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One Asia	ONE ASIA NETWORK INDIA PVT. LTD. C-09 (Part) MIDC KHAMGAON.

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

	Prepared by	Checked by	Approved by	Authorized by
Sign/ Date	14/05/2022	14/05/2022	14/05/2022	14/05/2022
Name	Suraj Sapkal	Vinod Bhalgaonkar	B.V Mukhekar	B.A. Shelke
Dept.	QA	QA	QA	Operation

- 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, thesame 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.

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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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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Dept.	QA	QA	QA	Operation

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.

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

- Bach 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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Dept.	QA	QA	QA	Operation

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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):

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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

ONLINE CRQS - CHECK SHEET

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

Interval → / Time →	1st Hour		2nd Hour		3rd Hour		4th Hour	
DEFECT ↓	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)								

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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. : 2 of 2

Interval → / Time →	5th Hour		6th Hour		7th Hour		8th Hour	
DEFECT ↓	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

14/8/20

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Annexure-III

Quality Assurance Department	Format No. : QA/GEN/10/F/03-R/00
SOP Ref. No. : QA/GEN/10	Page No. : 1 of 1

ONE ASIA NETWORK INDIA PVT. LTD.

C-09 (Part) MIDC KHAMGAON.

PACKAGED COMMODITIES REGULATION ORDER (PCRO) Non-Aerosol

Product Name:

Batch No. : **Production Date:**

Shift : **Pack Size:**

Sr. No.	Empty Assembly Weight	Hourly 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.									

Gross Weight

No. of samples		Min. Weight (g)		Max. Weight (g)		Average Weight (g)		Std. Deviation	
	No's		g		g		g		

Net Fill Weight

No. of samples		Min. Weight (g)		Max. Weight (g)		Average Weight (g)		Std. Deviation	
	No's		g		g		g		
Corrected Average Net Fill Weight									g

Net Fill Volume

No. of samples		Min. Fill Vol. (ml)		Max. Fill Vol. (ml)		Average Fill Vol. (ml)		Std. Deviation	
	No's		ml		ml		ml	#DIV/0!	
Corrected Average Net Fill Volume									ml

Volume Per Stroke

Sample No.						Sp. Wt. Per ml (g/ml)
Time						
Initial Weight of sample (g)						
Weight of Sample After 10						
Weight Difference (g)						
Weight Per Actuation (g/stroke)						
Volume Per Stroke / Actuation (ml/st)						
Time						
Initial Weight of sample (g)						
Weight of Sample After 10						
Weight Difference (g)						
Weight Per Actuation (g/stroke)						
Volume Per Stroke / Actuation (ml/st)						
Time						
Initial Weight of sample (g)						
Weight of Sample After 10						
Weight Difference (g)						
Weight Per Actuation (g/stroke)						
Volume Per Stroke / Actuation (ml/st)						
Time						
Initial Weight of sample (g)						
Weight of Sample After 10						
Weight Difference (g)						
Weight Per Actuation (g/stroke)						
Volume Per Stroke / Actuation (ml/st)						

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Annexure-IV

Quality Assurance Department	Format No. : QA/GEN/10/F/04-R/00
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ONE ASIA NETWORK INDIA PVT. LTD.

C-09 (Part) MIDC KHAMGAON.

PACKAGED COMMODITIES REGULATION ORDER [PCRO] Record

Product Name:

Batch No. : **Production Date:**

SS268 : **Pack Size:**

Sr. No.	Empty Can Weight	Hourly 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.									

Gross Weight

No. of samples		Min. Weight [g]		Max. Weight [g]		Average Weight [g]		Std. Deviation	
	No's		g		g		g		

Net Fill Weight

No. of samples		Min. Weight [g]		Max. Weight [g]		Average Weight [g]		Std. Deviation	
	No's		g		g		g	#DIV/0!	
Corrected Average Net Fill Weight									g

Net Fill Volume

No. of samples		Min. Fill Vol. [ml]		Max. Fill Vol. [ml]		Average Fill Vol. [ml]		Std. Deviation	
	No's		ml		ml		ml		
Corrected Average Net Fill Volume									ml

Can Samples					Total Average
Time					
Spray Rate @28°C [0.5 - 0.65 g/can]					
Average					
Can Pressure @ 28°C [350 - 400 Kpa]					
Average					
Can Pressure @ 55°C [700 - 800 Kpa]					
Average					

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Annexure-V

Quality Assurance Department	Format No. : QA/GEN/10/F/05-R/00
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STATUS CHANGE LABEL

ACCEPTED

B.No./ AR.No.: **Sign/Date.:**

Format No.: QA/GEN/10/F/05

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Annexure-VI

Quality Assurance Department	Format No. : QA/GEN/10/F/06-R/00
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INPROCESS CHECK STATUS LABEL

CHECKED
Sign/Date.:

Format No.: QA/GEN/10/F/06

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Annexure-VII

Quality Assurance Department	Format No. : QA/GEN/10/F/07-R/00
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STATUS CHANGE LABEL

HOLD

B.No. / AR.No.: Sign/Date.:

Format No.: QA/GEN/10/F/07

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Annexure-VIII

Quality Assurance Department	Format No. : QA/GEN/10/F/08-R/00
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STATUS CHANGE LABEL

REJECTED

B.No. / AR.No.:

Sign/Date.:

Format No.: QA/GEN/10/F/08