

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 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
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- R Raw Materials
- Dash
- 0001 Serial number of the sample
- / Slash
- Last two digit of the Year (15 for year 2015, 16 for year 2016... etc)



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	e.g. Fo	or Packagi	ng materials			
		P	-	0001	/	15
	P	Packing 1	Materials			
	-	Dash				
	0001 Serial number of the sample					
	/ Slash					
	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 t	en charact	ers.			
4.3.2	AR N	umber for	Finished product T	ablet and granules, Finished prod	uct Ointment &	Finish product
	capsul	le report w	vill consist of FT-se	rial number / 15, FO-serial number	er / 15 & FC- se	rial number /
	15.					
	e.g. F	or Finishe	d product Tablets/g	granules		
		FT	-	0001	/	15
	FT	Finished	product tablets			_
	-	Dash				
	0001	Serial nu	umber of the sample	,		
	/	Slash				
	15	Last two	digit of the Year (1	5 for year 2015, 16 for year 2016	etc) e.g. For 1	Finished
	produ	ct Ointme	nt			
		FO	-	0001	/	15
	FI	Finished	product Injection			
	11	Dash	product injection			
	0001		umbar of the sample			
	0001		imber of the sample			
	15	Slash	Ji ai4 of 41 - 37 (4	5 for year 2015 16 f	-t-)	
	15 E			5 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								
	Last two digit of the Year (15 for year 2015, 16 for year 2016 etc)								
4.3.3	AR Number for	Inprocess sample rep	oort will consist of IP-serial num	ber / 15.					
e.g. For Inprocess sample									
	IP - 0001 / 15								
	IP In process sample								
	- Dash								
	0001 Serial number of the sample								
	/ Slash								
	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 re	ference number for v	alidation samples shall have elev	ven characters.					
4.4.2	AR Number for	validation samples re	eport will consist of VAL-serial	number/15.					
	e.g. For Validati	on sample							
	VAL	-	0001	/	15				
	VAL Validation sample								
	- DASH								
	0001 Serial nu	mber of the sample							
	/ Slash								
	15 Last two	digit of the Year (15	for year 2015, 16 for year 2016.	etc)					
4.5			Water for Injection Samples &	•					
		, = 1122200 (110000 00)	202 2	and sumple.					



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5.1			er samples report w	ill consist of following mar	nner.				
		WS	-	0001	/	15			
	WS	Raw water sa	mple, Purified wate	r					
	- Dash								
	0001 Serial number of the sample								
	/	Slash							
	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							
	Last two digit of the Year (15 for year 2015, 13 for year 2016 etc)								
6	For E	TP water trea	tment sample:						
5.1	AR Number for ETP Water samples report will consist of following manner.								
	e.g.								
		ETP	-	0001	/	15			
	ЕТР	Effluent treate	ed plant water			•			
	_	- Dash							
	0001 Serial number of the sample								
	/ Slash								
	Last two digit of the Year (15 for year 2015, 16 for year 2016 etc)								
7	For P	re shipment o	r Free sample:	-					
7.1	AR Number for preshipments sample report will consist of following manner.								



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	e.g.		<u> </u>	T		1
		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 201	.6 etc)	
4.8	For Trial Batches:					
4.8.1	AR N	Number for trial	batches sample repo	ort will consist of followin	g manner.	
	e.g.					
		TR	-	001	/	15
	TR	Trial batches s	samples			
	-	Dash				
	001	Serial number	of the sample			
	/	Slash				
	15	Last two digit	of the Year (15 for	year 2015, 16 for year 201	6 etc)	
4.9	Anal	ytical referenc	e number for mi	crobiological section sh	all be given in	the following
	manı	ner. FOR EXA	MPLE:			
4.9.1	Micro	obial limit test r	eport	: MLT/0001/12		
4.9.2	Envi	ronmental, perso	onnel, surface and d	rain monitoring in,		
	Non	Sterile, Manufac	cturing and Testing	area : ENV/0001/1	2	
4.9.3	Miscellaneous test report : MIS/0001/12					
4.9.4	Nitro	gen gas Test rep	oort	: N/0001/12		
4.9.5	Com	pressed air Test	Report	: CA/0001/12		
	List	of the tentative	items described u	nder the Miscellaneous it	ems are enlisted	below:
	1.Cu	1.Culture dilution				

2. Biological indicator qualification for Total viable count determination

3. Gowning qualification



Slash

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	4. ML	.T/PET/DET/ n	nethod validation						
	5. Gro	owth promotion	test for newly proc	eured lot of media					
	6. LA	F qualification							
	7. Dis	infectant effica	cy test						
	8. Ult	ra violet light e	fficacy test						
	9. Rev	9. Revalidation of Autoclave, incubators, refrigerator, water bath, Oven, Thermo block etc.							
	10.Ca	libration of Zoi	ne reader						
	11. Ca	11. Calibration of Micro pipette							
	12. Fu	12. Fumigation and de-fumigation activity							
	13. Particle count of Microbiology area								
	14. M	14. Monthly monitoring of autoclave by using biological indicators etc.							
	15. Fo	15. For absence of Traces of previous product by microbiological method							
	NOT	NOTE: Any activity not reflected in any inward or not reflected in above mentioned list would be							
	added	added in the above miscellaneous inward. A.R.No. is sometimes may be referred as Report No. in							
	the do	cument.							
4.10	AR Number for Reagent sample analysis report will consist of following manner. e.g.								
		RS	-	0001	/	15			
	RS	RS Reagent samples							
	-	- Dash							
	0001								
	/								
	15								
4.11	AR N	umber for Con	sumable item analys	sis report will consist of f	following manner. e	.g.			
		CI	-	0001	/	15			
	CI	Consumable	item.						
	-	Dash							
	0001								



QC

: Quality Control

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		Proce	uure (SOP).					
7.0 ABBREVIATION (S) / DEFINITION (S):	7.0	ABBI	REVIATION (S) / DEFINITION	(S):			
SOP : Standard Operating Procedure					\~/ -			



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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	