

**UGEE CHEMICALS** 

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Quality Assurance SOP

# SOP

Standard Operating Procedure

RELEASE OF F&HC PRODUCTS							
SOP: UCL/IBDLAB/CD/Q/01.0	Issuance Date: Revision Date	As at Last Signature  Maximum 2 years from effective date	Reference: WQA SOP# LDR-S-07, UCL/IBDLAB/CD/Q/08, UCL/IBDSITE/CD/Q/11, UCL/IBDPSG/CD/Q/11, UCL/IBDPSG/CD/Q/10, NISARS 496, QAS-S-11				
	Effective Date:	20 working days from the issuance date	Page 1 of 12				

# **PURPOSE**

- Defines procedures for finished product sampling and control, which will ensure that product released for shipment meet all Finished Product Specification and are within FC's and SON specification limit.
- Establish positive release system for all products made and shipped and defines procedures for finished product release in ensuring that only quality products are delivered to our consumers.

#### SCOPE

- This SOP covers the process of releasing finished products Fabric and Homecare in Ibadan plant.

#### RESPONSIBILITY

- P&G ESS QA (For P&G products only): Define the responsibilities to release the first production lots on sites during validation, inform project leader and ensure this is documented in the validation/PQ protocol. He also verifies that release systems and capability to measure release criteria on site are in place prior to production. Authorizes the release of all Finished Products prior to delegation of release to Site QA Leader. Sign off the P&G Release Authorization document of the Batch Production Record to authorize the release of all products prior to delegation of release to Site QA leader.
- MSG Shift Leader: is responsible that line is using a previously released starting material. He is also
  responsible for producing to product specifications. They will complete all product documentation
  according to this SOP and participate in investigation and resolution of out-of-specification situations.
  He also counter signs the MSG BPR before collation.
- **PSG Shift Leader:** is responsible for ensuring that finished products meet TAMU standard. He is also responsible for ensuring that finished products made within his shift meet all packing standards and regulatory specifications. He will ensure finished products documentation is documented according to

SOP OWNER	HSE APPROVAL	QA APPROVAL	AUTHO	RISAT	ION
Spal	N/A				-
Adio Sakiru		Alawode Olujide	Sadik Abaşs		
Date: 21/02/2022		Date: 23-02-2022	Date: 28	02	2022

Q.C Manager's Signature / Date	Q.C Man							
					Release Date			
Criteria O Yes O No	Meet Product Specification Criteria				81742838 (55g)			
					81702144 (900g)			
					81742839 (75g)	61.		
					81704091/81730014 (60g)	81		
					81670215 (90g)			
					81742840 (170g)			Lab Notebook Page
					81702142/91730016(190g)	817	00-Jan-00	Analysis Date
Laboratory Stamp	-				81702143 (400g)			Day
					8017/81742841 (800g)	817		Night
					Total Oty Released [Cases]			Morning
			22-AHSMB-	22-A	QA Release #			
		MUALLIY ASSURVANCE DEPART MENUS DELISION	QUALITY ASSURANCE				REFERENCE	
						1	Target - na LSL-30 USL - na	Odour Grade - Neat ( AM 600866539
						1	Matches Standard - Pass or Fail	6 Appearance ( AM 60055687)
						4	Target na LSL na USL - 5.0	Particle size ( AM 64019677)
								Attributes
						4	Target - 525,0000 LSL - 472,5000 USL - 577,7000	Repour Cup / Bulk Density (gm/l) (AM 60050157)
						-	Target - 4.3265 LSL - 3.6776 USL - 4.9755	% CatSO <sub>3</sub> ( AM 80058808)
						n/a	Target - 5.6952 LSL - 3.9866 USL - na	Professe Activity (AM 95748041)
							Target - 0.2546 LSL - 0.2037 USL - 0.3056	% Available Oxygen ( AM 60050909)
	Sample 5	Sample 4	Sample 3	Sample 2	Sample 1	Samples	Specifications	Variables
							SICAL ANALYSIS	CHEMICAL / PHYSICAL ANALYSIS
B1742838 (55g)	81702144 (900g) B	9 (759)	81742839 (75g)	81704091/81730014 (60g)	81704091/8	0018 (25g)	81702146/81730018 (25g)	
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				0 0				xpiration Date
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2-Feb-22	N/A Document Date:	N/A D			Expiry Date:			Reason for Change: D2D
96430372 version 5	acking Instruction No.	99789813 version 010 Packing Instruction No.		No.	Making Instruction No.			IDADAN SITE, NIGERIA.
A-PQM-240	1-Feb-22 Document Ref. No.:	1-Feb-22 D			Effective Date:	n :014	GCAS #:90758265 Version :014	IDADAN CITE NICEDIA
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	Master file.	Hard copy with authorization signatures is on the QA Master file.	with authorization si	Hard copy				
Alawode Otujide	Authorized by				Sakiru Adio	Updated by:		(A)
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CONFIDENTIAL STRICTLY CONTROLLED			, , , , , , , ,					

SOP OWNER
Adio Sakiru
Adio Sakiru
Date: 11 02 2-022

HSE APPROVAL

**A** 

OA APPROVAL

Alawode Qiujide

Date: 23 12 222

Sadik Abass
Date: 38 37 727

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Product Name:			Batch #:			
Mfd. Date			Shift:			
Tick box if present and in compliance with th						
#	Document Name					
1 Crutcher Batch (MSG) 2 Line Process Audit sheet						
3 Finished Products On-Hold Sta	atus Sheet					
4 Weight Sample Sheet						
5 TAMU Chekclist/ Proficy Repo	rt					
6 PSG Line Clearance Sheet 7 MSG Line Clearance sheet						
8 Raw material Record						
9 P&G QA Release Authorization	n form					
10 Making Process Report						
11 MSG and PSG Shut-down and 12 BFM Start-up and Shut down 0						
13 PDR Record (PSG)	MOCKIST					
14 Admix Report						
15 Assay Report (Lab FP Analysis	5)					
PSG PRODUCTION	QUANTITY PRODUCED	UNIT	QUANTITY RELEASED	UNIT	QUANTITY ON HOLD	UNI
P CODE:		CASES		CASES		CASE
P CODE:		CASES		CASES		
		CASES		CASES		CASE
CODE:		CASES		CASES		CASE
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P CODE:		CASES				CASE
P CODE:		CASES		CASES		CASE
P CODE:				CASES		CASE
P CODE:		CASES		CASES		CASE
QA Leader(PSG)	Sign:					
Process leader (MSG)	Sign:					
PC Lab leader	Sign:					
ite Qa Leader	Sign:					
ON Analysis Completed and with	nin specs.		Y		N	
case of deviation : Site QA Comment						
case of deviation : Site QA Comment Site QA Approval		_				
	HSE APPRO	- OVAL	QA APPROV	AL	AUTHORISATI	ON
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this SOP prior to products release. He will participate in investigation and resolution of out of spec situations made within his shift.

- PSG Shift QA Leader: Collects all release documents in packing department, revise the data within these documents and insert all packaging production documents into the batch envelop as listed in the release packet. Ensures the line is using an updated blank standard document. Reviews and Signs off the PSG QA Leader's part of the release packet and forwards the batch envelop to the Process Leader (MSG). Archives completed batch envelop.
- MSG Process Leader or its designee (Making team leader): Collates, and reviews and insert all making production documents including admix production report into the batch envelop as listed in the release packet. Signs off the Process Leader's part of the release packet and forwards the batch envelop to the FHC Lab Leader.

Note that the designee does this only on weekends when the process leader is not around or on vacation

- Main/Satellite Laboratory Analyst: Conduct analytical tests on picked FP samples. He is responsible for FP release after all analysis are completed. He also collects and reviews all required documents from both MSG and PSG.
- QC Lab Leader: Prepares finished products assay reports for that production and inputs it into the batch envelope. Releases the product on the system after the approval from P&G ESS QA (for P&G products only) signs off the QC Lab Leader's part of the release packet. Stamps "Released" on the batch envelop and returns the completed batch envelop to the Shift QA Leader (PSG) for archiving and keeps retain samples of batch product.
- **PSG Line Operators:** is responsible for performing the Quality check and document the result on QW or TAMU checklist in case there is issue with Q-Proficy.
- Line QC: is responsible for performing the Weight check and record the result on both Line QW or the weight control checklist.
- RPM and FP SPOC is responsible for receiving FP at Warehouse location, both on SAP and physically.
- Site QA Leader: Responsible for final review of the BPR documents before it is approved by the Site ESS QA Leader for product release decision. He/She is also responsible for the overall compliance to this SOP

# POTENTIAL RISKS

Not Applicable

#### PPE REQUIRED

Not Applicable

#### PROCEDURE

### Sampling & Testing

 Three consecutives Samples (Each for Analysis, Density and Retention) are picked from the packaging line daily irrespective of SKU to represent the day's production batch in accordance to the Dry Laundry stratified sampling SOP, GCAS: 90570239.

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- Finished product Analysis will be performed by Main/Satellite lab analyst as defined in the Manufacturing and SON standards. A sample is retained every Finished Products batch according to Retained Sample management SOP UCL/IBOLAB/CD/Q/08.
- For product previously made and packed into another packaging batch, the Lab will carry out full SON
  analysis on the sample and use the Assay sheet of the previously made-analyzed data to release for
  P&G related tests.
- 4. When an out of specification is discovered on any of the parameters (either FC or SON parameter), inform the QA leader and P&G ESS QA and process leader immediately. Trace back to the buggy, batch, mixing time, buggy open time and date and block products produced during that period. Conduct extensive sampling on the product and certify that product is okay to go to the warehouse if defect was not continuous. Follow the Procter & Gamble Global HHC-Handling Atypical Analytical Result GCAS 98844300 and WQA global SOP on OOS, QAS-S-11-Analytical-Out-of-Specification-Investigations on handling out of specification products.
- 5. Document all actions taken in the out of specification investigation form e.g. Products blocked, what was done to defective products, corrective actions taken etc.
- 6. After each product batch, Team Leader and the lab analyst will complete all document listed in the Batch release summary sheet. He will also ensure that each pallet of the Finished Product is labeled using the appropriate label see pasting of label SOP UCL/IBDSITE/CD/Q/11.
- 7. Each pallet of the finished product must have a status label.
- 8. Results of the Finished Product tests will be recorded in the lab logbook, product Assay report and the Finished Product files on Quality Windows.

#### BATCH PRODUCTION RECORDS

- 9. At the start of each shift/batch, the line process leader or designee will ensure that the batch documentation required is present and distributed to all applicable areas of the line.
- 10. The line and lab will complete all required documents as detailed on the BPR summary sheet. Content of the BPR will be (as applicable)
  - Batch Release Summary Sheet
  - Assay Report
  - PSG Line Clearance Sheet.
  - Raw Material Records.
  - Line process audit sheets (Packing Process control record)
  - Finished product on hold status sheet (Sampling records to release Batch part when OOS is discovered)
  - Weight Sample sheet
  - TAMU checklist (Pallets TAMU records / Polybag and Polywoven)
  - MSG Line Clearance Sheet (Admix/Crutcher change over line clearance checklist)
  - PDR Record
  - Admix Report
  - Crutcher Report
  - Making Process report
  - P&G QA release Authorization document contained in Appendix 7 of QAA
  - Any Deviation documents (if appliable)

- MSG and PSG Shut-down and Start-up Checklist (As applicable)
- 11. Any deviation from procedure, Admix/Crutcher report, material tracking /production process as regards to finished products, Raw & pack material is attached to the BPR record. This must be indicated in the comment box of the batch production summary sheet.
- 12. All the component (both raw and pack material) of a production batch must be traceable to that particular batch.
- 13. The Shift QA, Satellite Lab Personnel and Process leader or their designee will check the Batch document for errors/omissions and correct wherever possible prior to close out.

# RELEASE PROCEDURE

- 14. All finished product release will be via a positive release system.
- 15. Site QA and P&G ESS QA (For P&G products only) is responsible for following established specifications and retains ultimate accountability for decisions to release the product.
- Lab QC technicians will carry out chemical and physical testing as stipulated in SQP, FC and SQN standard
- 17. Each batch of FP will be released upon completion of all required FC and SON Analysis, and the review of the Batch record for the batch.
- 18. Criteria for Finished Product Release:

Each batch may be released when:

- a. All finished product making and packing records have been reviewed and approved.
- b. Production control documentation and line quality data have been collected and checked against success criteria.
- Finished product analyses have been completed and are within Formula Card limits and SON Limits.
- d. The Lab leader will release the batch produced on the assay sheet and give a release number for the batch release.
- 19. Site QA leader and P&G ESS QA (For P&G products only) will give final approval for release of the finished product.
- 20. If any of the Release Envelope documents is not meeting its success criteria or OOL or OOS data is obtained either from FC or SON standards, the result will be investigated. The products are placed ON HOLD pending QA/QC decision for scrapping, rework or release. The Shift QA will paste On hold label.
- 21. If any of the release criteria are not met, the Product will be place on hold status, inform P&G ESS QA spoc, and start an investigation and site alert report. When releasing a reworked lot, the P&G Release Authorization document should refer to the rework instruction and sampling/sorting report.
- 22. All deviation from normal procedure that is product related must be documented in BPR.
- 23. All decisions relating to release of product not meeting Technical Standard and SON requirement must involve the Site QA, Plant Leader and P&G ESS QA Leader and will include any appropriate Technical and Regulatory review.

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#### **EXPORT PRODUCTS**

24. F&HC Lab leader ensures that the results in QW template and SON Log book are within FC limits and SON limits before release.

25. FHC Lab leader or Main Lab Analyst will prepare the copy of needed CoA for the batch released according to exported country regulation requirements for Site QA Leader and P&G ESS QA (For P&G products only) Approval. He will Scan and send it to the RPM and FP SPOC whenever requested.

#### **RELEASE CRITERIA:**

# From Packaging Stand Point

- 26 All samples evaluated against the TAMU grading system meet release requirements.
- 27 No sample weight is or below TU2. Any sample out of the range are to be treated as out of Spec, product, and the Shift QA Leader is to be informed immediately.
- 28 Total number of samples between TU1 and TU2 do not exceed 2% of total production.

### **Laboratory Stand Point**

- 29. The Lab releases only products that meet analytical limits and SON requirements.
  - a. Release of products on the system (i.e. SAP) is done by the F&HC Lab Leader or designee (trained and qualified lab analyst) who issues a release number on the system (Finished Products Assay) only when all required analysis has been completed, certified OK according to Lab test methods and all required documents are present according to the release packet check list reviewed by Site QA and ESS QA.
- 30 The packaging line QC checks if finished products meet release criteria according to Weight Control SOP (UCL/IBDPSG/CD/Q/11) and TAMU SOP (UCL/IBDPSG/CD/Q/10)
- 31 If the palletized FP meet the PSG release criteria, The Shift QA Leader puts the appropriate labels on it.
- 32 The FPQ Evacuation Personnel ensures that all PSG released products are transferred to the warehouse.
- 33 At the end of the shift, the PSG Shift QA Leader collates all packaging documents needed for release as outlined in the batch release packet Reviews and Signs off the PSG QA Leader's part of the release packet and forwards the batch envelop to the Process Leader (MSG).
- 34 Process Leader (MSG) collates and reviews all manufacturing documents from making stand point, inputs these documents into the batch envelop, signs off Process Leader's part of the release packet and forwards the batch envelop to the QC Lab Leader.
- 35 QC Lab leader inputs the results of the finished product analysis into the batch envelope, issues a release via the system, keeps retention samples of that batch production and returns the batch envelope to the QA Leader for archiving.

# **Deviation Handling**

36 If products within the lot sampling frequency do not meet release criteria, line QC will handle the situation according to TAMU & Weight control SOPs on handling deviations.

#### Regulatory Requirement:

- 37 Regulatory test would be done daily as outlined in the Nigeria Industrial Standard
- 38 Compliance to SON tests is a criteria for release of Finished Products.

#### Abbreviation:

RPM and FP Spoc: Raw & Pack Material and Finished Product owner

MSG: Making Synthetic Granules PSG: Packing Synthetic Granules

OOS: Out of Specification

OOL: Out of Limit

SON: Standard Organization of Nigeria

FC: Formular Card
QC: Quality Control
FP: Finished Product
QW: Quality Window

**QAA: Quality Assurance Agreement** 

# **REASON FOR UPDATE:**

Version 1: New SOP

# **End of Procedure**

# SOP RELATED ATTACHMENTS

Attachment 1 - Qualification sheet.

Attachment 2 - Model Answers.

Attachment 3 - FP Batch Release Packet Cover Sheet for F&HC products.

Attachment 4—Step-up card

Attachment 5 - Assay Sheet