Raw material labels

- Label the raw materials (Craisins®, Goldfish® pretzels, Skittles®, and plastic bags) using the Raw Materials Release labels as follows:
  - Skittles will be: SK - (team number)
  - Craisins will be: CR - (team number)
  - Goldfish pretzels will be: GP - (team number)
  - Plastic bags will be: PB - (team number)
- Update the Expiration dates as follows:
  - Skittles: 4/20/26
  - Craisins: 2/7/26
  - Goldfish pretzels: 8/10/25
  - Plastic bags: N/A

  Note: These labels are white with a fluorescent yellow border. This is to indicate that the raw materials have already been through the quarantine and release process before the manufacturing process begins.
- Initial on the QA line.

Equipment labels

- Label the equipment (Scoops and Paper plates) using the Equipment labels as follows:
  - 100 mL scoop - GP - (team number)
  - 50 mL scoop - CR - (team number)
  - 50 mL scoop - SK - (team number)
  - 25 mL scoop - ST - (team number)
  - Paper plate - MAN - (team number)
  - Paper Plate - QC - (team number)
- Calibration Date: xx/xx/xxxx
- Initial on the QA line.

Equipment labels

- On pages 2–5 add a Product Batch Number in the box toward the top of each page.
  - Your batch number will be: BIOT - (Team number).
  - Print, sign, and initial in the personnel identification table.

QC sample submission and tracking form

- In the top box the Form Number will be: SS - (team number).
- Everyone's Sample ID # will be 1.
- Purpose of Assay is quantitative inspection.

Test record form

- Test Record Number in top box will be: TR - (team number).

Distribute documents into folders for MAN and QC.

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QUALITY CONTROL SAMPLE SUBMISSION AND TRACKING FORM

Form No:	Supersedes: None	Issue Date:
QC Sample Submission and Tracking Form		Page 1 of 2

Master Document Approval		
Department Name		Date
Quality Control Director		
Quality Assurance Director		

Document Control Record	
Batch Number:	
This document is an accurate reproduction of the Master Document Control Record as found in the QA document file.	
Issued by: _____ Quality Assurance	Date: _____
Accepted by: _____ Manufacturing	Date: _____
Returned by: _____ Quality Control	Date: _____
Accepted by: _____ Quality Assurance	Date: _____

Manufacturing Submitter – Please fill out this section	
Attach a Sample Submission Label here: (Sample ID*, including Batch #)	
Sample Size: 25 mL scoop	Date Collected:
Storage Requirements (circle one): -80°C/ -20°C/ 2 - 8°C/ 20 - 25°C	
Name of Submitter:_____ (Must be same as manufacturing name in control record)	Date:

* Must match label on sample container.

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QUALITY CONTROL SAMPLE SUBMISSION AND TRACKING FORM

Form No:	Supersedes: None	Issue Date:
QC Sample Submission and Tracking Form		Page 2 of 2

Quality Control Submitter – Please fill out this section	
Batch Number:	
Sample Received by: (Must be same as Quality Control name in control record)	Date:

Test Requested	Test Record #	Test Record Started	Test Completed
Quantitative Inspection for Product Consistency		Initial: _____ Date: _____	Initial: _____ Date: _____

Comments

Record any deviations, additional observations, and/or comments that occurred. A Deviation Report must be filed if a deviation is noted.

Step	Comments	Initials	Date

Test Record No.:	Superseded: None	Issue Date:
Quantitative Inspection of Product		Page 1 of 4

Master Document Approval		
Department Signature		Date
Quality Control Director		
Quality Assurance Director		

Record Control
Batch Number: _____
This document is an accurate reproduction of the Master Test Record found in the QA document file.
Issued by: _____ Date: _____ Quality Assurance
Accepted by: _____ Date: _____ Quality Control
Returned by: _____ Date: _____ Quality Control
Accepted by: _____ Date: _____ Quality Assurance

Post-Testing Document Review
This completed test record has been reviewed and has been found to be complete, correct, and in conformance with relevant SOPs and related documents.
Signature: _____ Date: _____ Quality Assurance

Test Record No.:	Superseded: None	Issue Date:
Quantitative Inspection of Product		Page 2 of 4

Personnel Identification			
Title Print Name		Signature	Initials
Quality Assurance			
Quality Control			

General Instructions

- All procedures of this assay as described in the test record are designed to be carried out in compliance with cGMP. Personnel carrying out these procedures must be trained in cGMP concepts and all procedures required for this assay and must perform and document procedures according to the directions specified in this document and Standard Operating Procedures.

Samples to be tested

- Record information in Table 1. Attain the information from the label of the sample container when samples are removed from storage.

Table 1

Batch Number	Sample Number	Purpose of Assay	Initials and Date
		Quantitative Analysis	

Test Record No.:	Superseded: None	Issue Date:
Quantitative Inspection of Product		Page 3 of 4

Materials and Supplies (Record in Table 2)

Table 2

Material Description	Equipment #	Quantity	Exp. Date
Paper plate			
Performed by: _____ _____ Date: _____ Signature			

Procedure

- Record Test Start Date: _____ Operator initials: _____
- Record Test Start Time: _____ Operator initials: _____
- Open the plastic sandwich bag and empty contents onto the plate.
-
- Time: _____ Initials: _____
-
- Count the number of Goldfish® pretzels (or equivalent) and record in table 3.
-
- Count the number of Skittles® (or equivalent) and record in table 3.
-
- Count the number of Craisins® (or equivalent) and record in table 3.

  Time: _____ Initials: _____

- Pick up the plate and fold it while holding it over the plastic bag and pour the sample back into the plastic bag. Seal the bag. Transfer sample to QC storage.

  Time: _____ Initials: _____

- Record Test Completion Date: _____ Operator initials: _____
- Record Test Completion Time: _____ Operator initials: _____

Test Record No.:	Superseded: None	Issue Date:
Quantitative Inspection of Product		Page 4 of 4

Procedural Step	Description	Results
4 Number of		_____ Time: _____ Initials: _____
5	Number of	_____ Time: _____ Initials: _____
6	Number of	_____ Time: _____ Initials: _____

Test Record Review

- Complete QC Sample Submission and Tracking Form.
- Forward the completed Test Record and the QC Sample Submission and Tracking Form to Quality Assurance.

Revisions

- None

Comments

Record any deviations or observations from this Batch Record. If there were deviations, a Deviation Report must be filed.

Step #	Comments	Initials	Date

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FINAL PRODUCT SPECIFICATION FORM

Form No:	Supersedes: None	Issue Date:
Final Product Specification Form		Page 1 of 1

Master Document Approval		
Department Name		Date
Manufacturing Director		
Quality Assurance Director		

Product Description: cGMP mix			
Hazards: None			
Storage Conditions	Room Temperature (20–25 °C)	Supplier	Any Snack, Inc.

Specifications

Test	Method	Specification
Quantitative Inspection	Manual Count	No less than 3 Goldfish® pretzels per 25 mL or cc scoop or cup
Quantitative Inspection	Manual Count	No less than 2 Skittles® per 25mL or cc scoop or cup
Quantitative Inspection	Manual Count	No less than 4 Craisins® per 25mL or cc scoop or cup

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GMP AUDIT CHECKLIST

Task to complete	Check off	Initials of auditor
Verify Quality Assurance File has all needed documents by a QA associate.		
Verify Manufacturing Folder has all needed documents by QA associate.		
Verify Quality Control Folder has all needed documents by QA associate.		
All raw materials and equipment are in working order and in designated space.		
Random inspection that Manufacturing procedures are being executed properly.		
Random inspection that Quality Control procedures are being executed properly.		
Inspect released product to assure all procedures were followed properly.		
All raw materials are in the proper area after completion of manufacturing process and areas are clean.		
All equipment is in the proper area after the completion of manufacturing process and area are clean.		
All documentation is completed and returned to QA.		

Audit completed by _____ _____

Printed Name Signature

BioPathways
from Ohio Life Sciences

QUALITY ASSURANCE CHECKLIST

Document	QC Initial
A copy of the document workflow document	
QA Procedures	
Production Batch Record (to be given to Manufacturing)	
QC Sample Submission and Tracking Form (to be given to Manufacturing)	
Test Record (to be given to Quality Control)	
Final Product Specification Form (stays with QA)	
Product Quarantine labels [fluorescent yellow] (to be given to Manufacturing)	
Sample Submission labels (to be given to Manufacturing)	
Raw Material release labels (Food and plates, placed on raw materials by QA)	

Signature of Quality Assurance Associate _____

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MANUFACTURING CHECKLIST

Folder delivered to manufacturing: Date: _____ Time:_____

QA Signature: _____ MAN Signature: _____

Verification of Documentation (to be completed by Manufacturing associate)

Document	QC Initial
A copy of the document workflow document	
Production Batch Record (issued from QA)	
Quarantine Labels (issued from QA)	
Sample Submission Labels (issued from QA)	
QC Sample Submission and Tracking Form (issued from QA then given to QC)	

Folder delivered to Quality Assurance: Date: _____ Time: _____

MAN Signature: _____ QA Signature: _____

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QUALITY CONTROL CHECKLIST

Folder delivered to QC: Date: _____ Time:_____

QA Signature: _____ QC Signature: _____

Verification of Documentation (to be completed by QC associate)

Document	QC Initial
A copy of the document workflow document	
Test Record (after it is issued from QA)	
QC Sample Submission and Tracking Form (after it is received from MAN)	

Folder delivered to Quality Assurance: Date: _____ Time: _____

QC Signature: _____ QA Signature: _____

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DEVIATION REPORT FORM

Deviation Report Number:	Date:	Priority: (Circle one) Critical / Major / Minor
Reported by:	Team Responsible: (Circle one) MAN / QC / QA	

Deviation Report Type (Fill in appropriate type)

Customer Complaint Deviation

Customer Number:	Sales Order Number:	Delivery Document Number:

Material Deviation

Vendor Number:	Purchase Order Number:	Receiving Document Number:

Process/Procedural Deviation

Stage in process: (Circle one) Materials / Manufacturing / Testing		Production Batch Number:	Raw Material Number:

Audit Deviation

Audit Reference Number:	Audit Type:

Deviation Title:

Description:

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DEVIATION REPORT FORM

Management Response

Area Manager:
Tasks related to Deviation Report: Assign to: Follow-up Tasks: Submit to QA: Name: Signature: Date:
QA Manager:
Review potential impact on product. (Conduct Root Cause Analysis to develop CAPA.)   Determine impact on product and take appropriate actions–not releasing product, recalling product, making procedural changes.   Create CAPA based on deviation for implementation:
Confirm Completion: _____ Date:_____ QA Director Signature

Production Batch Record No: PBR-1.3	Supersedes: PBR-1.2	Issue date:
cGMP Mix Production		Page 1 of 5

Master Document Approval		
Department Name		Date
Manufacturing Director		
Quality Assurance Director		

Document Control Record	
This document is an accurate reproduction of the Master Production Batch Record as found in the QA document file.	
Issued by: _____ Quality Assurance	Date: _____
Accepted by: _____ Manufacturing	Date: _____
Returned by: _____ Manufacturing	Date: _____
Accepted by: _____ Quality Assurance	Date: _____

Post Manufacturing Document Review	
This completed Product Batch Record has been reviewed and has been found to be complete, correct, and in conformance with relevant SOPs and related documents.	
Quality Assurance: _____ Signature	Date: _____

\

Production Batch Record No: PBR-1.3	Issue date:
cGMP Mix Production	Page 2 of 5
Product Batch Number: _____	

Personnel Identification			
Title	Print Name	Signature	Initials
Quality Assurance			
Manufacturing Operator			

General Instructions

All procedures of this process as described in this batch record are designed to be carried out in compliance with cGMP. Personnel carrying out these procedures must be trained in fundamental cGMP concepts and all procedures required for this assay and must perform and document procedures according to the directions specified in this document and applicable Standard Operating Procedures. All personnel involved in the performance or review of this record are identified by signing the table of page one.

Record dates in the following format: DD/MM/YYYY. Record time in a 24-hour format: HH:MM.

Materials and Supplies

Record materials and equipment used in Tables 1 and 2. Mark “N/A” if not used in this record.

Table 1: Raw Materials

Input Materials		Raw		Manufacturing Operator (Initials)	Released from Quarantine (QA Initials)
Goldfish® pretzels	100 mL				
Craisins®	50 mL				
Skittles®	50 mL				
Plastic sandwich bags	2 count				
Plate	1 count				

Production Batch Record No: PBR-1.3	Issue date:
cGMP Mix Production	Page 3 of 5
Product Batch Number: _____	

Table 2: Equipment

Equipment/Component	Equipment Number	Calibration Date
100 mL cup scoop (for Goldfish pretzels)		
50 mL cup scoop (for Skittles)		
50 mL (for Craisins)		
25 mL cup scoop (for sampling)		

Manufacturing Procedure

Production Start Date: _____ Operator Initials: _____

Production Start Time: _____ Operator Initials: _____

Open the plastic sandwich bag. Using the 100 mL cup scoop, add 100 mL of Goldfish pretzels into the plastic sandwich bag, then place the scoop back onto the plate. Do not seal the plastic sandwich bag.

Time: _____ Initials: _____

Using the 50 mL dried cranberries cup scoop, add 50 mL of Craisins into the open plastic sandwich bag that contains the 100 mL of Goldfish pretzels, then place the cup scoop back onto the plate.

Time: _____ Initials: _____

Seal the plastic sandwich bag completely, then mix the contents well by shaking the bag for 5 seconds.

Time: _____ Initials: _____

Reopen the plastic sandwich bag. Using the 50 mL Skittles cup scoop, add 50 mL of Skittles to the plastic sandwich bag that contains the 100 mL of Goldfish pretzels and 50 mL of Craisins, then place the scoop back onto the plate.

Seal the plastic sandwich bag, then mix the contents well by shaking for 5 seconds. Reopen the bag and place it flat on the table.

Time: _____ Initials: _____

Production Batch Record No: PBR-1.3	Issue date:
cGMP Mix Production	Page 4 of 5
Product Batch Number: _____	

Open one empty plastic sandwich bag. Using the 25 mL cup scoop for sampling, remove 25 mL of the snack mix from the plastic sandwich bag and place the contents into the empty plastic sandwich bag. Place the 25 mL cup scoop back on the plate.

Time: _____ Initials: _____

Seal both plastic bags completely. Apply a Sample Submission Label to the plastic sandwich bag that contains the 25 mL cup sample of the finished product.

Time: _____ Initials: _____

Apply a Sample Submission Label to the Quality Control Sample Submission and Tracking Form.

Time: _____ Initials: _____

Complete the QC Sample Submission and Tracking Form.

Time: _____ Initials: _____

Submit the QC Sample Submission and Tracking Form along with the 25 ml sample of the finished product that is in the sealed plastic sandwich bag to Quality Control.

Time: _____ Initials: _____

Apply a Quarantine Label to the remaining batch of the final product that is in the sealed plastic sandwich bag. Place the labeled, sealed bag of final product onto one plate, and transfer the plate to the Quarantine storage location.

Time: _____ Initials: _____

Record Production Finish Date: _____ Operator Initials: _____

Record Production Finish Time: _____ Operator Initials: _____

Production Batch Record No: PBR-1.3	Issue date:
cGMP Mix Production	Page 5 of 5
Product Batch Number: _____	

Storage Conditions: Store at room temperature

Revision History

Revision Number	Revision Date	Nature of Revision	Approved by

Comments

Record any deviations, additional observations, and/or comments that occurred in the Production Batch record. If a deviation is noted, a Deviation Report must also be filed.

Step #	Comments	Initials	Date