7. Disinfectant efficacy test
8. Ultra violet light efficacy test
9. Revalidation of Autoclave, incubators, refrigerator, water bath, Oven, Thermo block etc.
10. Calibration of Zone reader
11. Calibration of Micro pipette
12. Fumigation and de-fumigation activity
13. Particle count of Microbiology area
14. Monthly monitoring of autoclave by using biological indicators etc.
15. For absence of Traces of previous product by microbiological method

NOTE: Any activity not reflected in any inward or not reflected in above mentioned list would be added in the above miscellaneous inward. A.R.No. is sometimes may be referred as Report No. in the document.

4.10 AR Number for Reagent sample analysis report will consist of following manner. e.g.

| | | | | |
|----|---|------|---|----|
| RS | - | 0001 | / | 15 |
|----|---|------|---|----|

RS Reagent samples

- Dash

0001 Serial number of the sample

/ Slash

15 Last two digit of the Year (15 for year 2015, 16 for year 2016... etc)

4.11 AR Number for Consumable item analysis report will consist of following manner. e.g.

| | | | | |
|----|---|------|---|----|
| CI | - | 0001 | / | 15 |
|----|---|------|---|----|

CI Consumable item.

- Dash

0001 Serial number of the sample

/ Slash



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15 Last two digit of the Year (15 for year 2015, 16 for year 2016... etc)

4.12 AR Number for Market samples, samples from R&D or regulatory analysis report will consist of following manner. e.g.

| | | | | |
|---|---|------|---|----|
| M | - | 0001 | / | 15 |
|---|---|------|---|----|

M Market samples

- Dash

0001 Serial number of the sample

/ Slash

15 Last two digit of the Year (15 for year 2015, 16 for year 2016... etc)

4.13 For Stability Samples:

4.13.1 All analytical reference number for stability samples shall have ten characters. e.g.

| | | | | |
|----|---|------|---|----|
| SS | - | 0001 | / | 15 |
|----|---|------|---|----|

SS Stability samples

- Dash

0001 Serial number of the sample

/ Slash

15 Last two digit of the Year (15 for year 2015, 16 for year 2016... etc)

5.0 ANNEXURE (S):

Nil

6.0 REFERENCE (S):

SOP: Preparation, approval, distribution, control, revision and Destruction of Standard Operating Procedure (SOP).

7.0 ABBREVIATION (S) / DEFINITION (S):

SOP : Standard Operating Procedure

QC : Quality Control



PHARMA DEVILS
QUALITY CONTROL DEPARTMENT

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QA : Quality Assurance

AR No. : Analytical Reference Number

ETP : Effluent treatment Plant

LAF : Laminar Air Flow

REVISION CARD

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