

STANDARD OPERATING PROCEDURE

TITLE: FINISHED PRODUCT RELEASE FOR DISTRIBUTION AND SALE			
SOP No.	: QA/GEN/10	Page No.	: 1 of 7
Revision No.	: #02	Supersedes	: #01
Effective Date	: 17.05.2022	Next Review	: 16.05.2027

1. OBJECTIVE

This SOP provides guidelines for Finished Product Release for Distribution and Sale by Quality Assurance Department.

2. SCOPE

The scope of this SOP is limited to release the Finished Products at this site –ONE ASIA NETWORK INDIA PVT.LTD. C-09 (Part) MIDC KHAMGAON.

3. REQUIREMENTS

- Completed Batch record.
- Quality Control worksheet & COA (Certificate of analysis) of bulk and finished product
- Finished Product PCRO (Package Commodities Regulation Order) report.
- Finished Product Control sample for reference.
- Finished Product Acceptable Quality Level Report (AQL)

4. HISTORY

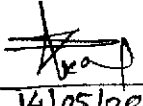
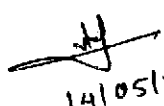
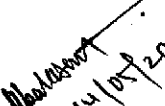
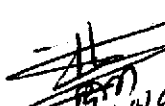
4.1 Rev No. #00

- This SOP is newly prepared.

4.2 Rev No. #01 SOP revised for

- Format as Per SOP QA/GEN/01.
- Sequential procedure for better understanding.
- Addition of Acceptable Quality Level Report (AQL) as Annexure-I and ultimately changes in all annexure numbering.
- Sampling plan added for better understanding.
- Addition of Package Commodities Regulation Order (PCRO) (Annexure-III & IV).

4.3 Rev No. #02 SOP revised for

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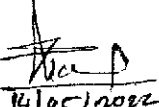
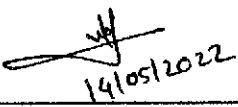
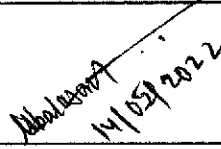
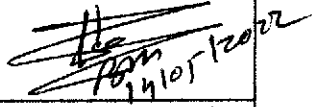
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- Procedure implementation as associated worksheet of bulk & finished products tested by QC Shall be attached with BMR.
- Online CRQS-Check Sheet (Annexure-II) revised for time interval.

5. PROCEDURE

- 5.1 Production department should submit the completed batch record with related attachments duly signed and closed for verification to Quality Assurance Department after the completion of the batch.
- 5.2 Quality Control Department should attach worksheet of bulk & Finished Product, COA of Bulk and Finished Good (FG) of the associate batch to the associate BMR.
- 5.3 CRQS Chemist / QA Associate should perform On-line product inspection as per Annexure-II (Format no. QA/GEN/10/F/02).
- 5.4 If during verification any unacceptable defects are noticed shall be categorize as amber or red as per the Annexure-I with format no. Format no. QA/GEN/10/F/01, the same should corrected from the production department with online corrective action. And submit the record to QA for verification.
- 5.5 Simultaneously Production Department Should perform the Package Commodities Regulation Order (PCRO) as per Annexure-III with format no. Format no. QA/GEN/10/F/03 and submit to QA for verification.
- 5.6 CRQS Chemist / QA Officer should perform CRQS check for Finished Product & Submit the record to QA.
- 5.7 CRQS for Finished Product shall be perform as per the Acceptable Quality Level Report (AQL) Annexure-I with format no. Format no. QA/GEN/10/F/01 and assign CHECKED Label or stamp as per Annexure-VI with format no. Format no. QA/GEN/10/F/06 to the CLD which was open for CRQS Check.

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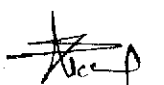

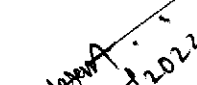

5.8 Before AQL Check, ensure that the batch is completed. Count the number of the pallets as per batch size & carry out physical verification of finished product Based on lot size, by using MIL-STD-105E General Inspection Level II find out number of samples to be checked.

Sampling plan as per MILS shall be as given below:

MIL-STD-105E General Inspection Level II

Lot size in Units	Sample size for Inspection
Up to 500	50
501 – 1,200	80
1,201 – 3,200	125
3,201 – 10,000	200
10,001- 35,000	315
35,001 – 150,000	500
150,001 – 500,000	800
500,001 up	1,250

- 5.9 CLD's Will be picked across the lot from all layers of stalking in zigzag (Diagonal Z corners) or Spiral layers manner. More CLD's can be picked if required to meet the sample size as per SOP. Sample size for CRQS shall be minimum as per above table for MILS std Normal Inspection Plan II but not limited. For selection of number of CLD's for evaluation use $\sqrt{n}+1$ formula.
- 5.10 **Red/ Major Defect:** A major defect is a defect, that is likely to result in failure or to reduce materially the usability of the units of the product for its intended purpose.

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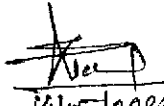
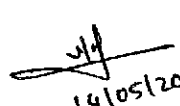
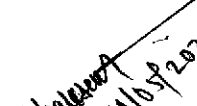
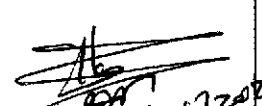
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- 5.11 **Amber/Minor Defect:** A amber/minor defect is a defect that is not likely to reduce materially that usability of the unit of the product for its intended purpose or it is departure from established standards having little bearing on the effective use of operation of the unit.
- 5.12 Acceptance criteria for amber defect is percentage of defect is not more than the 4% and for Red Defect percentage of defect is not more than 0%.
- 5.13 CRQS/ QA associate shall hold the entire pallet and bring in to the notice of PRD manager / Designee to rectify/ corrective action on the identified defect.
- 5.14 The batch yield (BP/ FP) should be calculated by PRD department and verified by QA person before final release of finished product batch.
- 5.15 Batch yield shall not be less than 98.0%.
- 5.16 For Less yield a proper justification shall be mentioned on Batch Report closure page by HOD of PRD department.
- 5.17 If during verification any minor deviation is noticed, the same should get corrected from the concerned department with proper justification on Batch Report or as a separate attachment.
- 5.18 If any major deviation is noticed or quality results not meeting the acceptance criteria, then the same should go through all the formalities as per SOP No.: QA/GEN/04 for Deviation Control.
- 5.19 All major or minor deviation associated batch shall assign the HOLD Label immediately, and batch will remain hold till associated QMS closer.
- 5.20 In such case production dept. shall initiate deviation and proceed for investigation to identify cause of non-conformance. Based on outcomes of investigation production dept. shall initiate appropriate corrective and preventive action.
- 5.21 QA will block the associate the rejected batch by assigning REJECTED Label.
- 5.22 If the deviation control formalities satisfy all the concerned & the outcome of the same is not having any impact on quality of product, QA Head/Designee should release the batch.
- 5.23 If the outcome of the deviation control formalities is having direct impact on product quality, then the batch will be rejected by QA Department after conclusion with Operational management.

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5.24 After complying all the requirements of finished product and closure of all the associated observations, QA Head/Designee shall release the batch for distribution and sale. The batch shall be transferred from under test area to the approved area and status changed accordingly by affixing label as 'ACCEPTED', as per (Annexure-V).

5.25 Follow the same above-mentioned procedure for the batch which is partially released.

6. RESPONSIBILITY

6.1 QC HOD/ Designee

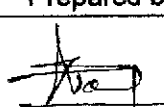
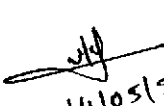
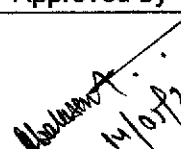

- To provide worksheet & Test certificate of analysis to QA department for batch release procedure.

6.2 PRD HOD/ Designee

- To provide PCRO/ In process check report to QA department for batch release procedure.
- Signing the Batch manufacturing report and submit to QA for closure.
- To verify and sign online CRQS/ In process report.

6.3 QA Officer/ Chemist/ Associate

- To co-ordinate with Production, QC Department for collecting all the documents for verification.
- To verify all the completeness of documents relating to the batch
- To perform the AQL and CRQS of finished products.
- To ensure CRQS report attached to the batch prior to release.
- To keep all the records as per good documentation practice.

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6.4 QA HOD/ Designee

- Supervision on minor and major deviation associated with the batch.
- To check on AQL/ CRQS/ In process check report.
- Accountable for implementation of SOP.
- QA Head/Designee will provide approval for Batch Report for closure.
- QA Head/ Designee will release the batch for distribution and sale.

6.5 General Manager Operation / Designee

- Auditing of the above formalities
- Taking decisions and signing the deviations if any.
- To ensure proper closure by QA Head/Designee and sign for authorized the Closed Batch Report.

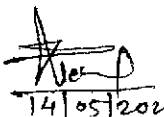
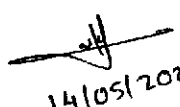
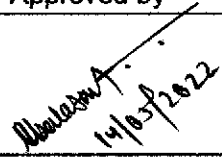
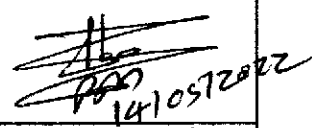
7. PRECAUTION

- Batch shall be released only after closure of all associated observations and QMS,

8. REFERENCE / ATTACHMENT

REFERENCE

- In House
- AQL Sampling Plan MIL 150E Std.
- Standards of Weights and Measures (Packaged Commodities) Rules, 2011

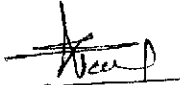
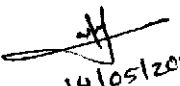
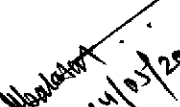

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ATTACHMENT

- Acceptable Quality Level Report (AQL) (Annexure-I) Format No. QA/GEN/10/F/01.- Execution Copy-Pre-Printed/Bound Book.
- Online CRQS-Check Sheet (Annexure-II) Format No. QA/GEN/10/F/02.- Execution Copy-Pre-Printed/Bound Book.
- Package Commodities Regulation Order (PCRO) for Non-Aerosol (Annexure-III) Format No. QA/GEN/10/F/03.- Electronic Sheet/Pre-date enter sheet/ Printed.
- Package Commodities Regulation Order (PCRO) for Aerosol (Annexure-IV) Format No. QA/GEN/10/F/04.- Electronic Sheet/Pre-date enter sheet/ Printed.
- Status Change Label-ACCEPTED (Annexure-V) Format No. QA/GEN/10/F/05.-Pre Printed Label.
- Status Change Label-CHECKED (Annexure-VI) Format No. QA/GEN/10/F/06. -Pre Printed Label.
- Status Change Label-HOLD (Annexure-VII) Format No. QA/GEN/10/F/07. -Pre Printed Label.
- Status Change Label-REJECTED (Annexure-VIII) Format No. QA/GEN/10/F/08. -Pre Printed Label.

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Annexure-I

Quality Assurance Department	Format No. : QA/GEN/10/F/01-R/00
SOP Ref. No. : QA/GEN/10	Page No. : 1 of 1

ACCEPTABLE QUALITY LEVEL REPORT

Product Name:	Batch No.:	Batch Size:
No. of Pallets:	Sample Qty.:	Pallet Label:

Sr. No.	Type of Defects	No. of Defects (Units)		Total
		Amber	Red	
01.	Position of any label / Sleeve / Wrapper on pack front & back or double label			
02	Color of All print anywhere on pack			
03	Quality of required print (Including legal text)			
04	Dust on pack can / carton			
05	Any Oil / Dirt / Grease can / Carton			
06	Deviation weight			
07	Any missing component			
08	Assembly wrong			
09	Corrosion of metal can / lid			
10	Damage - Cracking can / carton / top flap / leg			
11	Damage - Crush / Dent / Grease / Teared Can / Carton / Pin hole			
12	Damage - Scratches / Scuffing can / Carton / Hard Spots			
13	Locking device (i.e., CRC, tab, slider lock, twist lock etc.) not in standard position			
14	Opening device - Loose fitment (Cap or Actuator)			
15	Bar code - Un readable / missing / position can / carton			
16	Production code- missing / Illegible / position can / carton			
17	Shrink- wrapper / Over-wrapper / Loose bundles			
18	Standard No. of can in shrink bundle			
19	Text Missing/ Misprint			
20	Other			

Defects	Limits	Total Defects Found	% Defects
Red Defect	0%		
Amber Defect	4.0%		

Note: If defects exceeds than the acceptable limits, hold the complete batch & recheck whole batch. For defect free batch perform re-AQL to assure the batch quality before release for market.

Remark: Batch Release / Batch Hold (if any):

Checked By	Verified By

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Annexure-II

Quality Assurance Department	Format No. : QA/GEN/10/F/02-R/01
SOP Ref. No. : QA/GEN/10	Page No. : 1 of 2

Product Name:	Batch No.	MFG Dt.	Exp. Dt.	MRP (Inc. of All Taxes)	Batch Size (kg/Lit)	Batch Size (Units)	Shift	Line No

ONLINE CRQS - CHECK SHEET

DEFECT ↓	Interval Time →		1 st Hour		2 nd Hour		3 rd Hour		4 th Hour	
	Amber	Red	Amber	Red	Amber	Red	Amber	Red	Amber	Red
Position of any label / Sleeve / Wrapper on pack front & back or double label										
Color of All print anywhere on pack										
Quality of required print (Including legal text)										
Dust on pack can / carton										
Any Oil / Dirt / Grease can / Carton										
Any missing component										
Assembly wrong										
Corrosion of metal can / lid										
Damage - Cracking can / carton / top flap / leg										
Damage - Crush / Dent / Grease / Teared Can / Carton / Pin hole										
Damage - Scratches / Scuffing can / Carton / Hard Spots										
Locking device (i.e. CRC, tab, slider lock, twist lock etc.) not in standard position										
Opening device - Loose filament (Cap or Actuator)										
Bar code - Un readable / missing / position can / carton										
Production code- missing / Illegible / position can / carton										
Shrink- wrapper / Over-wrapper / Loose bundles										
Other										
Total Number of Sample Checked (80 Samples per hour)										
Vacuum Leak check (Freq-2 hours)										

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Annexure-II

Quality Assurance Department	Format No. : QA/GEN/10/F/02-R/01
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DEFECT ↓	Interval Time	5 th Hour		6 th Hour		7 th Hour		8 th Hour	
		Amber	Red	Amber	Red	Amber	Red	Amber	Red
Position of any label / Sleeve / Wrapper on pack front & back or double label									
Color of All print anywhere on pack									
Quality of required print (Including legal text)									
Dust on pack can / carton									
Any Oil / Dirt / Grease can / Carton									
Any missing component									
Assembly wrong									
Corrosion of metal can / lid									
Damage - Cracking can / carton / top flap / leg									
Damage - Crush / Dent / Grease / Teared Can / Carton / Pin hole									
Damage - Scratches / Scuffing can / Carton / Hard Spots									
Locking device (i.e., CRC, tab, slider lock, twist lock etc.) not in standard position									
Opening device - Loose fitment (Cap or Actuator)									
Bar code - Un readable / missing / position can / carton									
Production code- missing / illegible / position can / carton									
Shrink- wrapper / Over-wrapper / Loose bundles									
Other									
Total Number of Sample Checked (80 Samples per hour)									
Vacuum Leak check (Freq-2 hours)									

Defect Type	Total Defect	Total %
Amber		
Red		

In process QA CRQS
Sign/ Date

Shift In charge
Sign/ Date

14/12/2020

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Annexure-III

Quality Assurance Department
SOP Ref. No. : QA/GEN/10

Format No. : QA/GEN/10/F/03-R/00
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ONE ASIA NETWORK INDIA PVT. LTD. C-09 (Part) MIDC KHAMGAON. PACKAGED CONNECTIVITY REGULATION CASES (PCRI) Non-Resonant									
Product Name:					Production Date:				
Batch No. :					Pack Size:				
Sr. No.	Empty Assembly Weight	Hourly PG Gross Weight Recording							
		1st Reading	2nd reading	3rd reading	4th reading	5th reading	6th reading	7th reading	8th reading
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									
16									
Average									
Net Fill Wt.									
Gross Weight									
No. of sample		Min. Weight [g]		Max. Weight [g]		Average Weight [g]		Std. Deviation	
No's		g		g		g			
Net Fill Weight									
No. of sample		Min. Weight [g]		Max. Weight [g]		Average Weight [g]		Std. Deviation	
No's		g		g		g			
Corrected Average Net Fill Weight									
Net Fill Volume									
No. of sample		Min. Fill Vol. [ml]		Max. Fill Vol. [ml]		Average Fill Vol. [ml]		Std. Deviation	
No's		ml		ml		ml		SD 1978	
Corrected Average Net Fill Volume									
Volume Per Stroke									
Sample No.								g. Wt. Per Roll [g/roll]	
Year									
Initial Weight of sample [g]									
Weight of Sample After 10									
Weight Difference [g]									
Weight Per Rotation [g/rotation]									
Volume Per Stroke / Rotation [ml/g]									
Year									
Initial Weight of sample [g]									
Weight of Sample After 10									
Weight Difference [g]									
Weight Per Rotation [g/rotation]									
Volume Per Stroke / Rotation [ml/g]									
Year									
Initial Weight of sample [g]									
Weight of Sample After 10									
Weight Difference [g]									
Weight Per Rotation [g/rotation]									
Volume Per Stroke / Rotation [ml/g]									
Year									
Initial Weight of sample [g]									
Weight of Sample After 10									
Weight Difference [g]									
Weight Per Rotation [g/rotation]									
Volume Per Stroke / Rotation [ml/g]									
Year									
Performed By		Received By				Approved By			

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ONE ASIA NETWORK INDIA PVT. LTD.

C-09 (Part) MIDC KHAMGAON.

Annexure-IV

Quality Assurance Department

SOP Ref. No. : QA/GEN/10

Format No. : QA/GEN/10/F/04-R/00

Page No. : 1 of 1

ONE ASIA NETWORK INDIA PVT. LTD.									
C-09 (Part) MIDC KHAMGAON.									
PACKAGED COMMODITIES REGULATION ORDER (PCRO) Form									
Product Name:					Production Date:				
Batch No.:					Pack Size:				
Sr. No.	Empty Can Weight	Netly FG Gross Weight Recording							
		1st reading	2nd reading	3rd reading	4th reading	5th reading	6th reading	7th reading	8th reading
1									
2									
3									
4									
5									
6									
7									
8									
9									
10									
11									
12									
13									
14									
15									
16									
Average Net Fill Wt.									
No. of samples		Min. Weight [g]		Max. Weight [g]		Average Weight [g]		Std. Deviation	
No's		g		g		g		g	
No. of samples		Min. Weight [g]		Max. Weight [g]		Average Weight [g]		Std. Deviation	
No's		g		g		g		g	
No. of samples		Min. Fill Vol. [ml]		Max. Fill Vol. [ml]		Average Fill Vol. [ml]		Std. Deviation	
No's		ml		ml		ml		ml	
Can Sample Time		Min. Weight [g]		Max. Weight [g]		Average Weight [g]		Std. Deviation	
Spray Rate @ 20°C (B.S. - B.55 g/oz)		Min. Weight [g]		Max. Weight [g]		Average Weight [g]		Std. Deviation	
Average		Min. Weight [g]		Max. Weight [g]		Average Weight [g]		Std. Deviation	
Can Pressure @ 20°C (350 - 400 Kpa)		Min. Weight [g]		Max. Weight [g]		Average Weight [g]		Std. Deviation	
Average		Min. Weight [g]		Max. Weight [g]		Average Weight [g]		Std. Deviation	
Can Pressure @ 55°C (700 - 800 Kpa)		Min. Weight [g]		Max. Weight [g]		Average Weight [g]		Std. Deviation	
Average		Min. Weight [g]		Max. Weight [g]		Average Weight [g]		Std. Deviation	
Performed By		Reviewed By		Approved By					

Form No.: QA/GEN/10/F/04-R/00

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C-09 (Part) MIDC KHAMGAON.

Annexure-V

Quality Assurance Department

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SOP Ref. No. : QA/GEN/10

Page No. : 1 of 1

STATUS CHANGE LABEL

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B.No./ AR.No.:

Sign/Date.:

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C-09 (Part) MIDC KHAMGAON.

Annexure-VI

Quality Assurance Department	Format No. : QA/GEN/10/F/06-R/00
SOP Ref. No. : QA/GEN/10	Page No. : 1 of 1

INPROCESS CHECK STATUS LABEL

CHECKED

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Annexure-VII

Quality Assurance Department

Format No. : QA/GEN/10/F/07-R/00

SOP Ref. No. : QA/GEN/10

Page No. : 1 of 1

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Annexure-VIII

Quality Assurance Department

Format No. : QA/GEN/10/F/08-R/00

SOP Ref. No. : QA/GEN/10

Page No. : 1 of 1

STATUS CHANGE LABEL

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