UGEE CHEMICALS	UGEE CHEMICALS Quality Assurance SOP	SOP Standard Operating Procedure

LABORATORY CONTROLS

SOP #: UCL/IBDLAB/CD/Q/05.0	Issuance Date:	As at Last Signature	Reference: P&G WQA Policy LAB-P-01, UCL/IBDSITE/CD/Q/22
	Revision Date:	Maximum 2 years from Effective Date	
	Effective Date:	20 working days from the issuance date	Page 1 of 9

PURPOSE

- To lay down GMP guidelines and practices which apply to the QC laboratory.
- To establish a work procedure to make product quality decisions based on sound and accurate analytical data.

SCOPE

- Applies to all Laboratory practices in Quality control laboratory in Ugee Chemicals, Ibadan site

RESPONSIBILITY

- **Laboratory analysts:** are responsible for following this SOP strictly.
- **Site Laboratory Control Owner/Laboratory Leader** is responsible for the following:
    - Make sure that appropriate and current laboratory SOPs and technical standards (Test Method) are available in the laboratory.
    - Training and maintaining lab personnel capability
    - Facilities and equipment design and maintenance appropriately
    - Complete laboratory investigations according to P&G WQA SOP QAS-S-11
    - All analytical data used for release are back up in weekly basis
    - Lead periodical audit of all laboratory practices, outlined process is followed and reports progress and gaps to the QA Manager.

POTENTIAL RISKS

- Not Applicable

PPE REQUIRED

- Not Applicable

PROCEDURE

1 The Ibadan Plant laboratory is responsible for carrying out analysis of all raw and pack materials, In-process and Finished products in the site. The laboratory is also responsible for contracting out analysis which cannot be done in-house and for monitoring the performance of the contract labs. The test results are entered into the appropriate data bases to create product quality statistical summary reports and control charts. In order to complete this responsibility, several requirements must be met as shown below:

SOP OWNER	HSE APPROVAL	QA APPROVAL	AUTHORISATION
---------- Adio Sakiru Date: 06/04/22	----------N/A----------	----------N/A----------	---------- SITE QA: Afawode Olujide Date: 06/04/2022

1.1 **Lab Analysts & Trainer Qualification**:

1.1.1 Each lab analyst must be trained and pass a qualification demonstration before he/she is classified as a "stand alone" lab analyst.

1.1.2 Each trainer must have passed the same qualification as the lab analyst and must have developed technical skill on the analysis for at least 2 years.

1.1.3 It is required of all analysts to have mastery and technical in-depth of the analysis being performed.

1.2 **Lab Test Equipments**:

1.2.1 All new laboratory instruments must be qualified and validated with appropriate documentation

1.2.2 Each item of test equipment will be calibrated and maintained on a scheduled basis. The calibration will be documented, with appropriate remarks made as to any required equipment adjustments. Laboratory analyst also perform daily or shiftly calibration checks on selected test equipment.

1.2.3 A master list, by type and model/serial number, will be maintained of all test equipments in the calibration/maintenance system. Repairs of test equipment will be done in-house if possible, otherwise, equipment repair will be done by the appropriate vendor following plant guideline

1.2.4 All analysts must log-in with their access on Laboratory equipment and Quality window when performing analysis, documentation of data and also log-out after completion of Analysis.

1.3 **Test Methods and Procedures**:

1.3.1 All test methods and procedures will be in written form, master copies of which will be physically located in the laboratory.

1.3.2 Analytical methods are to be validated by Product development. Verification of methods is done via lab assessments and Co-op studies, coordinated by the laboratory leader. The verification document is kept in lab files owned by the laboratory Leader or Designated Analyst.

1.3.3 Upon receipt of new methods, the laboratory Leader will archive the superseded copy. Current technical standards must be available in the laboratory at all time.

1.3.4 All test must be stamped with the site technical standard approved copy green stamp.

1.4 **Formular Cards**:

1.4.1 Upon receipt of formula card changes, notification and distribution follow the normal distribution procedure.

1.4.2 Formular Card transcription to Quality Window is done by the Lab. Leader and approved by the site QA Leader

1.5 **Chemicals and Reagents**:

1.5.1 All chemicals used in the laboratory must be within their expiration dates. Any unused or expired chemical will be disposed according to site environmental requirements by the chemical management owner for the department.

1.5.2 All chemicals must be labeled with the appropriate safety hazard labels, date received or prepared expiration date, date opened, date exhausted, identity, concentration, and any special storage requirements.

1.5.3 Chemicals will be stored only in designated areas within the laboratory.

1.5.4 Prepared reagents must have an accompanying log book/sheet in which records of weights or volumes of ingredients and results from standardisation. (if applicable) are documented.

1.5.5 Labeling of reagents must include the full name of the reagent, its concentration, the date of preparation, its expiry date and the signature of the personnel responsible for the preparation.

1.6 **Record Keeping and Documentation**:

1.6.1 Test data is entered only on bonded paper or prepared data forms [which are QA approved] or directly into computer data base -no scrap pieces of paper will be used. All assay results and calculations must be clearly documented on lab registers and assay reports.

1.6.2 If a correction/alteration is required to a data value, the erroneous data will be marked through with one line, the corrected value written above [or beside] the erroneous one and the initials of the person making the correction will be placed next to the corrected value.

1.6.3 All completed notebooks or data forms will be kept or filed for historical record keeping and retrieval purposes.

1.6.4 All analytical test results must have the analyst's initial/signature and the date the test is performed so that all test results are traceable to the person performing the test and must be checked by another analyst. The checking analyst must initial and date the calculations they have checked.

1.6.5 Analytical data such as Assay sheet, Batch cards, Chemical expiration and Consumption etc. are to be opened for editing from Share point (TEAMS) location and locked with password after usage. QW data, FTIR and Bar code Scanner data are to be back-up once in a week on Share point (TEAMS) location..

1.6.5 There should be no blank spaces left where entries are required on documentation. 'NA" should be used when it is not necessary for a space to be filled in.

Refer to SOP on Record keeping. UCL/IBDSITE/CD/Q/22

1.7 **Handling of Out of Specification Results**:

1.7.1 Each analytical test will be performed only once, unless the analyst knowingly has made a procedural error or suspect equipment failure. When an out-of specification result occurs, the lab analyst places the product on hold and informs the Laboratory Leader or the QA Leader to take immediate action on the issue.

1.7.2 All out of limit results must be investigated immediately the result is detected. Investigation is initiated by the analyst who detected the result to be conducted alongside a peer analyst and Laboratory Leader.

1.8 **Scheduling Lab Testing Support:**

1.8.1 Only tests for which the site laboratory does not have the equipment in-house should be contracted to external labs. The external labs must be validated from time to time for consistence with applicable methods and procedures.

1.9 **Recording EOs/Special Project Test Results**:

1.9.1 Analytical test results obtained during EOs, special projects, initiative start-ups (Shippable products), etc are NOT to be recorded in the normal daily Quality Window data base

2.0 **Laboratory Daily Management Systems**:

2.0.1 F&HC analytical Laboratory must have a method control strategy which will be used to manage the capability of the Laboratory. There must be in place Laboratory PR and Control sample system and all analysts in the analytical Laboratory must be part of MCS.
The Laboratory capability measurement system is owned by Laboratory Leader. Show me qualification will be used for analysis that are not on Lab Capability program. Report of Laboratory Capability must be shared with all analyst in the analytical laboratory QA Leaders by 3rd working day of new month.

2.0.2 Unauthorized personnel are not to be allow in the Laboratory, Sensory rooms and Retention room.

2.0.3 Laboratory Temperature and humidity data logger are to be downloaded monthly by the Laboratory leader or designated Analyst and save on Share point (TEAMS) location.

2.1 **Right First Time:**

2.1.1 All laboratory analysis must meet right-first time and proper error correction done when applicable

2.2 **Audit Trail:**

2.2.1 Monthly Audit Trail of Laboratory equipment/Applications; Quality Window (Main and Satellite Lab.), FTIR, Gallery Analyzer, Moisture Analyzers and Auto- Titrator are to be done by the Laboratory Leader or his/her Back-up.

REASON FOR UPDATE

Version 0: New SOP

End of Procedure

SOP RELATED ATTACHMENTS

Attachment 1 – Qualification Sheet

Attachment 2 -- Model Answer