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Example Procedure

# PRODUCTION AND OPERATIONS

## 1. PURPOSE

This procedure describes the general principles for how [insert Company Name] will control and manage its operations and production.

## 2. SCOPE

This procedure covers all manufacturing operations at [insert Company Name].

The [insert relevant positions] are directly responsible for this procedure.

## 3. TERMS & DEFINITIONS

**SOP:** Standard Operating Procedure. These documents document and explain the high level requirements for each individual process, such as, grain milling, blending, pelleting, etc.

**Instruction:** Task or work instructions are ideally one page descriptions of how to perform an individual task within a SOP. For example, how to start up or shutdown a pellet press. Instructions include more detail of the individual task than that included in the applicable SOP.

## 4. PROCESS

Each stage of the manufacturing operations shall be described in written procedures and associated task instructions. The individual process stages should align with the HACCP Flow Chart.

Written procedures will define the monitoring and control of all identified critical control points.

Mixing records shall be maintained to chronicle the sequence and quantity of all batches produced on a daily basis. These will be recorded in the Daily Production Report.

- Maintain a complete and traceable history of production.
- Name and quantity of all drugs and high risk materials, including RAM.
- Alignment between formulation and batching.

Acceptable deviations of actual from theoretical batch weights shall be determined. All deviations to be reported on the Daily Production Report.

Record any deviation of actual production versus final load or bag count.

Product records to identify specific equipment and bins used in all batches.

Production records to include all batch and lot identifying numbers.

Production records to include all alarms and error messages.

All discrepancies are reported immediately to senior management.

All significant discrepancies are to be investigated and corrective action applied as required.

Production records to be reviewed to verify that the production formula agrees with the master formula.

All procedures shall be regularly reviewed to ensure effectiveness and continuous improvement.

# 5. DOCUMENTATION & RECORDS

The following records shall be maintained to assure this program was conducted according to the Quality Policy.

- Calibration & Maintenance Schedule
- Test Equipment Calibration Chart
- Calibration Reports
- Non-Conformance Reports

# 6. DOCUMENT HISTORY

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| Version No.: | | | |
| Last saved by: | | Date: | |
| Original Author: | | Date: | |
| | | | |
| Approved by: | | Date: | |
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