Master Batch Record Processing Notes Form

This form may be used to record any notes or tally's during the execution of a batch record. This form will be placed with the Batch Record at the end of the run.

Initial and date all notes or entries made on this form.

MBR#: 638 Rev 0 Date: 06/10/2020 WO#: 106718A Lot#: lot ~~2016201-01~~ 2016801-01 Pg 1 of 1

* changed Lot # due to changed in solution. HAS 6/17/20

Notes:

The No More Pill's Acetaminophen Oral Solution (AD/NMPHMO1) was not included on the Route/BOM, but it is documented in the MBR. This is an ENG Study only.

VERIFIED COPY
OF ORIGINAL
HAS 6/16/20

Form#: F1821
Rev: 1

Operations Approval/Date: 6/16/20

QA Approval/Date: AMC 6-10-20

APPROVED BY:

Aphena				
Designee	**Name**	**Title**	**Signature**	**Date**
Author	Megan Kunkowski	Technical Services Specialist	/s/Megan Kunkowski/s/	5/21/20
Reviewer	Rafeh Raza	Sr. Technical Services Specialist	/s/Rafeh Raza/s/	5/22/20
Reviewer	Heidi Jenkins	Production Supervisor	/s/Heidi Jenkins/s/	5/22/20
Reviewer	Katina Moaney	Sr. Project Manager	/s/Katina Moaney/s/	5/22/20
Approver	Sanjay Nimkar	Director of QA/RA	/s/Sanjay Nimkar/s/	5/26/20
No More Pills				
Designee	**Name**	**Title**	**Signature**	**Date**
Approver	Douglas Flint	AQPR Consulting	/s/Douglas Flint/s/	5/22/20

Note: pages in this batch record may be copied as needed for additional space. If additional copies of pages are made, pages should be labeled as follows: 1 of 3, 2 of 3, and 3 of 3, etc. The notation should be initialed and dated. The final page count should not be made until the end of the batch to ensure that all pages have been generated and accounted.

Work Order Number: 106857

LOT CODE ASSIGNMENT:

The Lot Code Format to be used during the manufacture of No More Pills' Acetaminophen Oral Solution 650mg/50mL Bottle product that is being produced is as follows:

LOT_YYDDDXZ–NN where:

LOT is a printed constant designation used to denote that the code that follows is the product's lot code

_ is used to denote a blank space

YYDDDXZ is the Lot Code of the Acetaminophen bulk solution that is being used for filling/packaging

– is a dash

NN is a two digit numeric value used to indicate the number of times that the specific Lot # of Acetaminophen bulk solution that is being used for filling has been used in manufacturing the Acetaminophen Topical Solution 0.1% (w/v) 60 mL Bottle product (i.e. 01 would be assigned for the first manufacturing run using a specific Lot # of the bulk, 02 for the second manufacturing run using the same Lot #, etc.)

Record the Lot Code of Acetaminophen bulk solution being used for filling/packaging (in format YYDDDXZ): 2016801

Review previous manufacturing history for the Acetaminophen Oral Solution 650mg/50mL Bottle product to determine if the Lot # of the Acetaminophen bulk solution being used for filling/packaging has been previously used. Based on the number of times the Lot # has been previously used (if any), record the two digit numeric designator (**NN** to be used in the Lot Code: 02

Based on the Lot Code of the Acetaminophen bulk solution being used for filling/packaging packaged (as listed above) and the numeric designator (**NN**) that has been determined based on if the Lot # of Acetaminophen bulk solution being used has been previously used in packaging, the Lot Code to be used during packaging is as follows (in the format LOT_YYDDDXZ–NN):

LOT 2016801 - 02

Examples:

The Lot Code that would be used for the manufacturing of Acetaminophen Oral Solution 650mg/50mL Bottle product that is being produced using Acetaminophen bulk solution which has a Lot Code of 1913501, and which is the first manufacture of Acetaminophen Oral Solution 650mg/50mL Bottle product that is being produced with that Lot of Acetaminophen bulk solution, would be **LOT 1913501–01**.

The Lot Code that would be used for the manufacturing of Acetaminophen Oral Solution 650mg/50mL Bottle product that is being produced using Acetaminophen bulk solution which has a Lot Code of 1913501, and which is the second manufacturing run Acetaminophen Oral Solution 650mg/50mL Bottle product that is being produced with that Lot of Acetaminophen bulk solution, would be **1913501–02**.

Assigned Lot Code Review and Approval:

6/18/20 _____ 6/18/20

Production Supervisor Date Quality Date

Work Order Number: 106357

EXPIRATION DATE CODE ASSIGNMENT:

The Expiration Date Code Format to be used during the manufacture of No More Pills' Acetaminophen Oral Solution 650mg/50mL Bottle product being produced is as follows:

EXP_MM_YYYY where:

EXP is a printed constant designation used to denote that the code that follows is the product's expiration date code

MM is the numeric two digit code representing the month that is the month in which the Acetaminophen bulk solution that is being used for filling/packaging was manufactured (to be determined based on the date of manufacture on the label of the Acetaminophen bulk solution container)

_ represents a blank space

YYYY is the four digit year that is 36 months from the year in which the Acetaminophen bulk solution that is being used for filling/packaging was manufactured (to be determined based on the date of manufacture on the label of the Acetaminophen bulk solution container)

Record the Date of Manufacturing of the Lot # of the Acetaminophen bulk solution being used for filling/packaging (from the label of the Acetaminophen bulk solution container): 06-16-20

Based on the Date of Manufacture of the Acetaminophen bulk solution being used for filling/packaging (as listed above), the Expiration Date Code to be used during packaging is (in the format EXP_MM_YYYY):

EXP 06 2023

Example:

The Expiration Date Code that would be used for the manufacturing of Acetaminophen Oral Solution 650mg/50mL Bottle product that is being produced using a Lot of Acetaminophen bulk solution that was manufactured on June 4, 2019, would be **EXP 06 2021**. (i.e. 06 represents June, the month that the bulk solution was manufactured in, and 2021 represents the year that is 24 months from the date of the bulk solutions date of manufacture)

Assigned Expiration Date Code Review and Approval:

Production Supervisor — Date: 6/18/20

Quality — Date: 6/18/20

Work Order Number: 106857

Determination of Net Fill Weight Specifications

From the Aphena Certificate of Analysis for the Lot of Acetaminophen bulk solution that is being used for filling/packaging, use the average Specific Gravity for the solution in the calculations below in order to determine the Minimum, Target and Upper Alert Limit Net Fill Weight specifications that will be used for the filling/packaging run. (Obtain Certificate of Analysis from Quality/Document Control and attach a copy of to this record)

Acetaminophen Bulk Solution Lot #: 2016801 Specific gravity: 1.0885

Minimum Net Fill Weight = 1.0885 (Specific gravity, enter above) x 50.0 mL (Label Claim Fill Volume) = 54.43 g

Target Net Fill Weight = 1.0885 (Specific gravity, enter above) x 51.5 mL (Target Fill Volume) = 56.06 g

Upper Alert Limit Net Fill Weight = 1.0885 (Specific gravity, enter above) x 53.0 mL (Maximum Net Fill Volume) = 57.69 g

Net Fill Weight Specifications Calculated By: MJ 6/18/20 (initials and date)

Verified By: HAS 6/18/20 (initial and date)

Work Order Number: 1006357

Pre-Production Line Clearance

The following information must be verified prior to start-up of the run. Any discrepancies must be reported through the proper quality system reporting tool and all issues must be resolved prior to beginning production. To be performed by the Operator and verified by the Supervisor.

	Verification Required	Checked by / Date	Verified by / Date
All product and packaging components from previous batches have been removed from the 1K2 line	Y	KR 6-24-20	HAS 6/24/20
All paperwork for previous batches has been removed from the packaging line	Y	KR 6-24-20	HAS 6/24/20

Pre-Production Component Reconciliation

To be performed by one qualified person (i.e., Inventory Control personnel, Supervisor) and Verified by a second different qualified person (e.g., Supervisor, a second Operator, Quality)

The following minimum requirements are necessary to ensure proper control for the packaging of finished products.

a) Solution Identification

A responsible person will check that each container of solution delivered to the packaging line is identified properly. This identification should include:

- Part Number **(Verify Part Number matches the part number listed for the solution in the table on the next page)**
- Name/Description of Solution **(Verify the Name/Description of the product matches the name/description of the solution listed in the table on the next page)**
- Lot Number **(Record the Lot number of the solution being used in the table on the next page)**
- Solution Bulk Hold Expiry: **(Record the bulk hold expiry date for the solution:** N/A **)***

*Check to ensure that the solution is being filled/packaged prior to it reaching it bulk hold expiry date.

Checked By: HAS 6/24/20 Verified By: MG 6/24/20

b) Printed Material/Labeling

- Include a sample of all printed items (examples: labels) used during this run to this record. **NOTE: If more than one lot of an item is used during the run, include a sample from each lot.**
- For all labels printed in house (PARP), a label from each label run must be include with this record and initialed and dated by the person who printed the label.
- The sample of each printed item (i.e. bottle label, shipper label, etc.) being included is to be checked by one person and verified by a second person, to ensure that the printed component corresponds to the product being packaged (product name, fill quantity, part # and version, etc.).

Documentation of the "checked by" and "verified by" activities will be documented by each of the persons initialing and dating the copy of each printed item that is being included in the executed MBR. if the printed item is attached to a page within the record, initial and date across the label onto the page.

Checked By: HAS 6/24/20 Verified By: MG 6/24/20

c.) Printed Lot Code and Expiration Code (as printed on bottle)

- For components that are printed with Lot Code and/or Expiration Date Code, include a printed copy, photo or photocopy of the lot code and expiration dating as printed on the component as applicable, to the batch record.
- The sample of each item with a printed Lot Code and/or Expiration Date Code that is included is to be checked by one person and verified by a second person, to ensure that the printed Lot Code and/or Expiration Date Code are correct (as determined on pages 2 and 3 of this MBR)

Documentation of the "checked by" and "verified by" activities will be documented by each of the persons initialing and dating the copy of each printed item that is being included in the executed MBR. if the printed item is attached to a page within the record, initial and date across the label onto the page.

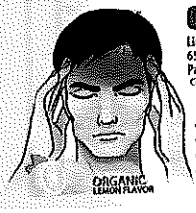
Checked By: HAS 6/24/20 Verified By: MG 6/24/20

Work Order Number: 106557

NEW **HEADACHE MAN**

NO MORE PILLS!

ONE SHOT



Liquid Headache-Pain relief
650mg Acetaminophen
Pain Reliever/Fever Reducer
Compare to Tylenol® Active Ingredient

- Works in Minutes
- Great Tasting
- Patented
- Contains Alcohol 1.1%

1.7 fl oz (50 mL)

ORGANIC LEMON FLAVOR

Drug Facts

Active Ingredient	Purpose
Acetaminophen 650 mg	Pain reliever/fever reducer

Uses

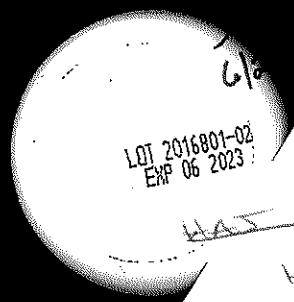
Temporarily relieves minor aches and pains due to:

- headache
- minor pain of arthritis
- cold and flu
- premenstrual and menstrual cramps
- temporarily reduces fever
- sore throat
- muscle aches
- toothache

3 73173 01050 4

HAJ 6/24/20

MY 6/24/20



~~HAS 6/25/20~~ EE 6/25/20

HAS 6/25/20

Pre-Production Component Reconciliation (continued)

To be performed by one qualified person (i.e., Inventory Control personnel, Supervisor) and Verified by a second different qualified person (e.g., Supervisor, a second Operator)

Material Name	P/N	Lot # or Receiving ID	Quantity In	U/M	Initials/Date	Verified By/ Date
No More Pills's Acetaminophen Oral Solution	AD/NMPHM01	2016801	912.0	Kg	HAJ 6/25/20	SG 6/25/20
33-400 White Cap	CP4410	N/A	7420	EA	HAJ 6/25/20	SG 6/25/20
50/60cc Bottle	CP4411	141457	5712	EA	HAJ 6/25/20	SG 6/25/20
Shrink Sleeve	CP1178	142028	12400	EA	HAJ 6/25/20	SG 6/25/20
English Label	CP8422	141930	13253	EA	HAJ 6/25/20	SG 6/25/20
Generic Shipper Bag	FL613	94247	356	EA	HAJ 6/25/20	SG 6/25/20
Generic Shipper	SP695/2	140396	181	EA	HAJ 6/25/20	SG 6/25/20

Work Order Number: 106857

Pre-Production Equipment and Room Verification

The following information must be verified prior to startup of the work order. Any discrepancies must be reported through the proper quality system reporting tool and all issues must be resolved prior to beginning production. To be performed by the Operator and verified by the Supervisor.

	Verification Required	Performed By/Date	Verified By/Date
Line Clearance performed from previous product/lot	Visual inspection	KR 6.24.20	HAS 6/24/20
Open Deviations for Process or Product? Review of Aphena Deviation Log. List any open deviations below and include a copy with the batch record.	Deviation #: Roberto Deviation #: ENG-002	KR 6.24.20	HAS 6/24/20
Preventive Maintenance per WIK202	Completion of Logs F1644 and F1646	KR 6.24.20	HAS 6/24/20
Room Sanitized within 72 hours of start-up	Verification of Room Cleaning Sanitization Log	KR 6.24.20	HAS 6/24/20
Work Surfaces Sanitized Prior to Start-Up with 70% IPA	Verification by Supervisor	KR 6.24.20	HAS 6/24/20
Equipment Set Up per WIK201	Completion of Logs F1641 and F1643	KR 6.24.20	HAS 6/24/20
Verify that the following product contact equipment components are installed on 1K2 for use in filling:	Verify that any equipment components that have specified ID #s are installed on the line by recording the ID #s below: Pump 1: NMP1 Pump 2: NMP2 Pump 3: NMP3 Pump 4: NMP4 Nozzle 1: NMPN1 Nozzle 2: NMPN2 Nozzle 3: NMPN3 Nozzle 4: NMPN4 Verify that all other components without specific ID #s are installed per the requirements listed.	KR 6.24.20	HAS 6/24/20

Description	QTY	UOM	Aphena ID #(s), if applicable
Hibar Pump	4	ea	Record Pumps Used
Filler Nozzle	4	ea	Record Nozzles Used
1.5" Sanitary Tee	3	ea	
2" Female Camlock	1	ea	
2" Tri-clamp	1	ea	
2" to 1.5" sanitary reducer	1	ea	
1.5" Sanitary 90° Elbow	2	ea	
1.5" Pump Manifold Supply Hose	72	inch	
3/8" ID Pump Supply Hose	288	inch	
1/4 " ID Fill Nozzle Hose	104	inch	

Work Order Number: 166857

Pre-Production Equipment and Room Verification (continued)

The following information must be verified prior to startup of the work order. Any discrepancies must be reported through the proper quality system reporting tool and all issues must be resolved prior to beginning production. To be performed by the Operator and verified by the Supervisor.

	Verification Required	Performed By/Date	Verified By/Date
Record the Product Code and Lot # for product that was last filled using the Pumps and Nozzles (and other product equipment components, if applicable) listed above, and verify that these components were successfully cleaned and sanitized, using the appropriate post-cleaning procedure for the product that was filled, and that all cleaning/sanitizations samples tested met the required specifications for that product. Product Code: N/A Lot # N/A From the last post-cleaning procedure that was performed on the listed equipment, record the date and time that the final sanitization was completed: Cleaning Form #_____ Date and Time Previous Sanitization was completed: Date: _____ Time: _____ AM / PM	Verification that previous cleaning and sanitization for the specified equipment being used was performed and all samples met the required specifications. Attach a copy of all testing specifications and results from the previous cleaning and sanitization performed.	KA 6-24-20	HAS 6/24/20
Based on the date and time that the previous sanitization was completed, determine if filling is beginning within 24 hours of the completion of that sanitization, or if the filling equipment needs to be re-sanitized. Check the appropriate box below: □ **Filling line is being used within 24 hours of the previous sanitization.** No further cleaning/sanitization activities are required. □**Filling line being used greater than 24 hours after the previous sanitization.** The filling line must be re-sanitized per the Aphena WIK203, and filling/packing of the product being produced under this MBR must being with 24 hours of the completion date and time of the re-sanitization. Record date and time in the space provided below that the re-sanitization was completed: Date and Time Re-Sanitization was completed: Date: _____ Time: _____ AM / PM	Verify if the previous sanitization of the equipment being used was completed within the previous 24 hours prior to its use in the run being performed under this MBR. If previous sanitization of the equipment being used was completed > 24 hours prior to its use in the run being performed under this MBR, the equipment must be re-sanitized within 24 hours of its use. Perform and document the re-sanitization using a copy of Aphena Form F2129	KA 6-24-20	HAS 6/24/20

N/A

Work Order Number: 104857

Pre-Production Equipment and Room Verification (continued)

The following information must be verified prior to startup of the work order. Any discrepancies must be reported through the proper quality system reporting tool and all issues must be resolved prior to beginning production. To be performed by the Operator and verified by the Supervisor.

	Verification Required	Performed By/Date	Verified By/Date
Verify the following equipment, as needed, is available and the calibration status is current (where applicable). Verify proper set-up of all scales and perform/confirm that daily weight check has been done to encompass the weight range for the materials being weighed, has been documented, and meets requirements. Equipment # / Calibration Due Date Scale: 3004 / 08/20 Torque Tester: 2412 / 08-13-21 Other: N/A / N/A	Documentation of serial numbers for equipment used and verification of calibration status (where applicable) Record usage of equipment in equipment log books.	KR 6-24-20	HAS 6/24/20
Record the below: Filler Speed: ~~35~~ 40 # * KR EIE 6-24-20	Record and verify documented machine parameters	KR 6-24-20	HAS 6/24/20

Work Order Number: 106857

Packaging Guidelines

The following activities are performed by the assigned operators:

- Setting up equipment and making required adjustments to the 1K2 filler/capper and any other required, portable ancillary secondary packaging equipment (i.e. labeler, ink jet printer, etc.), as necessary, to fill and package the product
- Completing downtime reports

The following activities are performed by the assigned packers:

- Place shrink sleeved, labeled bottles into generic shipper with liner.
- Tape shipper closed and place on pallet

Sampling Plan-Determination of Sample Size:
Sample size is determined following ANSI/ASQ Z 1.4 – General, Single Normal Inspection Level II. Using the planned production quantity, determine the total number of bottles that will be produced during the run and record below. Calculations are to be performed by Quality Representative, and verified by Production Supervisor.

Bottles = 1280 (K)

Based upon the following AQL Defect Levels and the total quantities of bottles calculated above, determine the sample size that are needed for testing of each attribute. (NOTE: If the sample size equals, or exceeds lot size, inspect 100% of samples). Once the number of samples is determined, divide the total number of samples required by the number of hours required to complete the job per the BOM to determine the hourly sample size.

Critical Defect Level -- AQL 0.065

Bottles: 200 (Total Samples Req.) / 1 (Total Hours for Job) = 200 (Hourly Sample Size) 0 (Accept) / 1 (Reject)

Major Defect Level -- AQL 1.0

Bottles: 125 (Total Samples Req.) / 1 (Total Hours for Job) = 125 (Hourly Sample Size) 3 (Accept) / 4 (Reject)

Minor Defect Level -- AQL 4.0

Bottles: 125 (Total Samples Req.) / 1 (Total Hours for Job) = 125 (Hourly Sample Size) 10 (Accept) / 11 (Reject)

Sampling Plan: Immediate Removal Torque (Non-ANSI):

Immediate Removal Torque: Measure and record the Immediate Removal Torque of 6 bottles per hour.

Sampling Plan Verification:

6/24/20
Calculated by/Date

6/24/20
Verified By/Date

Work Order Number: 106857

Inspection Summary Sheet

Based upon the number of hours inspected per day, in the table below document the daily number of samples inspected for each of the attributes/variables. Use the table during your last hourly check of the production run to determine the number of samples needed to complete the required sampling plan. Performed by Quality Representative, and verified by a second qualified person (i.e. QA/QC, production supervisor, etc.).

	# samples required (see sampling plan)	Date Tested 6/24/20	Date Tested N/A SG 6/25/20		Total # samples tested	Additional samples needed	Total # of Failed Samples
Critical Defect Level –AQL 0.065							
Bottle Integrity – No holes or foreign material embedded in bottle	200	201			201	0	0
Net Fill Weight – Must be equal to or fall within the weight range that corresponds to a fill volume of 50.0 – 53.0 mL		201			201	0	0
Cap Appearance/Placement - Cap is properly and securely applied with no crookedness, skewedness, cracks or damage		201			201	0	0
Shrink Sleeve is present and correct.		201	N/A		201	0	0
Bottle Label is present and correct.		201			201	0	0
Lot code (on bottle) – Lot code is present and located in the designated area on the bottle, is legible and correct		201	SG 6/25/20		201	0	0
Expiration date code (on bottle) – Expiration date code is present and located in the designated area on the bottle, is legible and correct		201			201	0	0
Induction Seal – Seal is present, sealed, and centered on bottles with no holes, tears, or damage.		201			201	0	0
Major Defect Level – AQL 1.0							
Bottle/Cap Exterior Appearance – Bottle and cap are free of any dirt/grease, product, etc., and does not have any major scuffing or damage	125	125			125	0	0
Bottle label is free of wrinkles that impact legibility of verbiage.		125	N/A SG 6/25/20		125	0	0
Shrink sleeve is complete and has no rips or tears from perforations.	125	125			125	0	0
Minor Defect Level– AQL 4.0							
Immediate Removal Torque - The average IRT of samples tested hourly is ≥ 4.0 in-lbs and ≤ 20.0 in-lbs	125		N/A	SG 6/25/20			
Completed By: Initials/Date		SG 6/25/20	N/A SG 6/25/20		SG 6/25/20	SG 6/25/20	SG 6/25/20

Actual # Bottles Produced: _____

Final Review and Verification By: Initials/Date SR 6/25/20

Work Order Number: 104557

First Piece Acceptance Testing: Net Fill Weight and Immediate Release Torque Sampling

Date and Time of FPA: 6/25/20 11:00 AM

Net Fill Weight	Record the Net Fill Weight (in grams) on six (6) samples for First Piece Approval. Record results to 2 decimal places (i.e. **xxx.xx**) Each filler pump should be set such that the delivered amount from the combined four (4) filler pumps is no less than 50.0 mL and no more than the Upper Action Limit of 53.0 mL; Target Net Fill of 51.5 mL (as measured by Net Fill Weight). All FPA Net Fill Weights must be at or above Minimum Net Fill Weight and below the Upper Action Net Fill Weight, as defined below (**record calculated Minimum, Target, and Upper Action Limit Net Fill Weights from page 4**), otherwise adjust pumps as needed and re-execute FPA. Minimum Net Fill Weight: 54.43 grams Target Net Fill Weight: 56.06 grams Upper Action Net Fill Weight: 57.69 grams	**Sample 1** Gross: 64.26 g Tare: 8.11 g Net: 56.15 g **Sample 2** Gross: 64.16 g Tare: 8.04 g Net: 56.12 g **Sample 3** Gross: 64.33 g Tare: 8.17 g Net: 56.16 g	**Sample 4** Gross: 64.17 g Tare: 8.07 g Net: 56.10 g **Sample 5** Gross: 64.28 g Tare: 8.07 g Net: 56.21 g **Sample 6** Gross: 64.44 g Tare: 8.11 g Net: 56.33 g
Immediate Removal Torque	Record the Immediate Removal Torque (in in-lbs) on six (6) samples for First Piece Approval. Record results to 2 decimal places (i.e. **xx.xx**) All FPA Immediate Removal Torque results must be at or above Minimum Immediate Removal Torque and below the Maximum Immediate Removal Torque specifications, which are defined as follows: Minimum Immediate Removal Torque: 4.0 in-lbs Target Immediate Removal Torque: 10.0 in-lbs Maximum Immediate Removal Torque: 20 in-lbs	**Sample 1:** 6.25 **in-lbs** **Sample 2:** 5.11 **in-lbs** **Sample 3:** 5.46 **in-lbs** **Sample 4:** 4.65 **in-lbs** **Sample 5:** 4.73 **in-lbs** **Sample 6:** 4.56 **in-lbs**	

Tested by (initials and date): JM 6/25/20

Verified by (initials and date): HAS 6/25/20

First Piece Acceptance Testing is to be conducted daily on a new set of samples, at the beginning of each shift. If the testing is not destructive, the verification does not need to be conducted at the same time as the initial inspection. If the testing is destructive (cannot be repeated on a sample without compromising the integrity of the product and would require immediate disposal), verification must occur at the same time as the initial inspection. For a destructive test, verification is defined as a visual confirmation of the result. If a defect or nonconformance is found, it must be corrected prior to release of the line for manufacturing and pack-off of any finished product.

Parameters	FPA Daily ☑ ☐		Hourly Inspections 1st	2nd	3rd	4th	5th	6th	7th	8th	9th	10th
Inspection Time	11:00 am	11:00 AM	11:00 am	11:30 am	12:00 pm					N/A SG 6/25/20		
Line Clearance: performed from previous run (initial/date)	SG 6/25/20	HAJ 6/25/20										
Critical Defects –AQL 0.065												
Bottle Integrity – No holes or foreign material embedded in bottle	O	O	O	O	O							
Net Fill Weight – Must be equal to or fall within the weight range that corresponds to a fill volume of 50.0 – 53.0 mL. **Net Fill Weight Hourly Data is recorded on page 16.**	**FPA for Net Fill Weights done on page 13**		O	O	O							
Cap Appearance/Placement - Cap is properly and securely applied with no crookedness, skewedness, cracks or damage	O	O	O	O	O							
Shrink Sleeve – Shrink Sleeve is present and correct.	O	O	O	O	O				N/A SG 6/25/20			
Bottle Label – Bottle Label is present and correct.	O	O	O	O	O							
Lot code (on bottle) – Lot code is present and located in the designated area on the bottom of the bottle, is legible and correct. Record the Lot Code (as determined on page 2, in the format LOT_YYDDDXZ–NN): **LOT** 2016801-02	O	O	O	O	O							
Inspected by (initials &date)	SG 6/25/20	HAJ 6/25/20	SG 6/25/20	SG 6/25/20	SG 6/25/20							

Work Order Number: 106857 Lot Number: 2016801-02 Date: 6-25-20

• Clarity SG 6/25/20

Parameters	FPA Daily ☑ ☐		Hourly Inspections 1st	2nd	3rd	4th	5th	6th	7th	8th	9th	10th
Inspection Time	11:00 am	11:00 AM	~~11:00~~ 11:00 am	11:30 am	12:00 pm							
Expiration date code (on bottle) – Expiration date code is present and located in the designated area on the bottom of the bottle, is legible and correct. Record the Expiration date code, as determined on page 3, in the format EXP_MM_YYYY): EXP 06 2023	0	0	0	0	0							
Induction Seal - Induction seal is present, sealed, and centered on bottles with no holes, tears or damage.	0	0	0	0	0							
Major Defects –AQL 1.0												
Bottle/Cap Exterior Appearance – Bottle and cap are free of any dirt/grease, product, etc., and does not have any major scuffing or damage	0	0	0	0	0							
Bottle Label- Bottle label is free of any wrinkles that impact legibility of verbiage	0	0	0	0	0							
Shrink Sleeve – Shrink sleeve is complete and has no rips or tears from perforations.	0	0	0	0	0							
Minor Defects –AQL 4.0												
Immediate Removal Torque (IRT) – Average IRT of the samples tested is within the specification range of 4.0 – 20.0 in-lbs, Target 10.0 in-lbs. **IRT Hourly Data is recorded on page 17.**	**FPA for Immediate Removal Torque done on page 13**		0	0	0							
Inspected by (initials &date)	SG 6/25/20	HAS 6/25/20	SG 6/25/20	SG 6/25/20	SG 6/25/20							

N A SG 6/25/20

N A SG 6/25/20

N SG 6/25/20

NET FILL WEIGHT DETERMINATION

Copy this form page as needed, Page 1 of 6

Check 67 bottles per hour. All weights to be recorded in grams, to two decimal places (i.e. xxx.xx)

Pre-weigh the required number of bottles needed for hourly testing and record each bottle's empty weight on it. The Line Operator will then run the pre-weighed bottles thru the filling system and remove them prior to the capping station. Weigh the filled bottles and record the Gross Weight of each filled bottle and its corresponding Empty Bottle Tare Weight in the appropriate spaces below. Using these weights, calculate the Net Fill Weight for each bottle. .

For each hourly inspection, calculate the Hourly Sum of all Net Fill Weights for the bottles tested that hour and record under the corresponding hourly inspection column.

NOTE: The table below provides sampling in groups of 10, however more or less than one group may be required for documenting the samples tested each hour based on hourly sampling plan requirements. N/A any unused sample spaces in group as needed to document the number of samples tested.

The Net Fill Weights will be evaluated against the following Net Fill specifications (transfer calculated weights from page 4 of this MBR)

Minimum Net Fill Weight	54.43	grams
Target Net Fill Weight	56.06	grams
Upper Action Limit Net Fill Weight	57.69	grams

Any Net Fill that is below the Minimum Net Fill Weight is considered a defect and will count towards the defined Accept/Reject criteria.

If a Net Fill meets or exceeds the Upper Action Limit Net Fill Weight, <u>this is not considered a defect so long as the solution is not overflowing from the bottle and there is sufficient headspace to allow for the sprayer pump cap to be inserted prior to use</u>, but will require the operator to monitor and, if needed, adjust the combined amount dispensed by the filler pumps back to target.

Note any adjustments made to filler on a copy of the Master Batch Record Processing Notes Form F1821.

Sample #	Gross Wt	−	Tare Wt	=	Net Wt
1	64.14	−	8.07	=	56.07
2	63.53	−	8.02	=	55.51
3	63.60	−	8.07	=	55.53
4	63.59	−	8.10	=	55.49
5	63.69	−	8.11	=	55.58
6	63.52	−	8.09	=	55.43
7	63.61	−	8.21	=	55.40
8	63.60	−	8.04	=	55.56
9	63.71	−	8.16	=	55.55
10	63.57	−	8.11	=	55.46
Time	11:00 AM			Sum:	555.58

Sample #	Gross Wt	−	Tare Wt	=	Net Wt
1	63.59	−	8.08	=	55.51
2	63.63	−	8.10	=	55.53
3	63.59	−	8.04	=	55.55
4	63.71	−	8.15	=	55.56
5	63.59	−	8.09	=	55.50
6	63.58	−	8.07	=	55.51
7	63.57	−	8.10	=	55.47
8	63.58	−	8.11	=	55.47
9	63.51	−	8.05	=	55.46
10	63.56	−	8.04	=	55.52
Time	11:00 AM			Sum:	555.08

Sample #	Gross Wt	−	Tare Wt	=	Net Wt
1	63.53	−	8.05	=	55.48
2	63.52	−	8.11	=	55.41
3	63.70	−	8.22	=	55.48
4	63.62	−	8.15	=	55.47
5	65.25	−	8.24	=	57.01
6	63.43	−	8.04	=	55.39
7	63.60	−	8.08	=	55.52
8	63.63	−	8.08	=	55.55
9	63.57	−	8.05	=	55.52
10	63.52	−	8.04	=	55.48
Time	11:00 AM			Sum:	556.31

Sample #	Gross Wt	−	Tare Wt	=	Net Wt
1	63.47	−	8.04	=	55.43
2	63.59	−	8.08	=	55.51
3	63.60	−	8.10	=	55.50
4	63.61	−	8.00	=	55.61
5	63.72	−	8.09	=	55.63
6	63.59	−	8.01	=	55.58
7	63.63	−	8.09	=	55.54
8	63.70	−	8.10	=	55.60
9	63.66	−	8.13	=	55.53
10	63.73	−	8.14	=	55.59
Time	11:00 AM			Sum:	555.52

Date Tested: 6.25.20 Tested By: MS

Daily: Record total number of bottles weighed: ⊗ **and total sum of all individual net fill weights for that day:** ⊗ **grams**

End of Work Order Run: Calculate and record the overall Avg Net Fill Weight for all samples tested: N/A/56.06/as/ao **g (xx.xx). Transfer Avg. Net Fill weight to the batch reconciliation page.**

Calculations reviewed and verified by (initials and date): SR 6/25/20

⊗ Refer to Pg 6 of 6 for weights MS 6/25/20

Work Order Number: 106857 Lot Number: 2016801-02 Date: 6.25.20

NET FILL WEIGHT DETERMINATION

Copy this form page as needed, Page 2 of 6

Check 67 bottles per hour. All weights to be recorded in grams, to two decimal places (i.e. xxx.xx)

Pre-weigh the required number of bottles needed for hourly testing and record each bottle's empty weight on it. The Line Operator will then run the pre-weighed bottles thru the filling system and remove them prior to the capping station. Weigh the filled bottles and record the Gross Weight of each filled bottle and its corresponding Empty Bottle Tare Weight in the appropriate spaces below. Using these weights, calculate the Net Fill Weight for each bottle. .

For each hourly inspection, calculate the Hourly Sum of all Net Fill Weights for the bottles tested that hour and record under the corresponding hourly inspection column.

NOTE: The table below provides sampling in groups of 10, however more or less than one group may be required for documenting the samples tested each hour based on hourly sampling plan requirements. N/A any unused sample spaces in group as needed to document the number of samples tested.

The Net Fill Weights will be evaluated against the following Net Fill specifications (transfer calculated weights from page 4 of this MBR)

Minimum Net Fill Weight 54.43 grams

Target Net Fill Weight 56.06 grams

Upper Action Limit Net Fill Weight 57.69 grams

Any Net Fill that is below the Minimum Net Fill Weight is considered a defect and will count towards the defined Accept/Reject criteria.

If a Net Fill meets or exceeds the Upper Action Limit Net Fill Weight, this is not considered a defect so long as the solution is not overflowing from the bottle and there is sufficient headspace to allow for the sprayer pump cap to be inserted prior to use, but will require the operator to monitor and, if needed, adjust the combined amount dispensed by the filler pumps back to target.

Note any adjustments made to filler on a copy of the Master Batch Record Processing Notes Form F1821.

Sample #	Gross Wt	−	Tare Wt	=	Net Wt
1	63.69	−	8.03	=	55.66
2	63.64	−	8.12	=	55.52
3	63.62	−	8.09	=	55.53
4	63.73	−	8.09	=	55.64
5	63.75	−	8.10	=	55.65
6	63.90	−	8.24	=	55.66
7	63.70	−	8.21	=	55.49
8	63.63	−	8.12	=	55.51
9	63.65	−	8.18	=	55.47
10	63.85	−	8.13	=	55.72
Time 11:00 AM				Sum:	555.85

Sample #	Gross Wt	−	Tare Wt	=	Net Wt
1	63.52	−	8.06	=	55.46
2	63.68	−	8.16	=	55.52
3	63.70	−	8.16	=	55.54
4	63.59	−	8.07	=	55.52
5	63.80	−	8.13	=	55.67
6	63.68	−	8.02	=	55.66
7	63.74	−	8.12	=	55.62
8	63.61	−	8.08	=	55.53
9	63.73	−	8.12	=	55.61
10	63.76	−	8.16	=	55.60
Time 11:00 AM				Sum:	555.73

1	63.73	−	8.13	=	55.60
2	63.65	−	8.01	=	55.64
3	63.86	−	8.10	=	55.76
4	63.69	−	8.10	=	55.59
5	63.77	−	8.15	=	55.62
6	63.82	−	8.19	=	55.63
7	63.65	−	8.06	=	55.59
8		−	N/A	=	
9		−	SG 6/25/20	=	
10		−		=	
Time 11:00 AM				Sum:	389.43

1		−		=	
2		−		=	
3		−		=	
4		−		=	
5		−	N/A	=	
6		−		=	
7		−	SG 6/25/20	=	
8		−		=	
9		−		=	
10		−		=	
Time				Sum:	

Date Tested: 6.25.20 Tested By: MY

Daily: Record total number of bottles weighed: ⊗ **and total sum of all individual net fill weights for that day:** ⊗ **grams**

End of Work Order Run: Calculate and record the overall Avg Net Fill Weight for all samples tested: ~~SG 6/25/20~~ N/A **g (xx.xx). Transfer Avg. Net Fill weight to the batch reconciliation page.**

Calculations reviewed and verified by (initials and date): SR 6/25/20

⊗ Refer to pg 4 of 6 for weights MY 6/25/20

Work Order Number: 106857 Lot Number: 2016801-02 Date: 6-25-20

NET FILL WEIGHT DETERMINATION

Copy this form page as needed, Page 3 of 6

Check 67 bottles per hour. All weights to be recorded in grams, to two decimal places (i.e. xxx.xx)

Pre-weigh the required number of bottles needed for hourly testing and record each bottle's empty weight on it. The Line Operator will then run the pre-weighed bottles thru the filling system and remove them prior to the capping station. Weigh the filled bottles and record the Gross Weight of each filled bottle and its corresponding Empty Bottle Tare Weight in the appropriate spaces below. Using these weights, calculate the Net Fill Weight for each bottle. .

For each hourly inspection, calculate the Hourly Sum of all Net Fill Weights for the bottles tested that hour and record under the corresponding hourly inspection column.

NOTE: The table below provides sampling in groups of 10, however more or less than one group may be required for documenting the samples tested each hour based on hourly sampling plan requirements. N/A any unused sample spaces in group as needed to document the number of samples tested.

The Net Fill Weights will be evaluated against the following Net Fill specifications (transfer calculated weights from page 4 of this MBR)

Minimum Net Fill Weight 54.43 grams

Target Net Fill Weight 56.06 grams

Upper Action Limit Net Fill Weight 57.69 grams

Any Net Fill that is below the Minimum Net Fill Weight is considered a defect and will count towards the defined Accept/Reject criteria.

If a Net Fill meets or exceeds the Upper Action Limit Net Fill Weight, this is not considered a defect so long as the solution is not overflowing from the bottle and there is sufficient headspace to allow for the sprayer pump cap to be inserted prior to use, but will require the operator to monitor and, if needed, adjust the combined amount dispensed by the filler pumps back to target.

Note any adjustments made to filler on a copy of the Master Batch Record Processing Notes Form F1821.

Sample #	Gross Wt	–	Tare Wt	=	Net Wt
1	63.90	–	8.12	=	55.78
2	63.85	–	8.07	=	55.78
3	63.93	–	8.06	=	55.87
4	63.88	–	8.11	=	55.77
5	63.98	–	8.06	=	55.92
6	63.84	–	8.09	=	55.75
7	63.73	–	8.00	=	55.73
8	63.86	–	8.14	=	55.72
9	63.70	–	8.05	=	55.65
10	63.86	–	8.07	=	55.79
Time 11:30 AM				Sum:	557.76

Sample #	Gross Wt	–	Tare Wt	=	Net Wt
1	63.94	–	8.10	=	55.84
2	63.86	–	8.07	=	55.79
3	63.85	–	8.15	=	55.70
4	63.81	–	8.03	=	55.78
5	63.77	–	8.06	=	55.71
6	63.70	–	8.10	=	55.60
7	63.79	–	8.04	=	55.75
8	63.88	–	8.07	=	55.81
9	63.66	–	8.08	=	55.58
10	64.02	–	8.14	=	55.88
Time 11:30 AM				Sum:	557.44

Sample #	Gross Wt	–	Tare Wt	=	Net Wt
1	63.75	–	8.06	=	55.69
2	64.46	–	8.04	=	56.42
3	63.90	–	8.08	=	55.82
4	64.39	–	8.07	=	56.32
5	63.79	–	8.03	=	55.76
6	63.86	–	8.10	=	55.76
7	64.01	–	8.22	=	55.79
8	63.91	–	8.04	=	55.87
9	63.92	–	8.08	=	55.84
10	63.79	–	8.05	=	55.74
Time 11:30 AM				Sum:	559.01

Sample #	Gross Wt	–	Tare Wt	=	Net Wt
1	63.90	–	8.13	=	55.77
2	63.83	–	8.07	=	55.76
3	63.92	–	8.11	=	55.81
4	63.79	–	8.08	=	55.71
5	63.96	–	8.06	=	55.90
6	63.95	–	8.05	=	55.90
7	63.91	–	8.10	=	55.81
8	63.92	–	8.12	=	55.80
9	63.71	–	8.06	=	55.65
10	63.21	–	8.10	=	55.11
Time 11:30 AM				Sum:	557.20

Date Tested: 6-25-20 Tested By: MJ

Daily: Record total number of bottles weighed: ⊗ **and total sum of all individual net fill weights for that day:** ⊗ **grams**

End of Work Order Run: Calculate and record the overall Avg Net Fill Weight for all samples tested: N/A **g (xx.xx). Transfer Avg. Net Fill weight to the batch reconciliation page.**

Calculations reviewed and verified by (initials and date): SR 6/25/20

& Refer to pg 6 of 6 for weights MJ 6/25/20

Work Order Number: 106857 Lot Number: 2016801-02 Date: 6-25-20

NET FILL WEIGHT DETERMINATION

Copy this form page as needed, Page 4 of 6

Check 67 bottles per hour. All weights to be recorded in grams, to two decimal places (i.e. xxx.xx)

Pre-weigh the required number of bottles needed for hourly testing and record each bottle's empty weight on it. The Line Operator will then run the pre-weighed bottles thru the filling system and remove them prior to the capping station. Weigh the filled bottles and record the Gross Weight of each filled bottle and its corresponding Empty Bottle Tare Weight in the appropriate spaces below. Using these weights, calculate the Net Fill Weight for each bottle. .

For each hourly inspection, calculate the Hourly Sum of all Net Fill Weights for the bottles tested that hour and record under the corresponding hourly inspection column.

NOTE: The table below provides sampling in groups of 10, however more or less than one group may be required for documenting the samples tested each hour based on hourly sampling plan requirements. N/A any unused sample spaces in group as needed to document the number of samples tested.

The Net Fill Weights will be evaluated against the following Net Fill specifications (transfer calculated weights from page 4 of this MBR)

Minimum Net Fill Weight 54.43 grams

Target Net Fill Weight 56.06 grams

Upper Action Limit Net Fill Weight 57.69 grams

Any Net Fill that is below the Minimum Net Fill Weight is considered a defect and will count towards the defined Accept/Reject criteria.

If a Net Fill meets or exceeds the Upper Action Limit Net Fill Weight, this is not considered a defect so long as the solution is not overflowing from the bottle and there is sufficient headspace to allow for the sprayer pump cap to be inserted prior to use, but will require the operator to monitor and, if needed, adjust the combined amount dispensed by the filler pumps back to target.

Note any adjustments made to filler on a copy of the Master Batch Record Processing Notes Form F1821.

Sample #	Gross Wt	–	Tare Wt	=	Net Wt
1	64.01	–	8.15	=	55.86
2	64.43	–	8.03	=	56.40
3	63.95	–	8.23	=	55.72
4	63.78	–	8.06	=	55.72
5	63.84	–	8.09	=	55.75
6	63.87	–	8.15	=	55.72
7	63.86	–	8.16	=	55.70
8	63.84	–	8.08	=	55.76
9	63.90	–	8.06	=	55.84
10	63.88	–	8.13	=	55.75
Time 11:30 am				Sum:	558.22
1	63.80	–	8.07	=	55.73
2	63.76	–	8.04	=	55.72
3	63.88	–	8.19	=	55.69
4	64.12	–	8.09	=	56.03
5	63.76	–	8.06	=	55.70
6	63.46	–	8.22	=	55.24
7	64.06	–	8.06	=	56.00
8		–		=	
9		–		=	
10		–		=	
Time 11:30 am				Sum:	390.11

Sample #	Gross Wt	–	Tare Wt	=	Net Wt
1	64.01	–	8.12	=	55.89
2	63.91	–	8.04	=	55.87
3	63.89	–	8.14	=	55.75
4	63.96	–	8.15	=	55.81
5	63.80	–	8.11	=	55.69
6	63.87	–	8.05	=	55.82
7	63.84	–	8.18	=	55.66
8	63.82	–	8.09	=	55.73
9	64.01	–	8.12	=	55.89
10	63.66	–	8.02	=	55.64
Time 11:30 am				Sum:	557.75
1		–		=	
2		–		=	
3		–		=	
4		–		=	
5	N/A	–		=	
6		–		=	
7	SG 6/25/20	–		=	
8		–		=	
9		–		=	
10		–		=	
Time 11:30 am EESG 6/25/20				Sum:	

Date Tested: 6.25.20 Tested By: hyj

Daily: Record total number of bottles weighed: ⊗ **and total sum of all individual net fill weights for that day:** ⊗ **grams**

End of Work Order Run: Calculate and record the overall Avg Net Fill Weight for all samples tested: N/A SG 6/25/20 g (xx.xx). **Transfer Avg. Net Fill weight to the batch reconciliation page.**

Calculations reviewed and verified by (initials and date): SR 6/25/20

⊗ Refer to pg 6 of 6 for weights hyj 6/25/20

Work Order Number: 106857 Lot Number: 2016801-02 Date: 6.25.20

NET FILL WEIGHT DETERMINATION

Copy this form page as needed, Page 5 of 6

Check 67 bottles per hour. All weights to be recorded in grams, to two decimal places (i.e. xxx.xx)

Pre-weigh the required number of bottles needed for hourly testing and record each bottle's empty weight on it. The Line Operator will then run the pre-weighed bottles thru the filling system and remove them prior to the capping station. Weigh the filled bottles and record the Gross Weight of each filled bottle and its corresponding Empty Bottle Tare Weight in the appropriate spaces below. Using these weights, calculate the Net Fill Weight for each bottle. .

For each hourly inspection, calculate the Hourly Sum of all Net Fill Weights for the bottles tested that hour and record under the corresponding hourly inspection column.

NOTE: The table below provides sampling in groups of 10, however more or less than one group may be required for documenting the samples tested each hour based on hourly sampling plan requirements. N/A any unused sample spaces in group as needed to document the number of samples tested.

The Net Fill Weights will be evaluated against the following Net Fill specifications (transfer calculated weights from page 4 of this MBR)

Minimum Net Fill Weight 54.43 grams

Target Net Fill Weight 56.06 grams

Upper Action Limit Net Fill Weight 57.69 grams

Any Net Fill that is below the Minimum Net Fill Weight is considered a defect and will count towards the defined Accept/Reject criteria.

If a Net Fill meets or exceeds the Upper Action Limit Net Fill Weight, this is not considered a defect so long as the solution is not overflowing from the bottle and there is sufficient headspace to allow for the sprayer pump cap to be inserted prior to use, but will require the operator to monitor and, if needed, adjust the combined amount dispensed by the filler pumps back to target.

Note any adjustments made to filler on a copy of the Master Batch Record Processing Notes Form F1821.

Sample #	Gross Wt	−	Tare Wt	=	Net Wt
1	63.93	−	8.09	=	55.84
2	63.71	−	8.05	=	55.66
3	63.95	−	8.15	=	55.80
4	63.88	−	8.09	=	55.79
5	63.74	−	8.05	=	55.69
6	63.83	−	8.02	=	55.81
7	63.77	−	8.12	=	55.65
8	63.80	−	8.07	=	55.73
9	63.76	−	8.04	=	55.72
10	64.11	−	8.11	=	56.00
Time 12:00 pm				Sum:	557.69

Sample #	Gross Wt	−	Tare Wt	=	Net Wt
1	63.70	−	8.14	=	55.56
2	63.90	−	8.08	=	55.82
3	63.66	−	8.04	=	55.62
4	63.89	−	8.11	=	55.78
5	63.93	−	8.10	=	55.83
6	63.93	−	8.18	=	55.75
7	64.00	−	8.13	=	55.87
8	63.76	−	8.11	=	55.65
9	63.92	−	8.21	=	55.71
10	63.97	−	8.11	=	55.86
Time 12:00 pm				Sum:	557.45

1	63.94	−	8.09	=	55.85
2	63.92	−	8.02	=	55.90
3	63.85	−	8.03	=	55.82
4	63.84	−	8.07	=	55.77
5	63.86	−	8.11	=	55.75
6	63.74	−	8.14	=	55.60
7	63.84	−	8.07	=	55.77
8	63.87	−	8.09	=	55.78
9	63.85	−	8.16	=	55.69
10	63.96	−	8.11	=	55.85
Time 12:00 pm				Sum:	557.78

1	63.76	−	8.07	=	55.69
2	63.92	−	8.11	=	55.81
3	63.85	−	8.11	=	55.74
4	63.84	−	8.08	=	55.76
5	63.81	−	8.09	=	55.72
6	63.97	−	8.09	=	55.88
7	63.88	−	8.10	=	55.78
8	63.93	−	8.10	=	55.83
9	63.75	−	8.05	=	55.70
10	63.96	−	8.10	=	55.86
Time 12:00 pm				Sum:	557.27

Date Tested: 6.25.20 Tested By: [illegible]

Daily: Record total number of bottles weighed: ⊗ **and total sum of all individual net fill weights for that day:** ⊗ **grams**

End of Work Order Run: Calculate and record the overall Avg Net Fill Weight for all samples tested: N/A 6/25/20 **g (xx.xx). Transfer Avg. Net Fill weight to the batch reconciliation page.**

Calculations reviewed and verified by (initials and date): SR 6/25/20

⊗ Refer to pg 6 of 6 for weights SR 6/25/20

Work Order Number: 106857 Lot Number: 2016801-02 Date: 6.25.20

NET FILL WEIGHT DETERMINATION

Copy this form page as needed, Page 6 of 6

Check 67 bottles per hour. All weights to be recorded in grams, to two decimal places (i.e. xxx.xx)

Pre-weigh the required number of bottles needed for hourly testing and record each bottle's empty weight on it. The Line Operator will then run the pre-weighed bottles thru the filling system and remove them prior to the capping station. Weigh the filled bottles and record the Gross Weight of each filled bottle and its corresponding Empty Bottle Tare Weight in the appropriate spaces below. Using these weights, calculate the Net Fill Weight for each bottle. .

For each hourly inspection, calculate the Hourly Sum of all Net Fill Weights for the bottles tested that hour and record under the corresponding hourly inspection column.

NOTE: The table below provides sampling in groups of 10, however more or less than one group may be required for documenting the samples tested each hour based on hourly sampling plan requirements. N/A any unused sample spaces in group as needed to document the number of samples tested.

The Net Fill Weights will be evaluated against the following Net Fill specifications (transfer calculated weights from page 4 of this MBR)

Minimum Net Fill Weight 54.43 grams

Target Net Fill Weight 56.06 grams

Upper Action Limit Net Fill Weight 57.69 grams

Any Net Fill that is below the Minimum Net Fill Weight is considered a defect and will count towards the defined Accept/Reject criteria.

If a Net Fill meets or exceeds the Upper Action Limit Net Fill Weight, this is not considered a defect so long as the solution is not overflowing from the bottle and there is sufficient headspace to allow for the sprayer pump cap to be inserted prior to use, but will require the operator to monitor and, if needed, adjust the combined amount dispensed by the filler pumps back to target.

Note any adjustments made to filler on a copy of the Master Batch Record Processing Notes Form F1821.

Sample #	Gross Wt	–	Tare Wt	=	Net Wt
1	63.79	–	8.07	=	55.72
2	63.92	–	8.21	=	55.71
3	63.80	–	8.07	=	55.73
4	63.96	–	8.11	=	55.85
5	63.66	–	8.04	=	55.62
6	63.75	–	8.04	=	55.71
7	63.95	–	8.09	=	55.86
8	63.87	–	8.09	=	55.78
9	63.72	–	8.14	=	55.58
10	63.89	–	8.09	=	55.80
Time 12:00 pm				Sum:	557.36

Sample #	Gross Wt	–	Tare Wt	=	Net Wt
1	63.75	–	8.11	=	55.64
2	63.83	–	8.02	=	55.81
3	63.87	–	8.09	=	55.78
4	63.75	–	8.12	=	55.63
5	63.94	–	8.10	=	55.84
6	63.70	–	8.05	=	55.65
7	63.70	–	8.05	=	55.65
8	63.64.10	–	8.11	=	55.90
9	63.93	–	8.15	=	55.78
10	63.80	–	8.11	=	55.69
Time 12:00 pm				Sum:	557.46

1	63.96	–	8.09	=	55.87
2	63.88	–	8.10	=	55.78
3	63.83	–	8.07	=	55.76
4	63.97	–	8.13	=	55.84
5	63.84	–	8.11	=	55.73
6	63.85	–	8.08	=	55.77
7	63.89	–	8.11	=	55.78
8		–	N	=	
9		–	SG 6/25/20	=	
10					
Time 12:00 pm				Sum:	390.53

1		–		=	
2		–		=	
3		–		=	
4		–	N	=	
5		–	M	=	
6		–	SG	=	
7		–	6/25/20	=	
8		–		=	
9		–		=	
10		–		=	
Time				Sum:	

Date Tested: 6.25.20 Tested By: MJ

Daily: Record total number of bottles weighed: 201 **and total sum of all individual net fill weights for that day:** 11197.05 **grams**

End of Work Order Run: Calculate and record the overall Avg Net Fill Weight for all samples tested: 557.1 **g (xx.xx). Transfer Avg. Net Fill weight to the batch reconciliation page.**

Calculations reviewed and verified by (initials and date): SR 6/25/20

Work Order Number: 106857 Lot Number: 2016801-02 Date: 6.25.20

QUALITY CONTROL IN-PROCESS CHECK OF IMMEDIATE REMOVAL TORQUE (IRT)

Copy this form page as needed, Page 1 of 1

- Test and record the immediate removal torque hourly.
- Record the date and time (AM/PM) samples are tested.
- Record the immediate removal torque values (in in-lbs) for each individual sample tested to two (2) decimal places (xx.xx)
- Calculate the Average Immediate Removal Torque for the six (6) samples tested at each time point **Round the Average Immediate Removal Torque result to one (1) decimal place.**
- The Average Immediate Removal Torque for each time point will be evaluated against the following specifications:

Minimum Average Immediate Removal Torque: 4.0 in-lbs

Target Average Immediate Removal Torque: 10.0 in-lbs

Maximum Average Immediate Removal Torque: 20.0 in-lbs

Note: Individual Immediate Removal Torque Results may test outside of the 4.0 – 20.0 in-lbs specification range, so long as the average of the six (6) samples tested at each time point falls within the specified range and there is no bottle/closure integrity (i.e. no leaking solution) and/or no visible damage to the closure.

- **Bottles tested for Immediate Removal Torque cannot be packed out and must be disposed of.**

•Circle wrong one JMS 6/25/20

Immediate Removal Torque (in in-lbs.)

Bottle	Sample Time 11:00 AM / PM	Sample Time 11:30 AM / PM	Sample Time 12:00 AM / PM	Sample Time ____ AM / PM	Sample Time ____ AM / PM	Sample Time ____ AM / PM	Sample Time ____ AM / PM	Sample Time ____ AM / PM	Sample Time ____ AM / PM	Sample Time ____ AM / PM
1	6.31	4.95	5.06							
2	6.45	6.13	5.83							
3	4.36	4.82	6.32				N	A		
4	5.21	6.04	5.86							
5	6.29	5.16	4.28				SG	6/25/20		
6	5.32	6.13	5.60				6/25/20			
Average	5.7	5.5	5.5							
Initial	SG	SG	SG							
Date	6/25/20	6/25/20	6/25/20							

The average immediate removal torque result from each time point is within the range of 4.0 – 20.0 in-lbs. ☑ Yes ☐ No

Results and Calculations Reviewed and Verified By: SR Date: 6/25/20

Work Order Number: [illegible] Lot Number: 2016801-02 Date: 6.25.20

FINISHED PRODUCT TESTING, RETAIN AND STABILITY SAMPLING:

To be pulled by Quality techs, with the appropriate samples being sent to the Analytical Lab and Micro Lab, upon completion of run.

Ensure that each sample is properly labeled as to its pull point identity (i.e. Beginning, Middle or End / B, M, E / etc.) so that Aphena's Analytical and Micro Labs can clearly distinguish the Lot Number and the portion of the run each sample is from.

- **Pull 36 bottles** (12 bottles from the Beginning of the run, 12 bottles from the Middle of the run, and 12 bottles from the End of Run) for Analytical Testing. Label each bottle with the appropriate sample identification information (i.e. product name, lot #, date sampled, sampled by, etc.), including whether it is from the Beginning, Middle or End of the packaging run. Submit all bottles with a completed Chain of Custody form, and a copy of the Analytical Testing requirements found on page 21 of this MBR, to the Aphena's Analytical Lab for testing.
- **Pull 6 bottles** (2 bottles from the Beginning of the run, 2 bottles from the Middle of the run, and 2 bottles from the End of Run) for Microbiological Testing. Label each bottle with the appropriate sample identification information (i.e. product name, lot #, date sampled, sampled by, etc.), including whether it is from the Beginning, Middle or End of the packaging run. Submit all bottles with a completed Chain of Custody form, and a copy of the Microbiological Testing requirements found on page 22 of this MBR, to the Aphena's Microbiological Lab for testing.
- **Pull 36 bottles** (12 bottles from the Beginning of the run, 12 bottles from the Middle of the run, and 12 bottles from the End of the run) for Retain storage. Label as Retains with Pull point ID (Beginning, Middle, and End), Work Order Number, Lot Number, and Part Number, forward to QA for storage.

Sample	**Analytical Samples** 36 Bottles: 12 Beginning, 12 Middle, and 12 End	**Micro Samples** 6 Bottles: 2 Beginning, 2 Middle, and 2 End	**Retain Samples** 36 bottles: 12 Beginning, 12 Middle, and 12 End	**Time** (circle AM or PM)	**Initials**	**Date**
Beginning	12	2	12	11:00 (AM) / PM	SA	6/25/20
Middle	12	2	12	11:30 (AM) / PM	SA	6/25/20
End	12	2	12	12:00 AM / (PM)	SA	6/25/20

Samples delivered by: _____ Date: 6/25/20

Work Order Number: 100557 Lot Number: 2016801-02 Date: 6-24-20

Analytical Testing of No More Pills Acetaminophen Oral Solution 650mg/50mL Bottle Product:

Test Parameter	Specification	Aphena Test Method
Acetaminophen Assay	12.4 – 13.7 mg/mL 95% - 105% Label Claim	WILAB199
API ID A	The retention time of the major peak of the samples solution corresponds to that of a standard solution as obtained in the assay.	
API ID B	The *RF* value of each principal spot in the chromatogram of the *Modified test solution* corresponds to that of the principal spot in the chromatogram obtained from each relevant *Standard solution* as appropriate for the active ingredient or ingredients specified on the label.	Thin Layer Chromatography (TLC)
Alcohol Content	0.99 – 1.265% 90.0% - 115.0% Label Claim	USP for Acetaminophen Oral Solution
Impurities – 4 Aminophenol	NMT 0.15% of 4-aminophenol relative to acetaminophen	USP for Acetaminophen Oral Solution
Appearance/Color*	For Information Only Tentative specification: Colorless to light brown, clear to slight opaque viscous liquid	WILAB59 WILAB186
Specific Gravity*	For Information Only	WILAB80
Viscosity*	For Information Only	WILAB42
pH*	For Information Only Tentative Specification: 3.0 – 3.5	WILAB08
Deliverable Volume	The average volume obtained from 10 containers is NLT 100% and the volume of each of the 10 containers lies within the range of 95 – 110% of the volume declared in the labeling.	USP for Acetaminophen Oral Solution

*For Information only

Aphena Pharma Solutions

Chain of Custody Form for Laboratory Analysis per LC 008

Product Information	MBR #: 638	Revision #: 0
Work Order or Study #: 106857	Cleaning Document #: N/A Tmc 6.24.20	Revision #: N/A Tmc 6.24.20
Part #: AD-NMPHM01	Equipment Line ID: K2	
Lot #: 2016801-02	Line Supervisor or Designated Contact: Heidi	

Sample Information

Select the Purpose of Sample Submission:

☐ Pre-Clean Validation/Verification ☐ Post-Clean Validation/Verification ☑ Finished Good Product Analysis

☐ In-Process/Finished Blend Analysis ☐ Raw Material Testing ☐ Routine Water System Testing

☐ Daily Tote Water ☐ Stability Protocol: N/A SG 6/24/20 ☐ Other: N/A SG 6/24/20

Sample Designation/Description	Date Sampled	Time Sampled	# Samples	# Retains	Sampled by
No more Pills Beginning	6.25.20	11:00 am	12	0	SG
No more Pills middle	6.25.20	11:30 Am	12	0	SG
No more Pills END	6.25.20	12:00 pm	12	0	SG
	N/A Tmc 6.24.20				

Sample Release

☒ Analytical Chemistry Laboratory ☐ Microbiological Laboratory ☐ External Laboratory: N/A

☒ Ambient Temperature ☐ Keep Refrigerated ☐ Other: SAG 6/24/20

Relinquished by: DL Date: 6.25.20 Time: 3:56 pm

For Laboratory Use Only

Received by: DL Date: 6-25-20 Time: 4:00 PM

Comments:

Aphena

APS Labs QC Certificate of Analysis

Product Description	No More Pills Headache Man
WO #	106857
Part #	AD-NMPHM01
Lot #	2016801-02
MBR#	638 Rev 0
Equipment Line#	K2
Purpose	Finished Good Analysis

Sample ID	Analysis	Specification	Result	Lab Notebook Reference
Beginning Middle End	Assay – Acetaminophen	12.4 – 13.7 mg/mL 95% - 105% Label Claim	96.3% 98.7% 96.2%	LN497/51,55,58
Beginning Middle End	API ID A	The retention time of the major peak of the sample solution corresponds to that of a standard solution as obtained in the assay.	Conforms Conforms Conforms	LN497/51,55,58
Beginning Middle End	API ID B	The RF value of each principal spot in the chromatogram of the *Modified test solution* corresponds to that of the principal spot in the chromatogram obtained from each relevant *Standard Solution* as appropriate for the active ingredient or ingredients specified on the label.	Conforms Conforms Conforms	LN497/62
Beginning Middle End	Alcohol Content	0.99% - 1.265% 90.0% - 115.0% Label Claim	1.11% (v/v) 98.8% Label Claim 1.14% (v/v) 101.3% Label Claim 1.13% (v/v) 100.4% Label Claim	LN475/153-155
Beginning Middle End	Impurities- 4 Aminophenol	NMT 0.15% of 4-Aminophenol relative to acetaminophen	0.000% 0.000% 0.021%	LN497/56-57
Beginning Middle End	Appearance/Color	For Information Only* Tentative specification: Colorless to light brown, clear to slight opaque viscous liquid	Conforms Conforms Conforms	LN506/3

Aphena

APS Labs QC Certificate of Analysis

Product Description	No More Pills Headache Man
WO #	106857
Part #	AD-NMPHM01
Lot #	2016801-02
MBR#	638 Rev 0
Equipment Line#	K2
Purpose	Finished Good Analysis

Sample ID	Analysis	Specification	Result	Lab Notebook Reference
Beginning Middle End	Specific Gravity @ 25°C*	For Information Only*	1.0886 1.0864 1.0887	LN502/58
Beginning Middle End	pH*	3.0-3.5	3.20 3.25 3.23	LN502/58
Beginning Middle End	Deliverable Volume	The average obtained from 10 containers is NLT 100% and the volume of each of the 10 containers lies within the range of 95-110% of the volume declard in the labeling.	Conforms	LN506/4

*For Information Only

☒ Meets Specifications ☐ Does Not Meet Specifications

Prepared By	K. Keller	Date	7/20/20
Reviewed By	Amanda Anders	Date	7-20-20

Microbiological Testing of Call Inc. Acetaminophen Oral Solution 650mg/50mL Bottle Product:

Aphena's Microbiological Lab will use bottles provided from each Lot to perform the following testing on samples from the Beginning, samples from the Middle, and samples from the End of the packaging run.

Finished Product Test	Test Method	Specification
Microbial Enumeration Test and Tests for Specified Microorganisms	WILAB69 and USP <61>	Total Aerobic Microbial Count (TAMC): Not More Than 10^2 CFU/g
		Total Yeasts and Molds Count (TYMC): Not More Than 10^1 CFU/g
	WILAB69 and USP <62>	*Staphylococcus aureus:* Absent
		Pseudomonas aeruginosa: Absent
		Salmonella: Absent
		Escherichia coli: Absent

Work Order Number: 106357 Lot Number: 2016801-02 Date: 4-24-20

Daily Production – Raw Materials – Usage Log

Daily Production

Lot Number	Daily Production (U/M per BOM)	Initials	Date
2016801-02	1058	HAJ	6/25/20

Solution – P/N: AD/NMPHM01

Total Quantity In FPA: 912 (total of all containers)

Lot #	Container Number	Daily Starting Wt.	Daily Ending Wt.	Total Used	Total Returned	Initials	Date
2016801	1	912	854.87	57.13	854.87	HAJ	6/25/20
Totals				57.13	854.87	HAJ	6/25/20

Determination of Residual Solution in Container:

When changing containers, determine the residual solution in containers below:

Container #	Total Weight of Container w/ Residual Solution	-	Tare Weight of Empty Container	=	Net Wt of Residual Solution in Container
1	kg	-	kg	=	kg solution in Cont 1
2	kg	-	kg	=	kg solution in Cont 2
			Total	=	Kg of solution

HAJ 6/25/20

Transfer the total residual solution quantity to The Final Batch Reconciliation page to determine total manufacturing loss.

Daily Production – Raw Materials – Usage Log (continued)

Bottle – P/N: CP4411

Lot #	Issued	Total Used	Qty of Waste/Rejects	Calculated Return	Actual Qty Returned	Initials	Date
141457	5712	1058	454			HAJ	6/25/20
						N/A	
	N					HAJ	6/25/20
	A	HAJ					
		6/25/20		4200	4200	HAJ	6/25/20
		Variance (end of run only)		0		HAJ	6/25/20

33-400 CR Cap – P/N: CP4410 Refer to ENG-002

Lot #	Issued	Total Used	Qty of Waste/Rejects	Calculated Return	Actual Qty Returned	Initials	Date
EV4123	7420	1058	341			HAJ	6/25/20
						N/A	
	N					HAJ	
	A	HAJ	6/25/20				6/25/20
				6021	6021	HAJ	6/25/20
		Variance (end of run only)		0		HAJ	6/25/20

Work Order Number: 16857

Daily Production – Raw Materials – Usage Log (continued)

Non-Lot Controlled Components

Part #	Total (U/M)	Qty of Rejects	Rejects Disposed? (Y/N)	Qty Returned	Initials	Date
CP1178	12460	793	Y	10549	HAJ	6/25/20
CP8422	13253	405	Y	11790	HAJ	6/25/20
F-L613	356	15	Y	341	HAJ	6/25/20
SP695/2	181	14	* Y	167	HAJ	6/25/20
		N/A				
		N/A	HAJ	6/25/20		

* EE HJ 6/25/20

NOTE: Forward a copy of all completed "Daily Production – Raw Materials – Usage" pages to the Inventory Control Manager daily

Confirm that printed material/label reconciliation (i.e. for bottle label and shipper label) is performed using the Label Control Inventory Release Form, F1622, and attach it to the batch record upon completion.

6/25/20
Confirmed by/Date

7/2/20
Verified By/Date

FINAL BATCH RECONCILIATION

Transferred Quantity of Bulk Solution to Filling Line: 912 kg

A. Filler Set-up	0.2	kg
B. Residual Product Loss in Tote Systems	0	kg
C. Other waste	0.2	kg
Total Filling Loss	0.4	kg

PACKAGING YIELD CALCULATION

A. Average Net Fill Weight*	55.71 grams	
B. Finished Good Count (bottles)	1058	
C. Packaged Product Usage (A x B) / 1000		58.94 kg
D. Samples Taken (bottles)**	78	
E. Sample Loss (A x D) / 1000		4.35 kg
F. Rejects (bottes)	21	
G. Reject Loss (A x F) / 1000		1.17 kg
H. Total Filling Loss (from above)		0.4 kg
I. Bulk Returned to Inventory		854.87 kg
J. Actual Yield (C+ E + G + H + I)		919.73 kg
K. Percent Yield (Actual Yield / Transferred Quantity to Line) x 100		101 %

Acceptable Percent Yield is 95 – 105%. If percent yield is outside of acceptable range, notify quality assurance.

Comments: N/A HAS 6/25/20

Entered by / Date: 6/25/20

Checked by / VL 7/2/20 Date:

***Average Net Fill Weight is the average of all in-process samples tested for Net Fill during the run (from page 18).**

****Samples Taken includes all samples taken for testing, retains, customer samples, etc., that are not included in the total Finished Good Count**

Work Order Number: 100857

REVISION HISTORY:

Revision 0 – New Issue per DCC # 20-409

Daily Time Sheet

SECTION 1

Date: 4/25/20 (4/24/20) Machine: K2 Clocked Cycles: 40

Product: AD-NMPHW01 Supervisor: HAJ

WO#: 10068557 Operator: 2

Start Time: 11:00 AM Packers: 3+1

End Time: 12:50 PM Units Produced: 1058 U/M: EACH

SECTION 2:

Name	O - Oper P - Packer	Set-Up (Y/N)	Time In	Time Out	Labor Hrs	Employee Skill Level
K. Kabanto	O	N	1100	1250		
J. Kabanto	O	N	1100	1250		
P. Carrasco	P	N	1100	1250		
V. Harrison	P	N	1100	1250		
K. Pannell	P	N	1100	1130		
L. Washington	P	N	1100	1250		

N/A HAJ 4/25/20 4/25/20

Labor Codes: 01 PM 02 - Breakdown 03 Training 04 Housekeeping/Cleaning 05 Q.C.
06 - WHS 07 Set Up 08 No People 09 Mat'l Short

SECTION 3:

		Total Daily Waste:	Total Set-Up Material:
Number of Cases Started			
Cases Produced (Tally)	1058		
	0	Gross:	
	0	Tare: N/A	4/25/20
	0	Net: HAJ	4/25/20
Total Produced:	1058	Meter:	

Total Hours:
Set-Up
Packer
Operator

Lot 2016501 - 02 4/25/20 EDHJ (Exp ~~2020~~ 2023 06 16)

SECTION 4: Comments:

Ran Down @ 02:
10 minutes

Form: F3A

DOWNTIME REPORT

DATE: 6/25/20 PRODUCT: AD-NMPHM01

WO #: 106857 MACHINE: K2 LOT: 2016801-02

TIME FROM	TIME TO	MINUTES DOWN	REASON	INITIAL & DATE
			N/A HAJ 6/25/20	

TOTAL MINUTES DOWN:

COMMENTS:

Form: F5 Rev 1

Transfer

EXCEPTION REQUISITION

From: K2 [illegible]
To: J3 [illegible]

Date: [illegible]
Work order #:
Requested by: [illegible]
Date needed: [illegible]
Delivery to: [illegible]
Filled by:

Part Number	Requisition Quantity	Actual Qty. Delivered	U/M	Location	Lot #	Reason Code
116B	14	14	EA		N/A	
[illegible]	14	14	EA		N/A	

Requisition Reason Codes:

A - Vendor Reject File
B - Set-up Materials
C - Rejects (Process related)
D - Samples
E - Non-standard job
F - AC 2010 - PRD
G - Other

Warehouse copy distribution:
Original – Data Entry
Copy – Placed with material when delivered

LOT CONTROL RETRIEVE -- 'LOTEDT'

PART NUMBER: AD-NMPHM01 QUANTITY: 0.0
DESCRIPTION: 1CP HEADACHE MAN ACETAMINOPHEN OR. SOL.,50ML,ENG.

NO LOTS EXIST FOR PART NUMBER AD-NMPHM01
<CR> TO CONTINUE?

New Lot Code 20116801-02 MS 6/18/20

LOT CONTROL RETRIEVE -- 'LOTEDT'

PART NUMBER: AD-NMPHM01 QUANTITY: 0.0
DESCRIPTION: 1CP HEADACHE MAN ACETAMINOPHEN OR. SOL.,50ML,ENG.

NO LOTS EXIST FOR PART NUMBER AD-NMPHM01
<CR> TO CONTINUE?

New Lot code 2016801-02
HAS 6/18/20

Heidi Jenkins

From: Bridget Trahan
Sent: Wednesday, June 17, 2020 8:45 AM
To: Heidi Jenkins
Subject: RE: AD/NMPHM01

Heidi

SG : 1.0885

From: Heidi Jenkins <HJenkins@aphenapharma.com>
Sent: Wednesday, June 17, 2020 8:27 AM
To: Bridget Trahan <btrahan@aphenapharma.com>
Subject: RE: AD/NMPHM01

Thanks Bridget

From: Bridget Trahan
Sent: Wednesday, June 17, 2020 8:22 AM
To: Heidi Jenkins <HJenkins@aphenapharma.com>; Easton Lab Results <eastonlabresults@aphenapharma.com>
Subject: RE: AD/NMPHM01

Heidi,

Sue is going to run the SG and send it to you asap. ☺

From: Heidi Jenkins <HJenkins@aphenapharma.com>
Sent: Wednesday, June 17, 2020 8:07 AM
To: Easton Lab Results <eastonlabresults@aphenapharma.com>
Subject: AD/NMPHM01

We need the solution (AD/NMPHM01) to be released or a conditional release to be done, also the specific gravity for the solution.

AD/NMPHM01 LOT 2016801

Thanks
Heidi

VERIFIED COPY
OF ORIGINAL
HJ 6/18/20

Run #2

AD-NMPHM01

WO106857

SPEC REV 1

AD-NMPHM01

WO106857

SPEC REV 1

BLEND LABEL

Part No.: AD/NMPHM01

Product Name: No More Pills

Container #: 1 of 1

Date of Manufacture: 06-16-20

Lot #: 2016801 MTC 6/18/20 HAJ 6/18/20

Exp. Date: N/A
(format: YYYYMMDD)

Gross Weight: 1026.0 kg
(including lid)

Tare Weight: 84.0 kg
(including lid)

Net Weight of Solution: 942.0 kg

Net Weight of Solution(from above) x 2.2 = N/A lbs

Initial RTH Date 06-16-20

VERIFIED COPY OF ORIGINAL

HAJ 6/18/20

Label Control Inventory Release Form

Finish Good Part Number: AD-NMPHM01 Work Order: 106857 Work Center: K2

Date Required: _____ Time Required: _____ AM / PM Requested by/Date: _____

Date Required: _____ Time Required: N AM / PM Requested by/Date: _____

Date Required: _____ Time Required: A AM / PM Requested by/Date: HAJ 6/25/20

(PRODUCTION) Attached the following documents to this form (F1622)

- A copy of the signature and LOT/EXP formatting pages from the approved Master Batch Record that you are requesting label for.
- A printed copy of the Parp Label Route Sheet
- Bulk CoA if applicable
- Purchase Order or Blanket order if applicable
- Forward the above documents to QC for printing

(QUALITY CONTROL) When printing labels Refer to the attached MBR for LOT/EXP formatting and requirements.

PARP Label Work order#	Part Number	Job Qty	Total Produced	Performed by (Initial/date)	Received and Verified by (Initial/date)	Verified by (Initial/date)
			N A	HAJ 6/25/20		

Document below any problems that happened while running labels that could affect the label count:

_____

_____

Label Control Inventory Release Form

Finish Good Part Number: AD-NMPHM01 Work Order: 106557 Work Center: 1C2

Reconciliation

Part Number	Lot #	Amount Issued	(-) Usage	(-) Reject	(=) Return Calculation	Actual Return	Discrepancy Calculation	Variance: Discrepancy / Usage + Reject (%)	*Tolerance (%)	% Tolerance Accepted **If NO; Investigation is required!
CP8422	141930	13253 ~~13298~~	1058	405	11790	11790	0	0%	5%	☑Yes ☐No
										☐Yes ☐No
										☐Yes ☐No
										☐Yes ☐No
				N/A	HAJ	6/25/20				☐Yes ☐No
										☐Yes ☐No
										☐Yes ☐No
										☐Yes ☐No

Tolerance: Cut label stock 3%, all other label stock 5% or BOM waste (whichever is higher)

**** Investigation is required for any Out of % Tolerance, if the component is to be WIP to the next production run the investigation must be completed prior to proceedings:** N/A HAJ 6/25/20

Reconciled by (initial/ date): HAJ 6/25/20 Calculations Verified by (initial/ date): u 7/2/20

PARP label count MUST be performed by TWO qualified personnel.

PARP LABEL COUNT IS CORRECT AND WITHIN TOLERANCE: ☐YES ☐NO ☐N/A

Performed By (initial/date): _____ Verified By (initial/date): _____

Disposition of unused PARP labels: **DISPOSED ☐YES ☐NO** *(If NO is circled an explanation must be documented)* N/A

Performed By (initial/date): _____ Verified By (initial/date): HAJ 6/25/20

*entry error HAJ 6/25/20

2e1C5801-02

ROUTE SHEET PRINT DATE 09:41:57 18 JUN 2020 PAGE 1

JOB NUMBER - W0106857 REF PART NUMBER - AD-NMPHM01

START DATE - 17JUN20 JOB QUANTITY - ~~1500.0~~ 1655 UM - BTL COMPLETION DATE - 18JUN20 QTY COMPLETE - 0.0

SALES ORDER REF -

DESCRIPTION: 1CP HEADACHE MAN ACETAMINOPHEN OR. SOL.,50ML,ENG.
REVISION 1 IMPLEMENTED ON 10JUN20

SPEC REVISION COMMENT: PER DCC#20-698
CC#19-037
FOR ENGINEERING TRIAL AND STABILITY
UPDATE THE BOM.
APPLICABLE PROCEDURES AND WORK INSTRUCTIONS:
MBR638 (PACK NMP ACETAMINOPHEN ORAL 650MG/50ML 1K2 REV 0) HAJ 6/18/20 LMB 6/18/20
FILL: AD/NMPHM01
PRODUCTION NOTES: LOT CODING PER MBR638

BILL OF MATERIALS:

ITM	PART NUMBER	REV	DESCRIPTION	U/M	QUANTITY	OP #
	SP695/2	2	BOX, CORRUGATED	EA	0.0201	
	FL613	1	BAG, GUSSETED, 23 X 14 X 38, UNPRTD	EA	0.0204	100
	CP8422	0	LABEL: NO MORE PILLS, 50ML, ENGLISH	EA	1.0500	100
	CP4411	0	BOTTLE: 50/60CC ROUND, HDPE/PP	EA	1.0500	100
	CP4410	0	CAP; PLASTIC (POLYPROPYLENE) WHITE, SMOOTH	EA	1.0500	100
	CP1178	1	LAY FLAT SHRINK SLEEVE, NO MORE PILLS	EA	1.0500	100

ROUTING :

OP #	L/C	RESOURCE	DESCRIPTION	QUANTITY	STD HRS
100	PRD	1K2	CAPMATIC FILLER #2 A	1500.00	0.74
SECONDARY RSRC		1MM	MECHANIC/OPERATOR		1.47
SECONDARY RSRC		1PK	PACKER CONVERTING		3.68