	<b>Halal Compliance Requirements</b>	
	Procedure	<b>SOP-HAL-001</b>
	Revision Date	260506
	Page No	1 of 5

## 1. Purpose:

To define the controls and requirements necessary to ensure that all Halal-certified products manufactured by Artisan Labs comply with Halal standards while maintaining full alignment with ISO 22716 Good Manufacturing Practices. This SOP establishes the segregation, cleaning, documentation, and production-planning controls required when Halal and non-Halal products are manufactured within the same facility for multiple customers.

## 2. Scope:

This procedure applies to all contract manufacturing activities, including:

- Customer-owned formulas
- Customer-specified raw materials
- Bulk manufacturing
- Filling and packaging
- Storage and warehousing
- Cleaning and sanitation
- Documentation and traceability

This SOP applies to all personnel involved in the handling of Halal and non-Halal materials, components, and finished goods.

## 4. Definitions

**Halal:** Materials, processes, and products permissible under Islamic law.

**Non-Halal:** Materials or processes not permissible under Islamic law.

**Shared Equipment:** Equipment used for both Halal and non-Halal production.

**Cross-Contamination:** Unintended transfer of non-Halal residues or materials into Halal production.

**Segregation:** Physical or procedural separation to prevent contamination or mix-ups.

## 5. Responsibilities

### Quality Manager


- Ensures compliance with Halal and ISO 22716 requirements.
- Approves production scheduling involving Halal products.
- Verifies cleaning and sanitation before Halal production.
- Maintains communication with the Halal certification body and customers.

### Production Manager / Compounding Team

- Ensures proper segregation of Halal and non-Halal materials during manufacturing.
- Confirms equipment readiness and line clearance.
- Ensures operators follow Halal-specific controls.

### Warehouse & Materials Team

- Segregates and labels Halal vs. non-Halal materials.

	<b>Halal Compliance Requirements</b>	
	Procedure	<b>SOP-HAL-001</b>
	Revision Date	260506
	Page No	2 of 5

- Ensures proper documentation and traceability.
- Prevents mix-ups during receiving, storage, and staging.

## Operators & Technicians

- Follow all Halal handling, cleaning, and documentation requirements.
- Report deviations immediately.

## 6. Procedure

### A. Customer Requirements & Formula Verification

- a. Because this is a contract manufacturing facility:
  - i. Each customer's Halal formula must be reviewed for Halal compliance.
  - ii. If a customer or supplier supplies raw materials, Halal status must be verified before acceptance.
  - iii. Customer-specific Halal requirements must be documented and followed.

### B. Raw Material & Packaging Controls


- a. All Halal-approved raw materials must be:
  - i. Received with proper documentation (COA, SDS, Halal certificate if required).
  - ii. Labeled **HALAL** upon receipt.
  - iii. Labeled Halal in the Data System
- b. All Halal materials must be stored separately.
  - i. Shared storage areas must use:
    1. Physical separation (racks, bins, or designated zones), or
    2. Controlled procedural segregation with documented controls.
- c. Halal packaging components must be stored in designated Halal-only areas or clearly segregated.

### C. Segregation Approach for Limited Halal Production

- a. Because the facility produces very few Halal products and the majority of production is non-Halal, segregation controls apply specifically to Halal-designated materials only
- b. Halal raw materials, components, intermediates, and finished goods must be segregated through:
  - i. Dedicated, clearly labeled Halal storage locations
  - ii. Physical or procedural separation during staging
  - iii. Controlled access during production
  - iv. Documented line clearance and cleaning verification
- c. Non-Halal materials do not require segregation from each other but must never come into contact with Halal materials during any stage of handling, manufacturing, or storage.

### D. Equipment & Utensil Controls

- a. Shared equipment may be used for Halal production only after:
  - i. Completion of a validated cleaning and sanitation cycle
  - ii. Documentation of cleaning in the Equipment Cleaning Log

	<b>Halal Compliance Requirements</b>	
	Procedure	<b>SOP-HAL-001</b>
	Revision Date	260506
	Page No	3 of 5

- iii. Quality verification (visual inspection required)
- iv. Dedicated utensils for Halal production may be used when available, but are not required

### **E. Production Scheduling**

- a. Halal production must be scheduled:
  - i. Before non-Halal production, whenever possible, or
  - ii. After a validated cleaning cycle, if non-Halal was run previously.
- b. Production planning must consider:
  - i. Customer deadlines
  - ii. Equipment availability
  - iii. Cleaning turnaround time
  - iv. Halal certification requirements
- c. Halal and non-Halal materials must never be staged simultaneously in the same area.
- d. Quality must approve the production schedule for all Halal batches.

### **F. Line Clearance & Pre-Production Checks**


- a. Before starting Halal production, the following must be verified and documented:
  - i. All previous materials and components were removed from the line.
  - ii. Equipment cleaned and approved for Halal use.
  - iii. Only Halal-approved raw materials and packaging are present.
  - iv. The batch record includes a Halal designation.
  - v. Customer-specific Halal requirements reviewed and confirmed.
  - vi. Pre-operations checklist form completed and signed by Production and Quality.

### **G. Manufacturing Controls**

- a. Operators must ensure no non-Halal materials enter the production area (line) during Halal manufacturing.
- b. Halal products must be protected from contamination at all times (covered vessels, closed transfer systems, clean utensils).
- c. If a customer provides bulk or intermediates, Halal status must be verified before use.
- d. Any deviation must be reported to Quality immediately.

### **H. Cleaning & Sanitation Requirements**

- a. Cleaning procedures must be followed and validated to remove residues of non-Halal materials and documented on:
  - i. Pre-weigh (Pre-weigh Cleaning Log SOP-005.5-1A)
  - ii. Compounding (Compounding Kettle Cleaning Log SOP-005.5-1B)
  - iii. Production (Line Equipment Cleaning Log SOP-005.5-1C)
- b. Cleaning must include:
  - i. Equipment disassembly (if applicable)
  - ii. Detergent wash
  - iii. Rinse
  - iv. Sanitization
- c. Cleaning verification must be documented and approved by Quality before Halal production begins.

	<b>Halal Compliance Requirements</b>	
	Procedure	<b>SOP-HAL-001</b>
	Revision Date	260506
	Page No	4 of 5

- d. If a customer requires additional Halal-specific cleaning steps, these must be added to the batch record or cleaning checklist.

#### **I. Packaging & Labeling Controls**

- a. Only Halal-approved packaging components may be used.
- b. Packaging lines must undergo full line clearance before Halal production.
- c. Finished goods must be labeled according to:
  - i. Customer requirements
  - ii. Halal certification body requirements
  - iii. Regulatory labeling standards

#### **J. Storage & Warehousing**

- a. Finished Halal products must be stored in a designated Halal area or segregated zone.
- b. Pallets must be clearly labeled **HALAL**.
- c. Non-Halal products must never be stored above Halal products.
- d. Customer-specific storage requirements must be followed.

#### **K. Documentation & Traceability**

- a. The following records must be maintained:
  - i. Raw material Halal verification
  - ii. Supplier documentation
  - iii. Cleaning logs
  - iv. Batch manufacturing records
  - v. Line clearance forms
  - vi. Customer-specific Halal requirements
  - vii. Deviation reports
  - viii. All documentation must comply with ISO 22716 requirements for traceability and record retention.


#### **L. Deviations & Non-Conformities**

- a. Any suspected or confirmed contamination event must be escalated to Quality immediately.
- b. A deviation report must be initiated.
- c. Impact assessment must determine whether the product must be quarantined or rejected.
- d. Customers must be notified if required by contract.
- e. The Halal certification body must be notified if required by certification rules.

#### **M. Training**

- a. All personnel involved in Halal production must receive training on:
  - b. Halal requirements
  - c. This SOP
  - d. ISO 22716 GMP principles related to segregation, cleaning, and documentation
  - e. Customer-specific Halal requirements
  - f. Training must be documented and repeated annually or when changes occur.

### **7. Associated Documents**

	<b>Halal Compliance Requirements</b>	
	Procedure	<b>SOP-HAL-001</b>
	Revision Date	260506
	Page No	5 of 5

Sanitation Plan SOP-004.1, Production Cleaning Plan SOP-004.2, Daily Cleaning and Shut Down  
 Chekclist SOP-004.2-1A, Equipment Cleaning Plan SOP-005.5

Rev. Date	Nature of Changes	Revisier
260507	New document	DH