

QUALITY CONTROL DEPARTMENT

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 Department.

3.0 RESPONSIBILITY:

Executive, Officer – Quality Control Department

Head – Quality Control Department

4.0 **DEFINITION**(S):

NA

5.0 PROCEDURE:

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

5.2 For Raw Materials & Packaging materials:

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

e.g. For Raw material

R	-	0001	/	X
				X

R Raw Materials

- Dash

0001 Serial number of the sample

/ Slash

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XX Last two digit of the Year (06 for year 2006, 07 for year 2007 ... etc) e.g. For Packaging materials

e.g. For Packaging materials

P	-	0001	/	XX
			1	

- P Packing Materials
- Dash
- 0001 Serial number of the sample
- / Slash
- XX Last two digit of the Year (06 for year 2006, 07 for year 2007 ... etc)

5.3 For Finished product Tablets, Capsules, & Inprocess sample:

5.3.1 All analytical reference number for finished product tablets and finished product capsules shall have 10 characters.

e.g. For Finished product Capsule

FC	-	0001	/	X
				X

- FC Finished product Capsule
- Dash
- 0001 Serial number of the sample
- / Slash
- XX Last two digit of the Year (06 for year 2006, 07 for year 2007 ... etc)
- 5.3.2 AR Number for Inprocess sample report will consist of 10 characters.
 - e.g. For Inprocess sample

IP	-	0001	/	X
				X

- IP Inprocess sample
- Dash

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No.:
tive Date:
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No.:
_

0001 Serial number of the sample

/ Slash

XX Last two digit of the Year (06 for year 2006, 07 for year 2007 ... etc)

5.4 For Validation Samples:

5.4.1 AR Number for validation samples report will consist of 11 characters.

e.g. For Validation sample

VAL	-	0001	/	X
				X

VAL Validation sample

- Dash

0001 Serial number of the sample

/ Slash

XX Last two digit of the Year (06 for year 2006, 07 for year 2007... etc)

5.5 For Raw water, Purified water & swab sample:

5.5.1 AR Number for Water samples report will consist of 10 characters.

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

WS	-	0001	/	X
				X

WS Raw water sample, Purified water,

- Dash

0001 Serial number of the sample

/ Slash

XX Last two digit of the Year (06 for year 2006, 07 for year 2007... etc)

e.g. For swab samples (Wash water)

SW	-	0001	/	X

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	SW Swab water sample	
	- Dash	
	0001 Serial number of the sample	
	/ Slash	
	XX Last two digit of the Year (06 for year 2006,	07 for year 2007 etc)
5.6	For Pre shipment or Free sample:	
5.6.1	AR Number for preshipments sample report will con	nsist of 10 characters.
	e.g.	
	PS - 0001 / X	
	X	
	PS Preshipment or free samples	
	- Dash	
	0001 Serial number of the sample	
	/ Slash	
	XX Last two digit of the Year (06 for year 2006)	6, 07 for year 2007 etc)
5.7	For Trial Batches:	
5.7.1	AR Number for trial batches sample report will cons	sist of 10 characters.
	e.g.	
	TR - 0001 / X	
	X	
	TR Trial batches samples	
	- Dash	
	0001 Serial number of the sample	
	/ Slash	



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XX Last two digit of the Year (06 for year 2006, 07 for year 2007... etc)

5.8 For Microbiological samples:

5.8.1 AR Number for microbiological section shall have 10 Characters.

e.g.

MS	-	0001	/	X
				X

MS Microbiological samples

- Dash

OOO1 Serial number of the sample

/ Slash

XX Last two digit of the Year (06 for year 2006, 07 for year 2007... etc)

5.9 AR Number for Reagent sample analysis report will consist of 10 characters e.g.

RS	-	0001	/	X
				X

RS Reagent samples

- Dash

0001 Serial number of the sample

/ Slash

XX Last two digit of the Year (06 for year 2006, 07 for year 2007... etc)

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5.10 AR Number for Consumable item analysis report will consist of 10 characters.

e.g.

CI	-	0001	/	X
				X

CI Consumable item.

- Dash

OOO1 Serial number of the sample

/ Slash

XX Last two digit of the Year (06 for year 2006, 07 for year 2007... etc)

5.11 AR Number for Market samples, samples from R&D or regulatory analysis report will consist of 09 characters.

e.g.

M	-	0001	/	X
				X

M Market samples

- Dash

0001 Serial number of the sample

/ Slash

XX Last two digit of the Year (06 for year 2006, 07 for year 2007... etc)

6.0 ABBREVIATION(S):

QCD - Quality Control Department

SOP - Standard Operating Procedure

7.0 REFERENCE(S):

NA



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8.0	ANNEXURE(S):		
	Nil		

9.0 REVISION CARD:

S.No.	REVISION No.	REVISION DATE	DETAILS OF REVISION	REASON (S) FOR REVISION