



1.0 Purpose

This procedure describes the process for approval or rejection of incoming film for the Manufacturing facility.

2.0 Scope

This procedure applies to all incoming film for Manufacturing.

3.0 Responsibility

Quality Associate is responsible for inspecting all incoming film.

4.0 Safety Considerations

Steel-toed shoes and safety glasses are required while on production floor. Safety glasses are required for lab work. Gloves are required when handling the Accu Dyne Test marker.

Safety is a consideration of employment. Employees are not authorized to work in an unsafe manner and are prohibited from harming the environment of the facility or community.

5.0 Materials/Equipment

- Mitutoyo 0-1" Caliper
- Accu Dyne Test Markers #34 or #36
- Ruler

6.0 Procedure

1. Incoming film will be placed in the Quality Hold area following the *Quarantine and Auditing of Products (Q12-PR-100-012)* procedure. If the area is full, each incoming pallet will be tagged with an *Incoming Raw Material Hold* placard (*Q12-FM-100-012*) to serve as a visual instruction that this film has not been inspected by Quality and is not available for use by Production.
2. Quality Associate will perform a cursory inspection of the film rolls for visible defects or printing mistakes before collecting the attached representative roll samples from the rolls to be tested. A minimum of three rolls from each shipment will be inspected.
3. Once representative roll samples are collected, Quality Associate will transport all samples to cGMP Library for testing.

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GILES CHEMICAL ~ PREMIER MAGNESIA

Company Procedure

Title: **Incoming Film Check**

Number: **P12-QA-100-074**

Owner: **Ashley Williams**

Revision: **04**

Effective Date: **7/1/2015**

Page: **2 of 3**



4. Quality Associate will consult the appropriate specification sheet and fill in the associated form.
5. A Quality assigned lot number will be given to each shipment of film. This lot number will be based upon the date of receipt and the type of film. Record the lot number in the designated area on the corresponding film checklist.

Example - 062515MAG

06 – Month film was received

25 – Day film was received

15 – Year film was received

MAG – Type of film (Magriculture)

6. Set the calipers unit of measure to inches. Tare the calipers to zero. Adjust the tips of the calipers to fit across the points to be measured. Compare the thickness measurement to the specifications.
7. Using a ruler, compare the length and width of the film sample to the specifications.
8. Visually check the film for color clarity, correct labeling, and the UPC code listed on the specifications.
9. Use an Accu Dyne Test marker #34 or #36 to test the non-printable area. Shake the test marker before opening. Apply 2 to 3 streaks across the width of the film. The area that is non-printable should bead off. The printable area will have purple streaks.
10. Using a ruler, measure and compare the perforations on the film to the specifications.
11. All specifications must be met for film rolls to be approved.
12. If any roll does not meet all specifications, it will be rejected. The Director of Quality and the Plant Manager will be informed of all rejected rolls. Upon rejection, the Quality Associate will then conduct an audit of all rolls in the shipment to determine the number of useable rolls. Rejected rolls will be labeled with a *Quality Rejected* placard (*Q13-FM-100-007*), returned to the supplier, and a supplier complaint will be initiated.
13. Once film has been approved for use, Quality Associate will place all completed Film Checklists in the Film Check binder in the cGMP Library. Quality Associate will place a *Quality Approved* placard (*Q13-FM-100-006*) on each roll of approved film. Quality Associate will also fill out a *Film Use Log (P15-QA-100-F074I)* with assigned lot number, product, and date of Quality approval. This form will be put into a protective sleeve, rolled up, and placed inside the cardboard

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roll in the center of each roll of film. This form will be used by Production until rolls have been spent and then will be returned to Quality for retention.

14. A sample of each roll of film inspected will be kept in the Quality Lab for three months, and then moved to long term storage until one (1) year past expiry date.

7.0 Reference Documents

Film Specifications - Tech Film 25 kg (P12-QA-100-F074e)
Film Specifications - Tech Film 50 lb. (P12-QA-100-F074f)
Film Specifications - USP Film 50 lb. (P12-QA-100-F074g)
Film Specifications - USP Film 16.8 kg (P12-QA-100-F074h)
Film Check - Tech Film 25 Kg Checklist (Q12-PR-100-F022a)
Film Check - Tech Film 50 lb Checklist (Q12-PR-100-F022b)
Film Check - USP Film 50 lb Checklist (Q12-PR-100-F022c)
Film Check - USP Film 16.8 Kg Checklist (Q12-PR-100-F022d)
Film Check - Brandt Film 50lb. Checklist (P12-QA-100-F074i)
Film Check - San Francisco Salt Company 50lb. Checklist (P12-QA-100-F074j)
Film Check - Magriculture Film 50lb. Checklist (P12-QA-100-F074k)
Quarantine and Auditing of Products (Q12-PR-100-012)
Quality Rejected (Q13-FM-100-007)
Quality Approved (Q13-FM-100-006)
Film Use Log (P15-QA-100-F074l)
Incoming Raw Material Hold placard (Q15-FM-100-012)

8.0 Change Information

Added Quality assigned lot number
Added Incoming Raw Material Placard
Added Film Use Log

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