

GMP POPCORN EXERCISE CHECKLIST

Goal:

Make a batch of GMP popcorn within a specified timeframe (1.5 hours).

Objective:

Understand the complexity of a GMP process.

Gain appreciation of teamwork and cooperation of all departments.

How it mirrors industry:

- You will be frustrated at times
- You will be rushed.
- You will feel a sense of accomplishment once you made the batch!
- The actual time for the chemistry / fermentation / etc. is very small compared to the time it takes to get all GMP documentation in place.

Supplies:

1. Department tasks and deliverables
2. Approved labels
3. Quarantine labels
4. Box for approved and quarantine
5. Microwave Popcorn
6. Access to photocopier
7. Access to microwave
8. Water in a squirt bottle
9. 409 or other type of cleaning agent
10. Paper towels
11. Sponge
12. Measuring cups
13. Bags for the finished product

Teams:

Material Control: 2 people

QC: 2 people that like to test material

QA: 2 people that have an eye for written details

Production: 4 people that like to WORK

QUALITY ASSURANCE

ROLE OF QA:

- Review and Approval all quality related documents.
- Issue all controlled documents.
- Provide oversight on the production campaign.
- Disposition Raw materials and final products.

Checklist of Items to Accomplish:

- Review and Approve Raw Material Master Specification Sheet
- Review and Approve Final product Master Specification Sheet
- Review and Approve Master Batch Record
- Approve actual Raw Materials for use
- Inspect Microwave for Cleanliness
- Review completed Batch Record after production is complete
- Review QC data and Approve actual Popcorn

Your Tasks are:

1. APPROVING MASTER SPECIFICATIONS:

Production will be submitting for your review AND approval:

1. **RAW MATERIAL SPECIFICATION SHEET** for the KERNELS
2. **FINAL PRODUCT SPECIFICATION SHEET** for the POPCORN.

Instructions: Review to ensure all boxes that are **shaded** have been completed. All information provided should make sense and be reasonable. Try where possible to have the team write in quantitative specifications (i.e. "No more than 2 dark pieces of popcorn."). If you don't agree with the specifications, or have questions, feel free to go back to the Production Team for clarification.

HOW TO APPROVE A MASTER SPECIFICATION SHEET:

To make the **specification sheet** effective complete the following:

- a). **Sign** your name in the shaded box for "QA Approval".
- b). **Write** in an **effective date** (i.e. today's date) in the upper right hand corner.
- c). Make a **photocopy** (yes, go to the photocopier) of the original document you just signed and give a copy to QC.
- d). **File** the original in QA.

2. APPROVING A MASTER BATCH RECORD:

Production will be submitting for your review:

1. A Master **BATCH RECORD** to make the POPCORN.

Instructions: Review to ensure all boxes that are **shaded** have been

completed. All information provided should make sense and be reasonable. HINT: The production team should have quantitative numbers in the process (i.e. Pop popcorn for 1.5 – 2.5 minutes). If you don't agree with the process description or have questions feel free to go back to the Production Team for clarification.

HOW TO APPROVE A MASTER BATCH RECORD:

To make the BATCH RECORD effective complete the following:

- a). **Sign** your name in the shaded box for “QA Approval” on the front page and initial the bottom of all pages in the QA box designated.
- b). **Write in** an **effective date** (i.e. today's date) in the upper right hand corner on **ALL PAGES**.
- c). Make a **photocopy** of the Master Batch Record
- d). Write in the **Lot Number** on all pages (in the box for LOT NUMBER) **ON THE PHOTOCOPY OF THE BATCH RECORD**. (See below for instructions):

INSTRUCTIONS FOR ASSIGNING A UNIQUE LOT NUMBER:

Lot number should be POP-YEAR-001. For example: POP-03-001

- e). **File** the original batch record in QA.
- f). **Give the photocopy** of the batch record to production. (We call this “Issuing a batch record to production”)

3. APPROVING RAW MATERIALS:

Before production can use the kernels in their production run they must be approved by QC AND QA! Follow the instructions below to approve the raw materials (i.e. Kernals).

HOW TO APPROVE RAW MATERIALS:

1. Once QC finishes the “testing” on the Kernals, **review** the information written in on the specification sheet and the accompanying documentation to ensure no empty spaces.
2. If acceptable, sign your name in the box for QA at the bottom of the page on the **specification sheet** and check off “**Approved**”.
3. Fill in the spots on the **Approval labels**. **Make one for each container / package PLUS 1 extra for the receiving report.**
4. Complete the remaining boxes designated “QA” on the **Receiving report**. Place your extra label on the receiving report.
5. Give **approval labels** to Material Control.

4. INSPECTING EQUIPMENT:

Before production can use a piece of equipment it must be clean! It is a common practice in industry to have QA inspect the equipment after production cleans it.

HOW TO INSPECT EQUIPMENT:

1. Production will be requesting QA to **visually inspect** the microwave for cleanliness. If it is not satisfactorily clean, have Production re-clean the microwave.

2. Once acceptable, sign/date the **Cleaning Log** in the spot for “QA initials”

5. INTERNAL AUDITING:

Feel free to audit the production area during production!

6. REVIEWING COMPLETED PRODUCTION BATCH RECORDS:

Once production of the popcorn is complete, the Production team will be submitting the completed batch record for your review. Before the popcorn is “Dispositioned” QA must review the completed batch record AND completed Quality Control testing. BOTH items must be satisfactorily before the popcorn can be approved!

HOW TO REVIEW A COMPLETED BATCH RECORD:

1. Ensure all information is recorded and completed per requirements of the batch record.
2. If any items were not completed –return to production for correction.
3. The team must not of deviated from requirements in the batch record. (i.e: if it says to “Pop the popcorn in the microwave for 2-3 minutes they must not go over 3 minutes or under 2 minutes without some justification.)
4. Once you are satisfied with the completed record, sign your name in the “Reviewed by QA” box
5. **DO NOT YET APPROVE THE BATCH. YOU NEED THE QC DATA FIRST.**

7. REVIEWING COMPLETED QC DATA

Once the QC data is complete – review the QC information for completeness. If both the Batch Record and QC data are acceptable you may sign both documents as “APPROVED”. NOW THE POPCORN IS APPROVED.

HOW TO APPROVE QC DATA ON POPCORN

1. Once QC finishes the “testing” on the Popcorn, **review** the information written in on the specification sheet and the accompanying documentation to ensure no empty spaces.
2. If acceptable, sign your name in the box for QA at the bottom of the page on the **specification sheet** and check off “**Approved**”.
3. If the batch record is complete and the QC data is complete you can now fill out the **Approval labels!**
4. Complete the remaining boxes designated “QA” on the **Receiving report**. **Make one label for each container / package PLUS 1 extra for the receiving report.**
5. Place your extra label on the receiving report.
6. Give **approval labels** to Material Control.

MATERIAL CONTROL

ROLE OF MATERIAL CONTROL:

- MC controls the flow of materials and limits the access of materials to prevent against "off-grade" materials being used in production.
- Material Control inspects all incoming materials/packages for integrity.
- Material control offers expertise in packaging and storing of materials.

Your Tasks are:

1. STORAGE AREAS:

Designate two separate areas: "**Quarantine**" and "**Approved.**" Use the boxes provided and label them appropriately.

2. **Inspect** all incoming packages for possible signs of damage during shipping.

3. RECEIVING RAW MATERIALS:

You will receive raw materials to enter into your system.

Instructions:

1. By using information on the package - fill in **SECTION 1** on the "**Receiving Report**". Use the template provide.
2. Give a "**RECEIVING NUMBER**" to the material. Use the following format: DDMMYY – 000
(i.e. for the first item received on January 2, 2007 write: 010207-001)
3. Write this receiving number on the Receiving Report. Attach the COA to the Receiving Report.
4. Complete a **Quarantine Label** and place the completed "**Quarantine**" label on the material and transfer to the "**Quarantine**" area.
5. Give the "**Receiving Report**" and COA to QC- this is their cue to sample the material and begin testing.

4. LABELING RAW MATERIALS APPROVED:

1. QA will give Material Control "Approval" labels to apply to the material that is in "Quarantine".
2. Place the Approval Label to cover up the word "QUARANTINE" on the quarantine label. Move the material to the "Approved" area.
3. Production may now have the material. Give only "Approved" material to production for their use.

5. RECEIVING FINAL PRODUCTS INTO QUARANTINE:

You will need to take the final product (i.e. popcorn) and place it in quarantine.

Instructions:

1. fill in **SECTION 1** on the "**Receiving Report**". Use the template provide. Ask production team for lot number.
2. Complete a **Quarantine Label** and place the completed "**Quarantine**" label on the material and transfer to the "**Quarantine**" area.
3. Give the "**Receiving Report**" to QC- this is their cue to sample the material and begin testing.
4. QA will give Material Control the "Approval" labels to apply to the material that is placed in "Quarantine". Move the material to the "Approved" area.

PRODUCTION

ROLE OF PRODUCTION:

- Execute the process according to the batch record to produce a product within specifications
- Coordinate the batch record, release of raw materials, and equipment

Checklist of Items to Accomplish:

- Write Master Raw Material Specification Sheet and circulate for approvals
- Write Master Final Product Specification Sheet and circulate for approvals
- Write Master Batch Record and circulate for approvals
- Ensure Raw Materials have been tested and approved
- Clean Microwave per SOP
- MAKE GMP Popcorn! And complete batch record as you go!

HINT: PRODUCTION HAS MANY DOCUMENTS TO WRITEIT IS BEST IF YOU MULTI TASK AND SPREAD THE WORK AMONG THE DEPARTMENT.

Your Tasks are:

1. WRITING MASTER SPECIFICATIONS:

Production must write the following specifications and give to QC and QA to review and approve:

1. **RAW MATERIAL SPECIFICATION SHEET** for the KERNELS
2. **FINAL PRODUCT SPECIFICATION SHEET** for the POPCORN.

Instructions:

Use the template in your package. Neatly complete all boxes (i.e. Vendor, storage conditions, specifications, etc.) that are **shaded** (except the signatures). All information provided should make sense and be reasonable. Try where possible to write quantitative specifications (i.e. "No more than 2 dark pieces of popcorn).

1. Circulate for signatures –
 - 1st: Production signer in "Written By"
 - 2nd: Production Supervisor signs
 - 3rd: QC Supervisor
 - 4th: QA

NOTE: QA will keep the final document.

2. WRITING A MASTER BATCH RECORD:

Production must write a Master Batch Record for the production of Popcorn.

Use the Template provided.

Instructions:

Enter all the information in the boxes that are **shaded**. You must describe what you think your process will be. All information provided should make sense and be reasonable.

HOW TO WRITE A MASTER BATCH RECORD:

- a). Complete all shaded areas. Sign your name on the front page
- b). Give to Production supervisor for review. Sign your name on the front page.
- c). Give to QA to review. Sign your name on the front page.
- d). Once QA is happy with the batch record, they will issue you a copy to conduct your production.

- 3. Don't forget to check with QC regarding the testing of your **raw materials (i.e.: Kernels)**.**

4. CLEANING EQUIPMENT:

Before production can use a piece of equipment it must be clean! It is a common practice in industry to have QA inspect the equipment after production cleans it.

HOW TO CLEAN EQUIPMENT:

1. Use the SOP provided to clean your equipment (i.e. Microwave).
2. Once the production operator has cleaned the Equipment, complete the documentation required on the Cleaning log and have the Supervisor inspect the equipment.
3. Request QA to **visually inspect** the microwave for cleanliness.
4. Once QA has inspected the equipment and found it acceptable, you may now use the equipment.

5. STARTING PRODUCTION!

1. Once you have the issued batch record from QA; APPROVED raw material; and CLEAN equipment, **you may start production of the POPCORN.**
2. Follow the process in your batch record and document as you go. Once the production of the popcorn is complete so should your batch record.

ENDING PRODUCTION:

1. Notify Material Control to remove your popcorn from the equipment and place it in quarantine.
2. While QC is testing the material, the Production Operator must review the record to ensure all information is complete.

3. Production supervisor must review and sign the back of the batch record.
4. Submit to QA for review.
5. Clean the equipment as documented above.
6. Wait to hear from QA if your material is approved!

QUALITY CONTROL

ROLE OF QC:

- Test all materials to be used by Production.

Checklist of Items to Accomplish:

- Review Raw Material (i.e. Kernals) Specification Sheet
- Test Raw Materials
- Review Final Product (i.e. Popcorn) Specification Sheet
- Test Final Product Materials

Your Tasks are:

1. APPROVING MASTER SPECIFICATIONS:

Production will be submitting for your review AND approval:

1. **RAW MATERIAL SPECIFICATION SHEET** for the KERNELS
2. **FINAL PRODUCT SPECIFICATION SHEET** for the POPCORN.

Instructions: Review to ensure all boxes that are **shaded** have been completed. All information provided should make sense and be reasonable. Try where possible to have the team write in quantitative specifications (i.e. "No more than 2 dark pieces of popcorn"). If you don't agree with the specifications or have questions feel free to go back to the Production Team for clarification.

HOW TO APPROVE A MASTER SPECIFICATION SHEET:

To approve the **specification sheet** complete the following:

- a). **Sign** your name in the shaded box for "QC Approval".
- b). Give to QA for their review.

2. DOCUMENTS NEEDED:

NOTE: QA will give you copies of the specification sheets to document the results of the testing for BOTH the kernels and the popcorn.

3. APPROVING RAW MATERIALS:

Before production can use the kernels in their production run they must be approved by QC AND QA! Follow the instructions below to test and approve the raw materials (i.e. Kernals).

HOW TO TEST AND APPROVE RAW MATERIALS:

1. Material Control will be giving you a **RECEIVING REPORT** for both **KERNELS** and **POPCORN** (once made). This is your cue that something is in quarantine and needs to be tested by QC. Take your

specification sheet to quarantine and begin to following the sampling and testing instructions.

2. Once the analyst completes the “testing” on the Kernals, **review** the information written in on the specification sheet and the accompanying documentation to ensure no empty spaces. The analyst will sign his/her initials and date in the column.
3. The QC Supervisor will review the package of data the analyst completed and If acceptable, sign your name in the box for QC approval at the bottom of the page on the **specification sheet** and check off “**Approved**”.
4. Give package to QA.

4. APPROVING FINAL PRODUCT (I.E: Popcorn):

Once production has made the popcorn, you will be required to test the material. Follow the instructions below to test and approve the final product (i.e. popcorn).

HOW TO TEST AND APPROVE FINAL PRODUCTS:

1. Material Control will be giving you a **RECEIVING REPORT** for the **POPCORN** (once made). This is your cue that something is in quarantine and needs to be tested by QC. Take your specification sheet to quarantine and begin to following the sampling and testing instructions.
2. Once the analyst completes the “testing” on the Popcorn, **review** the information written in on the specification sheet and the accompanying documentation to ensure no empty spaces. The analyst will sign his/her initials and date in the column.
3. The QC Supervisor will review the package of data the analyst completed and If acceptable, sign your name in the box for QC approval at the bottom of the page on the **specification sheet** and check off “**Approved**”.
4. Give package to QA.

Batch Production Record

Product Name: Popcorn

Effective Date:

Revision: 0

Written By:

Date:

**Production Supervisor
Approval:**

Date:

**Quality Assurance
Approval:**

Date:

MANUFACTURING DIRECTIONS FOR LAB SCALE BATCH:

Lot Number:

Effective Date:

COMPOUND: POPCORN

Revision: 0
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INPUT MATERIALS:

INPUT MATERIALS	PRODUCTION OPERATOR	CHECKED BY

Note:

Input Materials are materials used in your process (i.e. Kernals).

Document Approval

Quality Assurance Initial:	
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MANUFACTURING DIRECTIONS FOR LAB SCALE BATCH:

Lot Number:

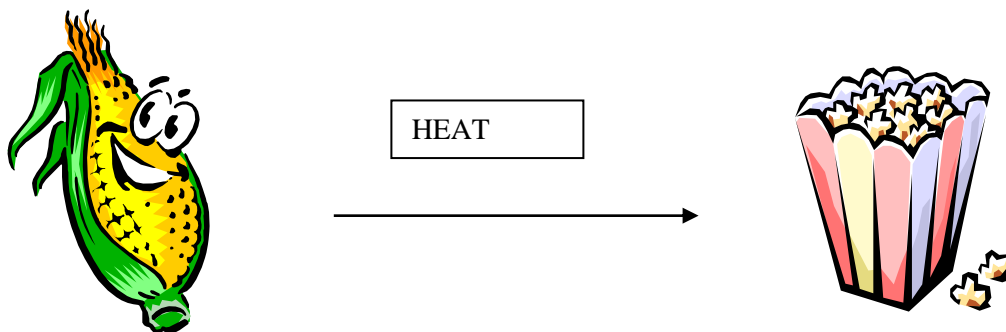
Effective Date:

COMPOUND: POPCORN

Revision: 0

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REACTION SCHEME



Document Approval

Quality Assurance Initial:

MANUFACTURING DIRECTIONS FOR LAB SCALE BATCH:

Lot Number:

Effective Date:

COMPOUND: POPCORN

Revision: 0

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EQUIPMENT CHECKLIST

(Standard batch size)

	Inventory Number	Production Operator Initial and date
Microwave Oven		

Document Approval

Quality Assurance Initial:

MANUFACTURING DIRECTIONS FOR LAB SCALE BATCH:

Lot Number:

Effective Date:

COMPOUND: POPCORN

Revision: 0
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PROCEDURE

Date:

		Operator init./time	Coworker init./time
1.			
2.			
3.			
4.			
5.			
6.			

Document Approval

Quality Assurance Initial:

MANUFACTURING DIRECTIONS FOR LAB SCALE BATCH:

Lot Number:

Effective Date:

COMPOUND: POPCORN

Revision: 0
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Date:

Operator Coworker
init./time init./time

7.			
8.			
9.			
10.			

Comments: (initial and date any comments)

Document Approval

Quality Assurance Initial:

MANUFACTURING DIRECTIONS FOR LAB SCALE BATCH:

Lot Number:

Effective Date:

COMPOUND: POPCORN

Revision: 0
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SUMMARY OF RESULTS

Actual Yield
%:

%

Operator:

Supervisor:

STORAGE OF MATERIAL

Total containers of product transferred to storage:

STORAGE CONDITIONS: Store at room temperature.

Document Approval

Quality Assurance Initial:

MANUFACTURING DIRECTIONS FOR LAB SCALE BATCH:

Lot Number:

Effective Date:

COMPOUND: POPCORN

Revision: 0
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CONCLUSION

Date Production Finished: Production Operator Initials:

Production Supervisor Approval: Date:

Quality Assurance Reviewer: Date:

DISPOSITION OF LOT # _____

Approved Non-Conforming

Quality Assurance Signature: Date:

Document Approval

Quality Assurance Initial:

RECEIVING REPORT

SECTION I : RECEIVING (Completed by Material Control)

Material Name:	Date Received:
Supplier:	Receiving Lot No.:
Quarantine Label Applied: Yes <input type="checkbox"/>	Number of Containers:
Completed by:	Date:

SECTION II: SAMPLING and INSPECTION (Completed by QC)

Total sample quantity (if final product otherwise N/A):	Number of Containers Sampled / Inspected:	By:	Date:
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SECTION III: LABELING (Completed by QA)

Number of labels issued: (QA)	By	Date:
Number of sample labels: (QA)	By	Date:
Attach Sample Label Below (QA)	By:	Date

Place sample label below:

RAW MATERIAL SPECIFICATION SHEET

Receiving Number:		Revision:	Effective Date:
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Item Description: KERNELS	
	Written By:
	Date:
	QC Approval:
	Date:
	Production Supervisor Approval:
	Date:
	QA Approval:
	Date:
Hazards:	MAY HARM TEETH!

Storage Condition:		Supplier:	
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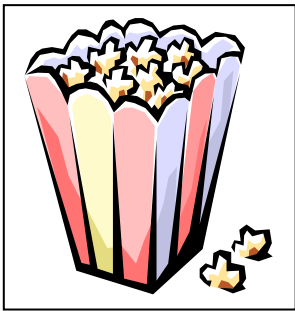
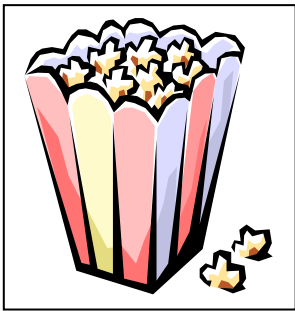
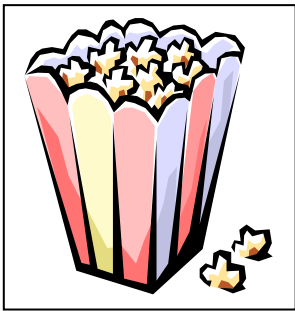
SPECIFICATIONS AND RESULTS

Test	Method	Specification	Result	QC Analyst Init. / Date
Physical Description	Visual			

QC Approval	<input type="checkbox"/> Approved <input type="checkbox"/> Non-Conforming	Date:
QA Approval	<input type="checkbox"/> Approved <input type="checkbox"/> Non-Conforming	Date:

FINAL PRODUCT SPECIFICATION SHEET

Lot Number:		Revision:	Effective Date:
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Item Description: POPCORN									
Structure:	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">  </td> <td style="width: 50%; background-color: #cccccc;"> Written By: _____ Date: _____ </td> </tr> <tr> <td style="background-color: #cccccc;">QC Approval: _____</td> <td style="background-color: #cccccc;">Date: _____</td> </tr> <tr> <td style="background-color: #cccccc;">Project Team Approval: _____</td> <td style="background-color: #cccccc;">Date: _____</td> </tr> <tr> <td style="background-color: #cccccc;">QA Approval: _____</td> <td style="background-color: #cccccc;">Date: _____</td> </tr> </table>		Written By: _____ Date: _____	QC Approval: _____	Date: _____	Project Team Approval: _____	Date: _____	QA Approval: _____	Date: _____
	Written By: _____ Date: _____								
QC Approval: _____	Date: _____								
Project Team Approval: _____	Date: _____								
QA Approval: _____	Date: _____								
Hazards:									

Storage Condition:		Supplier:	
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SPECIFICATIONS AND RESULTS

Test	Method	Specification	Result	QC Analyst Init./Date
Physical Description	Visual			

QC Approval	<input type="checkbox"/> Approved <input type="checkbox"/> Non-Conforming	Date: _____
QA Approval	<input type="checkbox"/> Approved <input type="checkbox"/> Non-Conforming	Date: _____

Receiving/Lot#: _____
Initials.: _____ Date: _____
Storage Conditions: _____
QUARANTINE

Receiving/Lot#: _____
Initials.: _____ Date: _____
Storage Conditions: _____
QUARANTINE

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Storage Conditions: _____
QUARANTINE

STANDARD OPERATING PROCEDURE

Procedure:	Procedure No.: CLN-0001	Revision: 0
PROCEDURE FOR THE PRODUCT CHANGEOVER CLEANING OF A MICROWAVE OVEN	Effective Date: 01/15/07	
	Replaces Document: New	
Written by:	Dept. Approval:	
Dept.: Production Date: 01/10/07	Dept.: Engineering	Date: 01/10/07
Content Review:	QA Approval:	
Dept.: Engineering Date: 01/10/07	Date: 01/13/07	

I. PURPOSE

This procedure is to ensure proper cleaning of equipment.

III. PROCEDURE

RESPONSIBILITY

3.1	Product Changeover Cleaning	
3.1.1	Enter the lot number of the batch on the “Equipment Cleaning Log”.	Production
3.1.2	Clean the equipment using water as a cleaning agent and paper towels as cleaning implements.	Production
3.1.3	First wipe the interior top of the microwave from back to front.	Production
3.1.4	Wipe the interior back of the microwave from top to bottom.	Production
3.1.5	Wipe the interior sides of the microwave from back to front, then top to bottom.	Production
3.1.6	Wipe the interior bottom of the microwave from back to front. If the microwave has a turntable inside, remove pieces and clean them using water as a cleaning agent. Visually inspect for contaminants. Replace them in the microwave when complete.	Production
3.1.7	Complete the “Cleaning Log”. Enter the SOP number used, cleaning agent, and time / date of person performing cleaning.	Production
3.1.8	Visually inspect for contaminants. If contaminants are present, repeat steps 3.1.2 through 3.1.7. If acceptance, initial column.	Supervisor
3.1.9	Notify QA to Inspect the equipment and verify that it is clean. Quality Assurance will sign the log in the “QA Initials Column” and check the product changeover box.	Production QA

