

STOCK LOCATION RETRIEVE - 'SLCEDT'

PART NUMBER: LB-NMPHM01 STOCK QUANTITY: 3,785.0
DESCRIPTION: 1LB SOL:NO MORE PILLS HEADACHE MAN

LOCATION	DATE	SUPP INV	QUANTITY	LOT NUMBER
2023001	24AUG20	'MAIN'	3,785.0	2023001

ENTER <CR> TO CONTINUE?
DISPLAY COMPLETE

STOCK LOCATION RETRIEVE - 'SLCEDT'

PART NUMBER: LB-NMPHM01 STOCK QUANTITY: 3,785.0
DESCRIPTION: 1LB SOL:NO MORE PILLS HEADACHE MAN

LOCATION	DATE	SUPP INV	QUANTITY	LOT NUMBER
2023001	17AUG20	QUAR	3,785.0	2023001

ENTER <CR> TO CONTINUE?
DISPLAY COMPLETE

Temporary Change Control

Aphena Site:
EASTON, MD
Date Issued: 08/17/2020

TCCR #
20-082

Description of Change

Current State:
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42.	Record the final weight of the tank.	Target: 3785.0 kg (Range: 3747.4 – 3822.6 kg)	Tank Weight: _____ kg		
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Proposed State:
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42.	Add a quantity sufficient (q.s.) of Purified Water into Tank B13 to obtain the final batch weight of 3785.0 kg. Record the weight of the tank before and after the addition of purified water.	Target: 3785.0 kg (Range: 3747.4 – 3822.6 kg)	Initial Tank Weight: <u>3724.7</u> kg Final Tank Weight: <u>3785.2</u> kg	<u>ml</u>	<u>ms</u> 8-18-20 8-18-20
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Rationale / Justification for change:
Switching the blend to a hot blend will cause water loss through evaporation.

Impact of Change / Risk Assessment:

The impact of the change is positive, compensating for potential water loss to obtain the current final batch size and API strength.

Effectivity of Change

Date: Start Date: 08/17/2020 End Date: 10/17/2020

Lot Specific: _____

Corrective Action

Revise MBR679 for future batches to include the water addition

Training Required:	<input type="checkbox"/> Yes – Subject Specific Training <input checked="" type="checkbox"/> Yes – Routine Training <input type="checkbox"/> No	Validation Affected:
		<input type="checkbox"/> Yes – CCR approval required by Validation <input checked="" type="checkbox"/> No

Actions Required to Complete

Action	Responsible	Due Date
Revise MBR679	Megan Kunkowski	10/17/2020

Completed by: Megan Kunkowski Date: 08/17/2020

Approval to Proceed with Temporary Change

Refer to Site Specific Change Control Approval Matrix for Required Approvers

Function	N/A	Name (print)	Signature	Date

Temporary Change Control

Aphena Site: TCCR #

EASTON, MD

Date Issued:

Operations	<input type="checkbox"/>	Kelly Hovis	S. Hovis	Aug 17, 2020
Purchasing	<input checked="" type="checkbox"/>	Rafeh Raza	Rafeh Raza	08/17/20
Validation	<input type="checkbox"/>			
Other:	<input checked="" type="checkbox"/>			
Other:	<input checked="" type="checkbox"/>			
Customer	<input type="checkbox"/>	KYLE A. REED	Kyle Reed	8/17/2020
Quality	<input type="checkbox"/>	Sanjay Nimkar	S. Nimkar	

Extension Request

Effectivity Change

Date: Revised End Date: _____

Revised Lot Specific: _____

Justification for Extension

Extension Requested by:	Signature:	Date:
Quality Approval by:	Signature:	Date:

Aphena Pharma Solutions

Master Batch Record for the Manufacturing No More Pills' Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL Acetaminophen Solution in Aphena Work Center B13	Document ID MBR679	Revision 0
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APPROVED BY:

Aphena				
Designee	Name	Title	Signature	Date
Author	Megan Kunkowski	Technical Services Specialist	/s/Megan Kunkowski/s/	8/13/20
Reviewer	Rafeh Raza	Sr. Technical Services Specialist	/s/Rafeh Raza/s/	8/13/20
Reviewer	Jerry Pappas	Blending Supervisor	/s/Jerry Pappas/s/	8/13/20
Reviewer	Katina Moaney	Sr. Project Manager	/s/Katina Moaney/s/	8/13/20
Reviewer	Amanda Jenkins	Chemistry Lab Manager	/s/Amanda Jenkins/s/	8/13/20
Reviewer	Julie Curie	Microbiology Supervisor	/s/Julie Curie/s/	8/13/20
Approver	Sanjay Nimkar	Director of QA/RA	/s/Sanjay Nimkar/s/	8/13/20
No More Pills				
Designee	Name	Title	Signature	Date
Approver	Ethan Flint	Consultant	/s/ Ethan Flint/s/	8/14/20

Work Order Number: 106705B

Aphena Pharma Solutions		
Master Batch Record for the Manufacturing No More Pills' Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL Acetaminophen Solution in Aphena Work Center B13	Document ID MBR679	Revision 0
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NOTE: Any page of this MBR may be copied as needed for additional space. If so, pages should be labeled as follows: If a printed page is copied three times, a hand written notation 1 of 3, 2 of 3, and 3 of 3 should be made under page number. The notation is to be initialed and dated.

LOT CODE ASSIGNMENT:

The Lot Code of the bulk solution is to be formatted as follows: YYDDDXZ

Where:

YY = Last 2 Digits of Year of Manufacture

DDD = Julian Date of Manufacture (defined as date of blending)

XZ = Sequential blend made on date of blending (must be expressed as two (2) digits, (i.e. 01 for first batch of No More Pills Headache Man Solution blended on a given day, 02 for the second batch of No More Pills Headache Man Solution blended on that day, etc.)

Record the date of the first day of blending below:

Date of Blending (record as MM/DD/YY): 08/17/20

Corresponding Julian Day for Date of Blending (record as DDD): 230

Based upon the Date of blending and the sequential batch number for the blend being produced on that day, the Lot Code to be used is (record as YYDDDXZ) as follows.

Lot # 2023001

Examples:

The first batch of Solution blended on January 19, 2019 would have an assigned Lot Code of 1901901 (i.e. manufactured in 2019, on Julian Date 019 which represents January 19th, and is the first Solution blend made on that day so has designator of 01)

The second batch of Solution blended on January 19, 2019 would have an assigned Lot Code of 1901902 (i.e. manufactured in 2019, on Julian Date 019 which represents January 19th, and is the second Solution blend made on that day so has designator of 02)

Jean Pappas
Blend Supervisor

8/14/20
Date

Monica Lutzi
Quality

8-14-20
Date

BULK HOLD EXPIRATION DATE ASSIGNMENT: A Bulk Hold Expiration Date has not been evaluated and established for this product.

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Aphena Pharma Solutions

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Master Batch Record for the Manufacturing No More Pills' Headache Man 3,785 kg Blend (LB-NMPPHM01) 650mg/50mL Acetaminophen Solution in Aphena Work Center B13		0 3 of 37

FORMULATION

The following table defines the formulation that will be used to manufacture 3,785 kg Blend:

Ingredient(s)	Aphena Part Number	Expiration Date	%w/w	Theoretical Amount Required in 3,785 kg Batch
Purified Water	<input type="checkbox"/> LB101PUR <input checked="" type="checkbox"/> UT2 Purified Hot Water	U\AQUA 8/17/20	74.0777 (\pm 1)	50.0 kg 10.0 kg 50.0 kg 10.0 kg
Hydroxypropyl Beta Cyclodextrin, USP	CP2647	20211202 / 20211222	12.5590 (\pm 1)	475.36 kg
Sucrose, NF	CP2533	20241123	10.2145 (\pm 1)	386.62 kg
Acetaminophen	CP2648	20230104	1.1729 (\pm 0.5)	44.39 kg
Organic Lemon Flavor	CP2649	20200903 / 20201121	1.1073 (\pm 1)	41.91 kg
Natural Bitterness Blocker	CP2650	20200903 / 20201121	0.2260 (\pm 1)	8.554 kg
Fine Citric Acid, Anhydrous USP	CP2442	20206813 / 20200218	0.5197 (\pm 1)	19.671 kg
Sodium Benzoate NF/FCC Powder	CP2462	20210322	0.1003 (\pm 1)	3.796 kg
Gellan Gum	CP2651	20210929	0.0226 (\pm 1)	0.4277 kg
		Total	100.00	3,785 kg

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Master Batch Record for the Manufacturing No More Pills[®]
Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL
Acetaminophen Solution in Aphena Work Center B13

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Component Issuance and Reconciliation

Verify/document receipt, and return after use, of the following components needed for manufacture of the batch to be produced under this MBR:

Material Name	Aphena PN	Manufacturers Lot #	QTY in	UM	Initials / Date	Verified By / Date	Blend Usage	Expected Return (E)*	Actual Return (A)	Differ (E-A)	Performed By Initials / Date	Verified By Initials / Date
Hydroxypropyl Beta Cyclodextrin, USP	CP2647	H4201911223	10.0	Kg	LL 8-17-20	GP 8-17-20	10.0	0	0	LL 8-17-20	GP 8-17-20	
Sucrose, NF	CP2533	140817 49476	933.11	Kg	LL 8-17-20	GP 8-17-20	386.62	546.49	546.00	.49	LL 8-17-20	GP 8-17-20
Acetaminophen	CP2648	140430 288159	77.4	Kg	LL 8-17-20	GP 8-17-20	44.39	33.01	33.01	0	LL 8-17-20	GP 8-17-20
Organic Lemon Flavor	CP2649	140789 288155	2.69	Kg	LL 8-17-20	GP 8-17-20	2.50	1.9	0	.19	LL 8-17-20	GP 8-17-20
Natural Bitterness Blocker	CP2650	140290 AF19H181CF	2.42	Kg	LL 8-17-20	GP 8-17-20	8.82.0	.42	0	.42	LL 8-17-20	GP 8-17-20
Fine Citric Acid, Anhydrous USP	CP2442	140263 K458098218	43.73	lb	LL 8-17-20	19.671	27.059	27.000	.059	8-17-20	GP 8-17-20	
Sodium Benzoate NF/FCC Powder	CP2462	141010 9543424	23.0	Kg	8-17-20	GP 8-17-20	3.796	19.204	19.500	.296	LL 8-17-20	GP 8-17-20
Gellan Gum	CP2651	141051	24.685	Kg	8-17-20	GP 8-17-20	0.85514	23.8296	23.8296	0	8-17-20	GP 8-17-20

*Note: Qty In – Blend Usage = Expected Return
 Operations/Blending Supervisor must provide a completed copy of this page to the Inventory Control Manager.

Work Order Number: W07105B

Aphena Pharma Solutions

Master Batch Record for the Manufacturing No More Pills® Headache Man 3.785 kg Blend (LB-NMPHM01) 650mg/50ml

ANNUAL

2005
LL 8-17-20

Verify/document receipt, and return after use, of the following components needed for manufacture of the batch to be produced under this MBRR

Component Issuance and Reconciliation

*Note: Qty. In - Blend Usage = Expected Return
Operations/Blending Supervisor must provide

Work Order Number: 106705B

Aphena Pharma Solutions

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Master Batch Record for the Manufacturing No More Pills[®]
Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL
Acetaminophen Solution in Aphena Work Center B13

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Material Name	Aphena P/N	Manufacturers Lot #	Received ID #	QTY in	U/M	Initials / Date	Verified By / Date	Blend Usage	Expected Return (E)*	Actual Return (A)	Differ. (E-A)	Initials/ Date	Verified By/Date
Tote	CP6063R			4	LR	RL 8-18-20	ES 8-18-20	4	0	0	0	ES 8-18-20	GP 8-18-20
Irradiated Tote Liner	CR6097	141718		6	LR	RL 8-18-20	ES 8-18-20	4	2	2	0	ES 8-18-20	GP 8-18-20
Tote Label	CP9223/1			4	LR	RL 8-18-20	ES 8-18-20	4	0	0	0	ES 8-18-20	GP 8-18-20

*Note: Qty. In – Blend Usage = Expected Return
 Operations/Blending Supervisor must provide a completed copy of this page to the Inventory Control Manager.

Work Order Number: 1042105B

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PHARMACY PRE-WEIGHING PROCESS

All materials are to be weighed by a qualified blender and the weights Verified by a second operator/qualified person.

SAFETY PROCEDURES

- For all chemicals being pre-weighed, handle and wear appropriate PPE as required by Safety Data Sheets (SDS).

- Handle all raw materials carefully; avoid any direct contact with vapors, dust, liquids, and solids.

PRE-WEIGH AREA PREPARATION

- Pre-weigh area, including Vent Hood, has been cleaned according to Cleaning Procedure; document in the appropriate cleaning and usage log(s). Please note below what the last product pre-weighed in the area was prior to weighing materials for this batch.

Same Product – Batch Change or Product Change

Previous product pre-weighed L3-J41552 Aphena Batch # 2022601

- Area is clear of all previous raw materials, products, containers, and documents
 - Verify all raw materials to be used are released and containers are properly labeled and have QA Release label.
 - All raw material containers are cleaned (i.e. wiped off with 70% Isopropyl Alcohol (LB181) and allowed to air dry) before entering pre-weigh area and being opened for dispensing.
- NOTE: After cleaning raw material containers, before opening and pre-weighing, operators must put on a new, clean, disposable lab coat and gloves.
- Verify all utensils to be used for weigh-out have been cleaned and sanitized with 70% Isopropyl Alcohol (LB181) and allowed to air dry prior to use in Non-XP Blending Washroom per WI3B001 and recorded in Activity Log F1891.
 - Verify proper set-up of all scales, confirm are within calibration date requirements, and perform/confirm that daily weight check has been done.
 - Prior to pre-weighing specified raw materials, verify proper operation of the appropriate air handling/ventilation system(s) that will be used based on the size of the bulk raw material container and the quantity of materials being pre-weighed in the Pharmacy.

LL 8-17-20

GP 8-17-20

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Master Batch Record for the Manufacturing No More Pills' Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL Acetaminophen Solution in Aphena Work Center B13

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L4 8-17-20

PHARMACY PRE-WEIGH OF INGREDIENTS

NOTE: Prior to pre-weighing, persons performing the weighing should put on a new, clean, disposable lab coat, appropriate gloves, and any other required personal protective equipment.

Components will be weighed into clean containers which are of suitable size and material of construction to ensure compatibility. Containers must be identified, at minimum, with material name, part number, lot number and weight and be initialed and dated.

Ingredient	Quantity Required	Quantity Weighed		Weighed by/ Date	Verified by/ Date
Acetaminophen (CP2648) RID: <u>140430</u> Scale ID used: <u>3028</u> Cal Due Date: <u>02/21</u>	Total <u>31,500</u> kg				
	Gross: <u>11,650</u> kg	Gross: <u>18,222</u> kg	Gross: <u>11,720</u> kg		
	Tare: <u>2,1650</u> kg	Tare: <u>4,722</u> kg	Tare: <u>2,720</u> kg		
	Net: <u>9,000</u> kg	Net: <u>13,500</u> kg	Net: <u>9,000</u> kg	Gp 8-17-20	L-L 8-17-20
Organic Lemon Flavor (CP2649) RID: <u>140189/141815</u> Scale ID used: <u>3028</u> Cal Due Date: <u>02/21</u>	Total <u>36.000</u> kg				
	Gross: <u>14,714</u> kg	Gross: <u>14,718</u> kg	Gross: <u>14,664</u> kg		
	Tare: <u>2,714</u> kg	Tare: <u>2,718</u> kg	Tare: <u>2,664</u> kg	Gp 8-17-20	L-L 8-17-20
	Net: <u>12.000</u> kg	Net: <u>12.000</u> kg	Net: <u>12.000</u> kg		

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Master Batch Record for the Manufacturing No More Pills'
 Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL
 Acetaminophen Solution in Aphena Work Center B13

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PQ 2082
LL 8-17-20

PHARMACY PRE-WEIGH OF INGREDIENTS

NOTE: Prior to pre-weighing, persons performing the weighing should put on a new, clean, disposable lab coat, appropriate gloves, and any other required personal protective equipment.

Components will be weighed into clean containers which are of suitable size and material of construction to ensure compatibility. Containers must be identified, at minimum, with material name, part number, lot number and weight and be initialed and dated.

Ingredient	Quantity Required	Quantity Weighed			Weighed by/Date	Verified by/ Date
Acetaminophen (CP2648)		Total	12.890	kg		
RID: <u>140430</u>	Target Net Wt.: 44.39 kg	Gross: <u>11.714 kg</u>	Gross: <u>10.844 kg</u>	Gross: <u>10.844 kg</u>		
Scale ID used: <u>3028</u>	Range: 44.17 – 44.62 kg	Tare: <u>2.716 kg</u>	Tare: <u>2.954 kg</u>	Tare: <u>2.954 kg</u>		
Cal Due Date: <u>02/21</u>		Net: <u>9.000 kg</u>	Net: <u>3.890 kg</u>	Net: <u>8-17-20</u>	GP 8-17-20	<u>LL 8-17-20</u>
Organic Lemon Flavor (CP2649)		Total	5.91	kg		
RID: <u>140789/41875</u>	Target Net Wt.: 41.91 kg	Gross: <u>8.81 kg</u>	Gross: <u>8.1720</u>	Gross: <u>8.1720</u>		
Scale ID used: <u>3028</u>	Range: 41.49 – 42.33 kg	Tare: <u>2.90 kg</u>	Tare: <u>4</u>	Tare: <u>4</u>		
Cal Due Date: <u>02/21</u>		Net: <u>5.91 kg</u>	Net: <u>4</u>	Net: <u>5.91 kg</u>	GP 8-17-20	<u>LL 8-17-20</u>

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Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL
Acetaminophen Solution in Aphena Work Center B13

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Ingredient	Quantity Required	Quantity Weighed		Weighed by/ Date	Verified by/ Date
Natural Bitterness Blocker (CP2650)	RID: <u>140790</u> Scale ID used: <u>3028</u> Cal Due Date: <u>02/21</u>	Total <u>8.554</u> kg			
	Target Net Wt.: 8.554 kg Range: 8.469 – 8.640 kg	Gross: <u>11.460 kg</u>	Gross:	Gross:	
	Tare: <u>2.906 kg</u>	Tare:	Tare:	Tare:	
	Net: <u>8.554 kg</u>	Net: <u>NA</u>	Net: <u>8-17-20</u>	GP 8-17-20	LL 8-17-20
Fine Citric Acid, Anhydrous USP (CP2442)	RID: <u>140763</u> Scale ID used: <u>3028</u> Cal Due Date: <u>02/21</u>	Total <u>19.671</u> kg			
	Target Net Wt.: 19.671 kg Range: 19.474 – 19.867 kg	Gross: <u>13.018 kg</u>	Gross: <u>12.864 kg</u>	Gross:	
	Tare: <u>3.183 kg</u>	Tare: <u>3.028 kg</u>	Tare: <u>NA</u>	Tare:	
	Net: <u>9.835 kg</u>	Net: <u>8.1720</u>	Net: <u>8-17-20</u>	GP 8-17-20	LL 8-17-20

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Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL
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Ingredient	Quantity Required	Quantity Weighed		Weighted by/Date	Verified by/ Date
Sodium Benzoate NF/FCC Powder (CP2462)	Total <u>3.796</u> kg				
RID: <u>141016</u>	Target Net Wt.: 3.796 kg	Gross: <u>6.743 kg</u>	Gross: <u>4</u>	Gross: <u>4</u>	
Scale ID used: <u>3028</u>	Range: 3.758 – 3.834 kg	Tare: <u>2.947 kg</u>	Tare: <u>4</u>	Tare: <u>4</u>	
Cal Due Date: <u>02/21</u>		Net: <u>3.796 kg</u>	Net: <u>4</u>	Net: <u>4</u>	Net: <u>4</u>
Gellan (Lo Acly) (CP2651)	Total <u>427.7</u> kg				
RID: <u>141051</u>	Target Net Wt.: 0.4277 kg	Gross: <u>844.4</u> g	Gross: <u>4</u>	Gross: <u>4</u>	
Scale ID used: <u>2552</u>	Range: 0.4234 – 0.4320 kg	Tare: <u>416.7</u> g	Tare: <u>4</u>	Tare: <u>4</u>	
Cal Due Date: <u>02/21</u>		Net: <u>427.7</u> g	Net: <u>4</u>	Net: <u>4</u>	Net: <u>4</u>
Gellan (Lo Acly) (CP2651)	Total <u>427.7</u> kg				
RID: <u>141051</u>	Target Net Wt.: 0.4277 kg	Gross: <u>844.7</u> g	Gross: <u>4</u>	Gross: <u>4</u>	
Scale ID used: <u>2552</u>	Range: 0.4234 – 0.4320 kg	Tare: <u>416.7</u> g	Tare: <u>4</u>	Tare: <u>4</u>	
Cal Due Date: <u>02/21</u>		Net: <u>427.7</u> g	Net: <u>4</u>	Net: <u>4</u>	Net: <u>4</u>
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Master Batch Record for the Manufacturing No More Pills,
Headache Man 3.785 kg Blend (LB-NMPHM01) 650mg/50mL
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Ingredient	Quantity Required	Quantity Weighed			Weighed by/ Date	Verified by/ Date
Purified Water for Side Phase	Target Net Wt.: 50.00 kg	Total	50.00	kg		
RID: <u>1/4 8-17-20 net</u>	Gross: <u>59.0</u> kg	Gross:		kg		
Scale ID used: <u>2401</u>	Tare: <u>9.0</u> kg	Tare:		kg		
Cal Due Date: <u>02/21</u>	Net: <u>50.0</u> kg	Net:	<u>8.17.20</u>	kg	<u>ES</u> <u>8-17-20</u>	
	Total	10.00		kg		
Purified Water for Rinsing	Target Net Wt.: 10.00 kg	Gross:		kg		
RID: <u>1/4 8-17-20 net</u>	Gross: <u>12.00</u> kg	Gross:		kg		
Scale ID used: <u>2401</u>	Tare: <u>2.00</u> kg	Tare:		kg		
Cal Due Date: <u>02/21</u>	Net: <u>10.00</u> kg	Net:	<u>8.17.20</u>	kg	<u>ES</u> <u>8-17-20</u>	

Work Order Number: 1046105B

Aphena Pharma Solutions

Master Batch Record for the Manufacturing No More Pills?
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Ingredient	Quantity Required	Quantity Weighed		Weighed by Date	Verified by/ Date
Purified Water for Side Phase	Total <u>50.00</u> kg				
RID: <u>4/4 8/17-20</u>	Target Net Wt.: 50.00 kg	Gross: <u>59.00</u> kg	Gross:	Gross:	
Scale ID used: <u>2601</u>	Range: 49.50 – 50.50 kg	Tare: <u>9.00</u> kg	Tare: <u>1.00</u>	Tare: <u>1.00</u>	
Cal Due Date: <u>02/21</u>		Net: <u>50.00</u> kg	Net: <u>8.17-20</u>	Net: <u>8.17-20</u>	ES <u>8/17-20</u>
	Total <u>10.00</u> kg				
Purified Water for Rinsing	Target Net Wt.: 10.00 kg	Gross: <u>12.00</u> kg	Gross:	Gross:	
RID: <u>4/4 8/17-20</u>	Range: 9.90 – 10.10 kg	Tare: <u>2.00</u> kg	Tare: <u>1.00</u>	Tare: <u>1.00</u>	
Scale ID used: <u>2601</u>		Net: <u>10.00</u> kg	Net: <u>8.17-20</u>	Net: <u>8.17-20</u>	ES <u>8/17-20</u>
Cal Due Date: <u>02/21</u>					

Work Order Number: 1020705B

Aphena Pharma Solutions

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PELU 8-17-20
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L4 8-17-20

Master Batch Record for the Manufacturing No More Pills'
Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL
Acetaminophen Solution in Aphena Work Center B13

Ingredient	Quantity Required	Quantity Weighed		Weighed by/ Date	Verified by/ Date
Sucrose, NF (CP2533)		Total	<u>3866.62</u> kg		
RID: <u>140817</u>	Target Net Wt.: 386.62 kg	Gross:			
Scale ID used: <u>2973</u>	Range: 382.75 – 390.49 kg	<u>201.81</u> kg	<u>201.71</u> kg	Gross:	
Cal Due Date: <u>02/21</u>	Tare:	<u>8.50</u> kg	Tare: <u>8.40</u> kg	Tare: <u>LL</u> Net: <u>8-17-20</u>	Gp 8-17-20
	Net:	<u>193.31</u> kg	Net: <u>193.31</u> kg	Net: <u>8-17-20</u>	<u>LL</u> 8-17-20
		Total	<u>209.2</u> kg	Gp 8-17-20	<u>LL</u> 8-17-20
Hydroxypropyl Beta Cyclodextrin, USP (CP2647)	Target Net Wt.: 475.36 kg	Gross:			
RID: <u>1408171541</u>	Range: 470.60 – 480.11 kg	<u>77.50</u> kg	<u>77.90</u> kg	Gross: Gp 8-17-20	<u>LL</u> 8-17-20
Scale ID used: <u>2973</u>	Tare:	<u>8.10</u> kg	Tare: <u>8.00</u> kg	Tare: <u>8-17-20</u>	<u>LL</u> 8-17-20
Cal Due Date: <u>02/21</u>	Net:	<u>69.4</u> kg	Net: <u>69.80</u> kg	Net: <u>70.00</u> kg	<u>LL</u> 8-17-20

Work Order Number: 104705B

Aphena Pharma Solutions

Master Batch Record for the Manufacturing No More Pills?
Headache Man 3,785 kg Blend (LB-NMPPHM01) 650mg/50mL
Acetaminophen Solution in Aphena Work Center B13

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PG 2020-10
LU 8-17-20

Ingredient	Quantity Required	Quantity Weighed		Weighed by/ Date	Verified by/ Date
Sucrose, NF (CP2533)		Total	kg		
RID:	Target Net Wt.: 386.62 kg Range: 382.75 – 390.49 kg	Gross: <i>H</i>	Gross:	Gross:	
Scale ID used:		Tare:	Tare:	Tare:	
Cal Due Date:		Net:	Net:	Net:	
		Total	50.05 kg	GP 8-17-20	L 8-17-20
Hydroxypropyl Beta Cyclodextrin, USP (CP2647)	Target Net Wt.: 475.36 kg Range: 470.60 – 480.11 kg	Gross: <i>38.10 kg</i>	Gross: <i>10.10 kg</i>	GP 8-17-20	L 8-17-20
RID: <i>144541</i>		Gross: <i>10.15 kg</i>	Gross: <i>8-17-20</i>	GP 8-17-20	L 8-17-20
Scale ID used: <i>2973</i>		Tare: <i>0.10 kg</i>	Tare: <i>0.10 kg</i>	GP 8-17-20	L 8-17-20
Cal Due Date: <i>02/21</i>		Net: <i>30.00 kg</i>	Net: <i>10.00 kg</i>	GP 8-17-20	L 8-17-20

Work Order Number: 106705B

Aphena Pharma Solutions

Master Batch Record for the Manufacturing No More Pills'
Headache Man 3.785 kg Blend (LB-NMPHM01) 650mg/50mL
Acetaminophen Solution in Aphena Work Center B13

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EEL 8-17-20
LL 8-17-20

Ingredient	Quantity Required	Quantity Weighed			Weighed by/ Date	Verified by/ Date
Sucrose, NF (CP2533)		Total		kg		
RID:	Target Net Wt.: 386.62 kg	Gross:	Gross:		Gross:	
Scale ID used:	Range: 382.75 – 390.49 kg	Tare:	Tare:		Tare:	
Cal Due Date:		Net:	Net:		Net:	
Hydroxypropyl Beta Cyclodextrin, USP (CP2647)	Total <u>30.10</u> kg		GP	<u>8-17-20</u>	<u>8-17-20</u>	
RID: <u>141541</u>	Target Net Wt.: 475.36 kg	Gross: <u>10.12</u> kg	Gross: <u>10.14</u> kg	Gross: <u>10.14</u> kg	GP <u>8-17-20</u>	<u>8-17-20</u>
Scale ID used: <u>2973</u>	Range: 470.60 – 480.11 kg	Tare: <u>0.10</u> kg	Tare: <u>0.10</u> kg	Tare: <u>0.10</u> kg	GP <u>8-17-20</u>	<u>8-17-20</u>
Cal Due Date: <u>02/21</u>	Net: <u>10.02</u> kg	Net: <u>10.04</u> kg	Net: <u>10.04</u> kg	Net: <u>10.04</u> kg	GP <u>8-17-20</u>	<u>8-17-20</u>

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Master Batch Record for the Manufacturing No More Pills'
Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50ml
Acetaminophen Solution in Aphena Work Center B13

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LL 8-17-20

Ingredient	Quantity Required	Quantity Weighed		Weighed by/ Date	Verified by/ Date
Sucrose, NF (CP2533)	Total _____ kg				
Target Net Wt.: 386.62 kg	Gross:	Gross:	Gross:		
Range: 382.75 – 390.49 kg	<i>N</i>	Tare:	Tare:		
Scale ID used: _____	Rate: <i>f</i>	Net:	Net:	<i>GP</i> 8-17-20	<i>LL</i> 8-17-20
Cal Due Date: _____					
Hydroxypropyl Beta Cyclodextrin, USP (CP2647)	Total <u>30.12</u> kg				
Target Net Wt.: 475.36 kg	Gross: <u>10.13</u> kg	Gross: <u>10.14</u> kg	Gross: <u>10.15</u> kg	<i>GP</i> 8-17-20	<i>LL</i> 8-17-20
Range: 470.60 – 480.11 kg	Tare: <u>0.10</u> kg	Tare: <u>0.10</u> kg	Tare: <u>0.10</u> kg	<i>GP</i> 8-17-20	<i>LL</i> 8-17-20
Scale ID used: <u>2923</u>	Net: <u>10.03</u> kg	Net: <u>10.04</u> kg	Net: <u>10.05</u> kg	<i>GP</i> 8-17-20	<i>LL</i> 8-17-20
Cal Due Date: <u>02/21</u>					

Work Order Number: 106705B

Aphena Pharma Solutions

Master Batch Record for the Manufacturing No More Pills?
Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL
Acetaminophen Solution in Aphena Work Center B13

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Ingredient	Quantity Required	Quantity Weighed		Weighed by/ Date	Verified by/ Date
Sucrose, NF (CP2533)		Total	kg		
RID:	Range: 382.75 – 390.49 kg	Gross: <i>14</i>	Gross: <i>14</i>	Gross:	
Scale ID used:		Tare:	Tare:	Tare:	
Cal Due Date:		Net:	Net:	Net:	
		Total 30.05	kg	<i>GP</i> 8-17-20	<i>L</i> 8-17-20
Hydroxypropyl Beta Cyclodextrin, USP (CP2647)	Target Net Wt.: 475.36 kg Range: 470.60 – 480.11 kg	Gross: <i>10.12</i> kg	Gross: <i>10.13</i> kg	Gross: <i>10.10</i> kg	<i>GP</i> 8-17-20
RID: /41541					<i>L</i> 8-17-20
Scale ID used: 2973		Tare: <i>0.10</i> kg	Tare: <i>0.10</i> kg	Tare: <i>1.10</i> kg	<i>GP</i> 8-17-20
Cal Due Date: 02/21		Net: <i>10.02</i> kg	Net: <i>10.03</i> kg	Net: <i>10.00</i> kg	<i>L</i> 8-17-20

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Master Batch Record for the Manufacturing No More Pills' Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL Acetaminophen Solution in Aphena Work Center B13

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Ingredient	Quantity Required	Quantity Weighed		Weighed by/ Date	Verified by/ Date
Sucrose, NF (CP2533) RID: _____	Target Net Wt.: 386.62 kg Range: 382.75 – 390.49 kg Scale ID used: _____ Cal Due Date: _____	Total Gross: Tare: Net:	Gross: Tare: Tare: Net:	Gross: Tare: Tare: Net:	LL 8-17-20 LL 8-17-20 LL 8-17-20
Hydroxypropyl Beta Cyclodextrin, USP (CP2647)	Target Net Wt.: 475.36 kg Range: 470.60 – 480.11 kg Scale ID used: <u>2973</u> Cal Due Date: <u>2/21</u>	Total <u>30.10</u> kg Gross: <u>10.13</u> kg Tare: <u>0.10</u> kg Net: <u>10.03</u> kg	Gross: <u>10.14</u> kg Tare: <u>0.10</u> kg Net: <u>10.04</u> kg	Gross: <u>10.13</u> kg Tare: <u>0.10</u> kg Net: <u>10.03</u> kg	GP 8-17-20 GP 8-17-20 GP 8-17-20

Work Order Number: 1002053

Aphena Pharma Solutions

Master Batch Record for the Manufacturing No More Pills,
Headache Man 3,785 kg Blend (LB-NMPPHM01) 650mg/50mL
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Ingredient	Quantity Required		Quantity Weighed		Weighed by/ Date	Verified by/ Date
Sucrose, NF (CP2533)			Total	kg		
RID: _____	Target Net Wt.: 386.62 kg Range: 382.75 – 390.49 kg	Gross: <i>✓</i>	Gross:	Gross:		
Scale ID used: _____	Tare: <i>A</i>	Tare:	Tare:	Tare:	<i>LL</i>	<i>LL</i>
Cal Due Date: _____	Net:	Net:	Net:	Net:	<i>8-17-20</i>	<i>8-17-20</i>
Hydroxypropyl Beta Cyclodextrin, USP (CP2647)	Total <i>29.79</i>	kg	Gross <i>8-17-20</i>	L <i>8-17-20</i>		
RID: <i>141541</i>	Target Net Wt.: 475.36 kg Range: 470.60 – 480.11 kg	Gross: <i>9.80 Kg</i>	Gross: <i>10.14 Kg</i>	Gross: <i>10.15 Kg</i>	Gross <i>8-17-20</i>	L <i>8-17-20</i>
Scale ID used: <i>2973</i>	Tare: <i>0.10 Kg</i>	Tare: <i>0.10 Kg</i>	Tare: <i>0.10 Kg</i>	Gross <i>8-17-20</i>	L <i>8-17-20</i>	<i>LL</i>
Cal Due Date: <i>02/21</i>	Net: <i>9.70 Kg</i>	Net: <i>10.04 Kg</i>	Net: <i>10.05 Kg</i>	Gross <i>8-17-20</i>	L <i>8-17-20</i>	<i>LL</i>

P9 Tef 10
CL 8-17-20

Work Order Number: *106205B*

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Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL
Acetaminophen Solution in Aphena Work Center B13

Ingredient	Quantity Required	Quantity Weighed		Weighed by/ Date	Verified by/ Date
		Total _____ kg			
Sucrose, NF (CP2533)	Target Net Wt.: 386.62 kg Range: 382.75 – 390.49 kg	Gross: 11	Gross: 11	Gross: 11	L 8-17-20
RID: _____		Tare: 11	Tare: 11	Tare: 11	L 8-17-20
Scale ID used: _____		Net: 11	Net: 11	Net: 11	L 8-17-20
Cal Due Date: _____		Total <u>30.11</u>		GP 8-17-20	<u>L</u> <u>8-17-20</u>
Hydroxypropyl Beta Cyclodextrin, USP (CP2647)	Target Net Wt.: 475.36 kg Range: 470.60 – 480.11 kg	Gross: <u>10.14</u> kg	Gross: <u>10.14</u> kg	Gross: <u>10.13</u> kg	GP 8-17-20
RID: <u>/H/541</u>		Tare: <u>0.10</u> kg	Tare: <u>0.10</u> kg	Tare: <u>0.10</u> kg	GP 8-17-20
Scale ID used: <u>2973</u>		Net: <u>10.04</u> kg	Net: <u>10.04</u> kg	Net: <u>10.03</u> kg	GP 8-17-20
Cal Due Date: <u>02/21</u>					<u>8-17-20</u>

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 Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL
 Acetaminophen Solution in Aphena Work Center B13

Ingredient	Quantity Required	Quantity Weighed			Weighed by/ Date	Verified by/ Date
Sucrose, NF (CP2533)	Total _____ kg					
RID: _____	Target Net Wt.: 386.62 kg Range: 382.75 – 390.49 kg	Gross: <i>10.12</i>	Gross: <i>10.12</i>	Gross: <i>10.12</i>	<i>GP 8-17-20</i>	<i>LL 8-17-20</i>
Scale ID used: _____	Tare: <i>0.10 kg</i>	Tare: <i>0.10 kg</i>	Tare: <i>0.10 kg</i>	Tare: <i>0.10 kg</i>	<i>GP 8-17-20</i>	<i>LL 8-17-20</i>
Cal Due Date: _____	Net: <i>10.02 kg</i>	Net: <i>10.02 kg</i>	Net: <i>10.02 kg</i>	Net: <i>10.02 kg</i>	<i>GP 8-17-20</i>	<i>LL 8-17-20</i>
Hydroxypropyl Beta Cyclodextrin, USP (CP2647)	Total <u>30.67</u> kg					
RID: <u>141541</u>	Target Net Wt.: 475.36 kg Range: 470.60 – 480.11 kg	Gross: <i>10.12 kg</i>	Gross: <i>10.12 kg</i>	Gross: <i>10.12 kg</i>	<i>GP 8-17-20</i>	<i>LL 8-17-20</i>
Scale ID used: <u>2973</u>	Tare: <i>0.10 kg</i>	Tare: <i>0.10 kg</i>	Tare: <i>0.10 kg</i>	Tare: <i>0.10 kg</i>	<i>GP 8-17-20</i>	<i>LL 8-17-20</i>
Cal Due Date: <u>02/21</u>	Net: <i>10.02 kg</i>	Net: <i>10.02 kg</i>	Net: <i>10.02 kg</i>	Net: <i>10.02 kg</i>	<i>GP 8-17-20</i>	<i>LL 8-17-20</i>

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Master Batch Record for the Manufacturing No More Pills,
Headache Man 3,785 kg Blend (LB-NMPPHM01) 650mg/50mL
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Ingredient	Quantity Required	Quantity Weighed		Weighed by/ Date	Verified by/ Date
Sucrose, NF (CP2553)		Total	kg		
Range:	382.75 – 390.49 kg	Gross:	Gross:		
RID:		Tare:	Tare:		
Scale ID used:		Net:	Net:		
Cal Due Date:					
Hydroxypropyl Beta Cyclodextrin, USP (CP2647)		Total	5.82	GP 8-17-20	LL 8-17-20
Range:	470.60 – 480.11 kg	Gross:	Gross:	GP 8-17-20	LL 8-17-20
RID:	141541	Tare:	Tare:	GP 8-17-20	LL 8-17-20
Scale ID used:	2973	Net:	Net:	GP 8-17-20	LL 8-17-20
Cal Due Date:	02/21	Net:	5.82 kg	Net:	Net:

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10 0410
L2 8-17-20

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PRE PRODUCTION LINE CLEARANCE

The following information must be verified prior to execution 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 work order. Line clearance is to be checked by the supervisor and verified by quality.

	Verification Required	Performed by / Date	Verified by / Date
There are no components, raw materials, labels, and blending paperwork from the work center.	Visual Inspection	JDS 8/17/20	SG 8/17/20
All previous finished blends have been removed from the work center.	Visual Inspection	JDS 8/17/20	SG 8/17/20

Work Order Number: 102105B

Aphena Pharma Solutions

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PRE-PRODUCTION BLENDING EQUIPMENT AND AREA VERIFICATION**SAFETY PROCEDURES**

1. When dispensing/charging chemicals into Tank B13, handle and wear appropriate PPE as required by Safety Data Sheets (SDS).
2. Handle all raw materials carefully; avoid any direct contact with vapors, dust, liquids, and solids.

BLENDING AREA PREPARATION

3. Operators have Verified and thoroughly understand batch procedures.
4. Line Clearance has been completed from previous blending or cleaning process.

5. If manufacturing a single blend, or if blend is the first blend of a campaign, verify that all equipment to be used in the manufacture of the blend (i.e. Tank B13, pumps, piping and hoses, valves, etc.) has been cleaned and sanitized in accordance with the approved procedure: E2420 and that all cleaning requirements have been met based on the Final rinse samples meeting the requirements defined in the procedure.

Prior to manufacturing the blend, obtain a copy of the cleaning results to include with the executed copy of the MBR.

NOTE: Bioburden results will not be completed and are not required prior to manufacture of the blend.

Please note below what was blended in the tank(s) just prior to manufacturing this batch.

Same Product – Batch Change or Product Change

Previous product blended LB-N3VB502 Aphena Batch #Q322420-01

6. Verify that all equipment and utensils (single use/disposable) to be used are clean, dry and properly identified per W13B001 and recorded in Activity Log F1891.
7. Complete all equipment use logs for all equipment being used (i.e. tank use log)
8. Verify in the Deviation Log if there are any open Deviations for Process or Product, and if applicable, attach a copy.
9. Verify all raw material containers containing blend ingredients are properly labeled with material name, raw material lot #, quantity, and blend lot # to be used in.

Performed by/Date:
(Initial/Date)
ES 8-17-20

Reviewed by/Date:
(Initial/Date)
ES 8-17-20

Performed by/Date:
(Initial/Date)
ES 8-17-20

Reviewed by/Date:
(Initial/Date)
ES 8-17-20

Performed by/Date:
(Initial/Date)
ES 8-17-20

Reviewed by/Date:
(Initial/Date)
ES 8-17-20

Performed by/Date:
(Initial/Date)
ES 8-17-20

Reviewed by/Date:
(Initial/Date)
ES 8-17-20

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PRE-PRODUCTION BLENDING EQUIPMENT AND AREA VERIFICATION (CONTINUED)

10. All raw material pre-weigh containers are cleaned (i.e. wiped off with 70% IPA) before being opened and dispensed.
11. Record the equipment ID for Recirculation pump: 354357-04
12. Record the equipment ID for Discharge pump: 394362-05
13. Side Phase Container(s): N52489

PLC 8-17-20 ES 8-17-20
MC 8-17-20 ES 8-17-20
MC 8-17-20 ES 8-17-20
PLC 8-17-20 ES 8-17-20

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Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL
Acetaminophen Solution in Aphena Work Center B13

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BLEND MANUFACTURING

For all raw materials being dispensed/charged into the blend, refer to each material's SDS or consult Aphena HS&E coordinator or the Blending Supervisor for any special handling requirements.

Step	Parameters Formulation	Component Amounts / Mixing Times		Performed By / Date	Verified By / Date
		Target/Range	Recorded/Actual		
1.	B13 Ensure Tank B13 is clean and empty prior to blending. Verify that tank discharge valve is closed.			ES 8-17-20	ES 8-17-20
2.	Zero out the tank.			ME 8-17-20	ES 8-17-20
3.	Add Purified Water to tank B13.	Target: 2683.8 kg (Range: 2657.0 – 2710.7 kg)	Initial Tank Gross: <u>2685.6</u> kg Final Tank Gross: <u>2685.6</u> kg Net Wt.: <u>2685.6</u> kg	ME 8-17-20	ES 8-17-20
4.	Set temperature of tank to 66°C ± 3°C.			ME 8-17-20	ES 8-17-20
5.	If Purified Water from a tote was used, disconnect infeed hose from tote and reverse infeed pump to drain any residual water from the infeed hose/piping. If using Purified Water dispensed directly into the Tank from the RO Water System, mark this step as "N/A" and move to Step 11.			ME 8-17-20	ES 8-17-20
6.	SIDE PHASE #1 Ensure stainless steel container is clean and sanitized prior to blending.			ME 8-17-20	ES 8-17-20

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Master Batch Record for the Manufacturing No More Pills²
Headache Man 3.785 kg Blend (LB-NMPHM01) 650mg/50mL
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Step	Parameters Formulation	Component Amounts / Mixing Times		Performed By / Date	Verified By / Date
		Target/Range	Recorded/Actual		
7.	Record tare weight of the container.		Tare wt: <u>9.0</u> kg	<u>ME</u> 8-17-20	<u>ES</u> 8-17-20
8.	Add 50.0 kg of purified water into stainless steel container.			<u>ME</u> 8-17-20	<u>DBW</u> 8-17-20
9.	Heat water to a minimum of 85°C.	Temperature: Minimum of <u>85</u> °C		<u>ME</u> 8-17-20	<u>DBW</u> 8-17-20
10.	Add Gelian Gum (CP2651) to container.	Target: 0.4277 kg (Range: 0.4234 – 0.4320 kg)		<u>ME</u> 8-17-20	<u>DBW</u> 8-17-20
11.	Mix overhead until dissolved.	Propeller speed: Record speed Mix Time: minimum of 10 minutes Total Mix Time: <u>20</u> minutes	<u>1759</u> RPM Mix Start Time: <u>5:40</u> am/ <u>pm</u> Mix Stop Time: <u>6:00</u> am/ <u>pm</u>		
12.	TRANSFER TO MAIN PHASE- B13	Target: 66°C ± 3°C.	<u>64</u> °C	<u>ME</u> 8-17-20	<u>DBW</u> 8-17-20
13.	Open the Tank B13 Recirculation/Discharge valve on the bottom of the tank, so that the product in the tank will be directed to the recirculation line.			<u>ME</u> 8-17-20	<u>DBW</u> 8-17-20

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Step	Parameters Formulation		Component Amounts / Mixing Times		Performed By / Date	Verified By / Date
	Target/RANGE	Recorded/Actual				
14.	Turn Side Sweep Agitator, T-bar Mixer, and recirculation loop “ON”				JKL 8-17-20	JRW 8-17-20
15.	White agitating, add Side Phase #1 mixture into B13.					
16.	Rinse side phase container into B13 using pre-weighed 10.0 kg of purified water.	Target: 10.0 kg (Range: 9.9 kg – 10.1 kg)	Initial Tank Gross 2734.42 kg Final Tank Gross 2734.42 kg Net Wt.: 10.0 kg	JKL 8-17-20	JRW 8-17-20	JRW 8-17-20
SIDE PHASE #2			JKL 8-17-20	JRW 8-17-20		
17.	Ensure stainless steel container is clean and sanitized prior to blending.					
18.	Record tare weight of the container.	Tare wt: 90 kg	JKL 8-17-20	JRW 8-17-20		
19.	Add 50.0 kg of purified water into stainless steel container.		JKL 8-17-20	JRW 8-17-20		
20.	Heat water to a minimum of 85°C.	Temperature: Minimum of 85°C	JKL 8-17-20	JRW 8-17-20		

Work Order Number: 100705B

Aphena Pharma Solutions

Master Batch Record for the Manufacturing No More Pills™
Headache Man 3.785 kg Blend (LB-NMPHM01) 650mg/50mL
Acetaminophen Solution in Aphena Work Center B13

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Step	Parameters Formulation	Component Amounts / Mixing Times		Performed By / Date	Verified By / Date
		Target/Range	Recorded/Actual		
21.	Add Gellan Gum (CP2651) to container.	Target: 0.4277 kg (Range: 0.4234 – 0.4320 kg)		ML 8/17/20	QJL 8/17/20
22.	Mix overhead until dissolved. Propeller speed: Record speed Mix Time: minimum of 10 minutes		1759 RPM Mix Start Time: 8:05 am/pm Mix Stop Time: 8:33 am/pm Total Mix Time: 28 minutes		
23.	<u>B13</u> Turn Side Sweep Agitator, T-bar Mixer, and recirculation loop "ON"		ML 8/17/20	QJL 8/17/20	

Work Order Number: 106705B

Aphena Pharma Solutions

Document ID
MBR679

Master Batch Record for the Manufacturing No More Pills' Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL Acetaminophen Solution in Aphena Work Center B13

FOR USE WITH
PPQ2020-007 ONLY

Step	Component Amounts / Mixing Times		Performed By / Date	Verified By / Date
	Target/Range	Recorded/Actual		
24.	Side Sweep Motor Speed: 22 ± 5 RPM T-bar Speed: 37 ± 5 RPM Recirculation pump speed: Record Mix Time: Record Target: 50.4 kg (Range: 49.9 – 50.9 kg)	T-bar: <u>37</u> RPM Side Sweep: <u>37</u> RPM Recirculation pump: <u>154.3</u> RPM Initial Tank Gross: <u>272.1</u> kg Final Tank Gross: <u>272.4</u> kg Net Wt.: <u>49.2</u> kg Initial Tank Gross: <u>272.6</u> kg Final Tank Gross: <u>274.4</u> kg Net Wt.: <u>7.8</u> kg	8-12-20	QAD 8-17-20
25.	Rinse side phase container into B13 using pre-weighed 10.0 kg of purified water.	Target: 10.0 kg (Range: 9.9 kg – 10.1 kg)		QAD 8-17-20

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Master Batch Record for the Manufacturing No More Pills[®]
Headache Man 3.785 kg Blend (LB-NMPHM01) 650mg/50mL
Acetaminophen Solution in Aphena Work Center B13

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Step	Parameters Formulation	Component Amounts / Mixing Times		Performed By / Date	Verified By / Date
		Target/Range	Recorded/Actual		
26.	Mix and recirculate until homogeneous mixture is observed.				
27.	While agitating, bulk add HydroxyPropyl Beta Cyclodextrin, USP (CP2647) Turn agitation off as necessary prior to recording end gross weight of the tank.	<p>Target Net Wt.: 475.36 kg Range: 470.60 – 480.11 kg Net Wt.: <u>451.5</u> kg</p> <p>Total Mix Time: <u>5</u> minutes</p>	<p>T-bar: <u>22</u> 37 RPM Side Sweep: <u>22</u> RPM</p> <p>Side Sweep Motor Speed: 22 ± 5 RPM</p> <p>T-bar Speed: 37 ± 5 RPM</p> <p>Recirculation pump speed: Record</p> <p>Mix Time: Record</p> <p>Mix Start Time: <u>9:49</u> am (pm)</p> <p>Mix Stop Time: <u>9:53</u> am (pm)</p> <p>Initial Tank Gross: <u>1184.0</u> kg Final Tank Gross: <u>3235.5</u> kg</p> <p>Net Wt.: <u>451.5</u> kg</p> <p><u>8-18-20</u> <u>9:59 AM</u> <u>8/18/20</u></p>		

① See Tech 20-0824488118120

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Aphena Pharma Solutions

Master Batch Record for the Manufacturing No More Pills,
Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL
Acetaminophen Solution in Aphena Work Center B13

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Step	Parameters Formulation	Component Amounts / Mixing Times		Performed By / Date	Verified By / Date
		Target/Range	Recorded/Actual		
28.	Mix and recirculate until HydroxyPropyl Beta Cyclodextrin, USP is dissolved. Set Scale Frequency to RPM target for Agitation.	Side Sweep Motor Speed: 22 ± 5 RPM T-bar Speed: 37 ± 5 RPM Recirculation pump speed: Record Mix Time: Record	T-bar: <u>37</u> RPM Side Sweep: <u>22</u> RPM Recirculation pump: <u>154.3</u> RPM Mix Start Time: <u>12:00</u> am/pm Mix Stop Time: <u>12:10</u> am/pm Total Mix Time: <u>10</u> minutes	<u>12:18-20</u>	<u>12:18-20</u>
29.	While agitating, add the following material: Acetaminophen (CP2648)	Target: 44.39 kg (Range: 44.17 – 44.62 kg)	Initial Gross: <u>3235.5</u> kg Final Gross: <u>3273.0</u> kg Net Wt.: <u>42.50</u> kg (<u>41.8-20</u>)	<u>41.8-20</u>	<u>41.8-20</u>

⑥ See TCEP 20-082 Quar 8/18/20

Work Order Number: 1046105B

Aphena Pharma Solutions

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Master Batch Record for the Manufacturing No More Pills'

Headache Man 3,785 kg Blend (LB-NMPPHM01) 650mg/50mL

Acetaminophen Solution in Aphena Work Center B13

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Step	Parameters Formulation	Component Amounts / Mixing Times		Performed By / Date	Verified By / Date
		Target/Range	Recorded/Actual		
30.	Mix and recirculate until homogeneous solution is observed. Set Scale Frequency to RPM target for Agitation.	Side Sweep Motor Speed: 22 ± 5 RPM T-bar Speed: 37 ± 5 RPM Recirculation pump speed: Record Mix Time: Minimum of 5 minutes	T-bar: <u>37</u> RPM Side Sweep: <u>22</u> RPM Recirculation pump: <u>154.3</u> RPM Mix Start Time: <u>12:20</u> am/pm Mix Stop Time: <u>12:25/12:55</u> am/pm Total Mix Time: <u>35</u> minutes		
31.	While agitating and recirculating, add the following materials:			<u>ME</u> 8/18/20	<u>ME</u> 8/18/20
32.	Bulk add of Sucrose, NF (CP2533). Turn off agitation as necessary prior to recording end gross weight of the tank.	Target: 386.62 kg (Range: 382.75 – 390.49 kg)	Initial Tank Gross: <u>3277.0</u> kg Final Tank Gross: <u>3658.0</u> kg Net Wt.: <u>381.00</u> kg	<u>ME</u> 8/18/20	<u>ME</u> 8/18/20

⑧ See TCCR 20-682 Q4B
8/18/20Work Order Number: 102705B

Aphena Pharma Solutions

Master Batch Record for the Manufacturing No More Pills[®]
Headache Man 3,785 kg Blend (1B-NMPPHM01) 650mg/50mL
Acetaminophen Solution in Aphena Work Center B13

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Step	Parameters Formulation	Component Amounts, Mixing Times		Performed By / Date	Verified By / Date
		Target/Range	Recorded/Actual		
33.	Fine Citric Acid, Anhydrous USP (CP2442)	Target: 19.671 kg (Range: 19.474 – 19.867 kg)	Initial Gross: <u>3658.0</u> kg Final Gross: <u>3626.4</u> kg Net Wt.: <u>18.40</u> kg	RE 8/18/20	MS 8/18/20
34.	Sodium benzoate NF/FCC Powder (CP2462)	Target: 3.796 kg (Range: 3.758 – 3.834 kg)	Initial Gross: <u>3676.4</u> kg Final Gross: <u>3679.0</u> kg Net Wt.: <u>2.60</u> kg	RE 8/18/20	MS 8/18/20
35.	Natural Bitterness Blocker (CP2650)	Target: 8.554 kg (Range: 8.469 – 8.640 kg)	Initial Gross: <u>3679.0</u> kg Final Gross: <u>3686.4</u> kg Net Wt.: <u>7.40</u> kg	RE 8/18/20	MS 8/18/20
36.	Organic Lemon Flavor (CP2649)	Target: 41.91 kg (Range: 41.49 – 42.33 kg)	Initial Gross: <u>3686.4</u> kg Final Gross: <u>3724.5</u> kg Net Wt.: <u>40.10</u> kg	RE 8/18/20	MS 8/18/20

⑥ See BCEL 20-082
JWD 8/18/20

Work Order Number: 106705B

Aphena Pharma Solutions

Document ID
MRR679

REVISION

Master Batch Record for the Manufacturing No More Pills® Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL Acetaminophen Solution in Aphena Work Center B13

PPQ2020-007 ONLY

Step	Parameters Formulation		Component Amounts / Mixing Times		Performed By / Date	Verified By / Date
	Target/Range	Recorded/Actual				
37.	Mix and recirculate until homogenous solution is observed.		<p>T-bar: <u>37</u> RPM</p> <p>Side Sweep: <u>22</u> RPM</p> <p>Side Sweep Motor Speed: 22 ± 5 RPM</p> <p>T-bar Speed: 37 ± 5 RPM</p> <p>Recirculation pump speed: Record</p> <p>Mix Time: Record</p> <p>Mix Start Time: <u>154:30</u> am/pm</p> <p>Mix Stop Time: <u>2:15</u> pm</p> <p>Total Mix Time: <u>15</u> minutes</p>			
38.	Stop Agitation and Recirculation Run Pump in Reverse to drain the Recirculation line.				OK 8/14/20	MS 8/18/20

Work Order Number: (067)058

Aphena Pharma Solutions

Master Batch Record for the Manufacturing No More Pills[®]
Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL
Acetaminophen Solution in Aphena Work Center B13

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Step	Parameters Formulation	Component Amounts / Mixing Times		Performed By / Date	Verified By / Date
		Target/Range	Recorded/Actual		
39.	<p>In a glass jar, take one (1) samples (approximately 500 mL) that is a composite of solution taken in approximately equal quantities from the top and bottom of the solution in the tank and submit the sample to the Analytical Lab, along with this page, to have the pH of the blend determined As states below:</p> <p>pH according to Work instruction WILAB208 at 25°C</p> <p>pH Specification: 2.70 – 2.95, Target: 2.80</p> <p>pH Meter ID#: <u>2838</u> Verify Daily Calibration Performed (Initial/Date): <u>PD 08/18/2020</u> Record temperature of sample: <u>25</u> °C and pH: <u>2.83</u></p> <p>If the pH of the sample meets specification, proceed to Step 41 and N/A all pages and steps in between.</p> <p>If the pH is above 2.95, have the lab analyst determine the approximate amount of Citric Acid (CP2442) needed to adjust the batch to a pH of approximately 2.80 and then proceed to the next step.</p>				

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8 - 18 - 20

PD 08/18/2020
and
8-18-20

2838 PD 08/18/2020
PD 25°C 2-79
Per TCCP # 20 - 082

Work Order Number: 100705B

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Determination of Quantity of Citric Acid (CP2442) needed for pH Adjustment (to be performed by Analytical Lab Analyst):

Based on the initial pH result, the Lab is to titrate a known weight of the sample with Citric Acid (CP2442) to a pH value of 2.70 to 2.95 Target 2.80. The Lab will then determine the approximate quantity of Citric Acid (CP2442) needed to adjust the batch, and will weigh and provide that quantity to Operations, as follows:

Batch Quantity: 3785.0 kg (3,785,000 grams)

Transfer a portion of the batch sample into an appropriate sized container (i.e. beaker) containing an appropriated sized magnetic stir bar.

Place empty container with stir bar on an Analytical Balance and "zero" out weight of empty container and stir bar.

Analytical Balance ID #:

Verify Daily Balance Check has been performed prior to use (Initial / Date):

Add a portion of the sample from Step # 62 into the container with magnetic stir bar.

Record weight of sample before titration (to 2 decimal places, xx.xx): _____ grams; Record pH of sample before titration: _____

Place container of solution on stirrer and adjust stirrer to gently stir the solution. Place pH probe in solution, making sure it is properly secured or held so that it is in the solution at approximately the middle depth, and is at a position that it will not be damaged by the spinning stir bar.

While mixing, slowly add Citric Acid to the blend sample, monitoring the pH until the solution is approximately 2.8 (Range 2.70 – 2.95)

Citric Acid Lot #: _____

Once the pH of the solution is approximately 2.80 (Range 2.70 – 2.95), remove and weigh the container of solution with stir bar, and calculate the quantity of Citric Acid required to adjust the pH:

Record weight of sample after titration (to 2 decimal places, xx.xx): _____ grams; Record pH of sample after titration: _____

Weight of sample after titration – Weight of sample before titration = Weight of Citric Acid (CP2442) used to titrate sample

_____ grams - _____ grams = _____ grams of Citric Acid (CP2442) used to titrate sample

Lab Analyst: _____ Date: _____

Qty. Citric Acid added to sample (g) x Batch Weight (g) = Required Quantity of Citric Acid (CP2442) needed to adjust pH of batch

Weight of sample before titration (g)

Citric Acid (g) x 3,785,000 grams = _____ grams of Citric Acid (CP2442) needed to adjust pH of batch

Wt of sample before titration (g) _____ Date: _____ Verified by: _____ Date: _____

Calculated by: _____ Work Order Number: 102105.B _____

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**Master Batch Record for the Manufacturing No More Pills®
Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL
Acetaminophen Solution in Aphena Work Center B13**

Step	Parameters Formulation	Component Amounts / Mixing Times	Performed By / Date	Verified By / Date
		Target/Range	Recorded/Actual	
40.	<p>After adjustment quantity is added, turn "ON" the Tank B13 Side Sweep Mixer and Bar-style Mixer, at the specified speeds. Mix solution for 10 minutes, and then turn "OFF", both the Side Sweep Mixer and the Bar-style Mixer. Record Mix Start and Stop times in the table below.</p> <p>After each adjustment and mixing, in a glass jar, take one (1) sample (approximately 125 mL per sample) that is a composite of solution taken in approximately equal quantities from the top and bottom of the solution in the tank, and check the pH of the composite sample determined as stated below:</p> <p><input type="checkbox"/> pH according to Work Instruction WILAB208, at 25°C</p> <p>pH Specification: 2.70 – 2.95, Target: 2.80</p> <p>pH Meter ID #: _____</p> <p>Verify Daily Calibration Performed (Initial/Date): _____</p> <p>Record pH of the solution after each adjustment in table on the next page.</p> <p>Continue pH adjustment process by adding half of the remaining 50% Citric Acid Solution after each adjustment, mixing, sampling and testing per WILAB08, until the batch pH is within the range of 2.70 – 2.95, Target 2.80. If the pH is still not within the required range after the calculated quantity of Citric Acid has all been added, additional Citric Acid may be added in small increments, and the additional added quantity recorded in the table below or on a copy of Aphena Form F1821 Master Batch Record Processing Notes Form.</p>	<p>Side Sweep Motor Speed: 22 ± 5 RPM <i>14.8.14.20 m</i></p> <p>T-bar Speed: 37 ± 5 RPM</p> <p>Side Sweep: _____ RPM</p> <p>T-bar: _____ RPM</p> <p>Mix Start Time: _____ am/pm</p> <p>Mix Stop Time: _____ am/pm</p> <p>Total Mix Time: _____ minutes</p>		

Work Order Number: 1026705B

Aphena Pharma Solutions

**Master Batch Record for the Manufacturing No More Pills,
Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL
Acetaminophen Solution in Aphena Work Center B13**

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<u>Step</u>	<u>Parameters Formulation</u>				<u>Component Amounts / Mixing Times</u>		<u>Performed By / Date</u>	<u>Verified By / Date</u>
	<u>Target/Range</u>	<u>Recorded/Actual</u>						
Mix Start / Stop Time	Weight of Citric Acid Added (g)	pH / °C	Analysts Initial / Date					

Record Total Mix Time.

If this Lab testing confirms that the pH of the sample is within the specific pH range of 2.70 – 2.95, Target 2.80, proceed to next step 41. If not confirmed to be within the specified pH range, continue pH adjustments as required.

U A 8-18-20

Work Order Number: 102-105B

Aphena Pharma Solutions

Master Batch Record for the Manufacturing No More Pills'®
Headache Man 3.785 kg Blend (LB-NMPPHM01) 650mg/50mL
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BULK BLEND TRANSFER

Step	Parameters Formulation	Component Amounts / Mixing Times		Performed By / Date	Verified By / Date
		Target Range	Recorded/Actual		
41.	Record temperature of tank	Target: 66°C ± 3°C.	66 °C	me 8/18/20	me 8/18/20
42.	Record the final weight of the tank.	Target: 3785.0 kg (Range: 3747.4 – 3822.6 kg)	Tank Weight: kg 8-18-20	me 8/18/20	me 8/18/20
43.	The finished blend will be transferred into Totes.		RPM		
44.	If Totes are not filled within 24 hours, Turn ON agitator immediately before filling Totes for a minimum of 10 minutes	Target: Minimum 10 minutes	Mix Start Time: am/pm 8/18/20		
			Mix Stop Time: am/pm 8/18/20		
			Total Mix Time: minutes		
45.	Label the required number of Tote Systems (where a Tote System consists of a tote, tote liner and tote lid) needed for the blend with a CP9223/1 label.			me 8/18/20	me 8/18/20
46.	Prior to use, weigh each of the selected Totes (with lids and liners) to obtain each empty tote weight. Record tote weights of the empty Totes in the "DETERMINATION OF BLEND TRANSFER YIELD" section that follows.			me 8/18/20	me 8/18/20

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Master Batch Record for the Manufacturing No More Pills' Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL Acetaminophen Solution in Aphena Work Center B13

Step	Parameters/Formulation	Target/Range	Recorded/Actual	Performed By / Date	Verified By / Date
47.	If not already installed, place an inline 60 mesh Tri-clamp screen gasket in the discharge line, in order to filter the blend as it is being discharged from the Tank into Totes.			RL 8-18-20	MS 8-18-20
48.	Open Valve on the Tank B13 Recirculation/Discharge Pump so that product will be directed to the Tote.			ML 8-18-20	MS 8-18-20
49.	Connect Discharge Hose to Tote Liner			ML 8-18-20	MS 8-18-20
50.	Manually OPEN Tank B13 Discharge Valve.			ML 8-18-20	MS 8-18-20
51.	Turn "ON" the Tank B13 Recirculation/Discharge Pump and set Scale Frequency to an appropriate discharge speed	Target: As needed	Discharge Pump Speed: 330 S RPM	ML 8-18-20	MS 8-18-20
52.	Discharge the bulk from the tank into the Tote.			GP 8-18-20	JW 8-18-20
53.	Collect three (3) 4-oz. sterile sample containers (1 Beginning, 1 Middle, and 1 End of discharge) for Analytical samples. Collect three (3) 4-oz. sterile sample containers (1 Beginning, 1 Middle, and 1 End of discharge) for Retains samples. Collect one (1) 4 oz. sterile sample container form the end of discharge for Micro sampling.			GP 8-18-20	JW 8-18-20
54.	Once all bulk has discharged from Tank B13, turn "OFF" Discharge Pump and Close Discharge Pump Valve			GP 8-18-20	JW 8-18-20
55.	Any solution remaining in the discharge piping from the Tank B13 Recirculation/Discharge Pump will be manually drained into a cleaned and sanitized stainless steel container and added into Tote			GP 8-18-20	JW 8-18-20
56.	Weigh the filled Totes and record weight of the filled Totes in the "DETERMINATION OF BLEND TRANSFER YIELD" section that follows.			GP 8-18-20	JW 8-18-20

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POST PRODUCTION LINE CLEARANCE

The following information must be verified after completion 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 next work order. Line clearance is to be checked by the supervisor and verified by quality.

	Verification Required	Performed by / Date	Verified by / Date
Remove all components, raw materials, labels, and blending paperwork from the work center.	Visual Inspection	✓ 8/18/20	Cesar 8/18/20
Remove all finished blends from the work center.	Visual Inspection	✓ 8/18/20	Cesar 8/18/20

Work Order Number: 1046705B

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DETERMINATION OF PERCENT OF BLEND THEORETICAL YIELD

Upon completion of the blending process, calculate the % of Blend Theoretical Yield for the batch as follows:

$$\frac{\text{Final Batch Weight from Step 42}}{\text{Theoretical Blend Weight}} \times 100 = \% \text{ Yield}$$

$$\frac{3785.2}{3,785 \text{ kg}} \text{ lb.} \times 100 = 100.0 \% \text{ Yield}$$

Note: % of Theoretical Yield must be $\pm 1.0\%$ (99.0 – 101.0%). If outside this range, notify QA immediately.

Calculated by LSP Date 8/18/20

Checked by DML Date 8/18/20

Work Order Number: 156705B

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DETERMINATION OF BLEND TRANSFER YIELD:

Upon completion of the transferring of all the bulk solution from Tank B13 into the three stainless steel Totes, calculate the % Transfer Yield for the batch as follows. Enter Net Weight of solution in the tote onto tote label CP/9223/1.

Tote #	Weight of Filled Tote kg	Tare Weight of Empty Tote kg	=	Net weight of solution in Tote kg
1	10.31.0	84.0	=	947.0
2	10.24.0	84.0	=	940.0
3	10.29.5	84.0	=	945.5
4	10.16.0	84.0	=	932.0

Total Weight of Solution Transferred into Totes = 3764.5 kg of solution

$$\frac{3764.5 \text{ kg}}{3,785 \text{ kg}} * 100 = 99.5 \% \text{ Yield}$$

NOTE: Record to one decimal

Calculated by LSP

Checked by JH

Date 8-18-20

Date 8-18-20

LABELING OF TOTE

After filling and the determination of net weight of solution in the tote, complete and attach a Lot Control Inventory Tag form F1293 and complete the CP/9223/1 that includes the following information, on each filled tote:

- Part No: LB-NMPHM01
 - Product name: No More Pills Headache Man 650mg/50mL Acetaminophen Solution
 - Container # (of)
 - Date of Manufacture:
 - Solution Batch(Lot) #
 - Expiration Date: N/A
- The total weight of the filled tote (Gross weight)
 - The tare weight of the empty tote (Tare weight)
 - The net weight of solution in the tote in kg (Net weight)
 - Initials of operator filling in label information and the date

Work Order Number: (D)7C5B

Aphena Pharma Solutions

Document ID

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Master Batch Record for the Manufacturing No More Pills' Headache Man 3,785 kg Blend (LB-NMPPHM01) 650mg/50mL Acetaminophen Solution in Aphena Work Center B13

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ANALYTICAL TESTING OF NO MORE PILLS HEADACHE MAN SOLUTION FLAVORBATCH NUMBER: 2023001

Aphena Laboratory Analysts will obtain Beginning, Middle, and End of discharge samples for conducting the tests noted in the table below, which are being performed by Aphena. Individual results for each sample to be reported on an Aphena Laboratory Certificate of Analysis.

Test Parameter	Specification	Aphena Test Method
Acetaminophen Assay <i>(Alex) 8/18/20</i>	12.4 – 13.7 mg/mL 95% - 105% Label Claim	LIN447/tes-10C WILAB199
API DD A <i>(Brain) 8/18/20</i>	The retention time of the major peak of the samples solution corresponds to that of a standard solution as obtained in the assay.	Thin Layer Chromatography (TLC)
API DD B	The <i>RF</i> value of each principal spot in the chromatogram of the <i>Modified test solution</i> corresponds to that of the principal spot in the chromatogram obtained from each relevant <i>Standard solution</i> as appropriate for the active ingredient or ingredients specified on the label.	WILAB59 WILAB186
Appearance/Color	Tentative specification: Colorless to light brown, clear to slight opaque viscous liquid	WILAB80
Specific Gravity	For Information Only	
pH	For Information Only Tentative Specification: 2.70 – 2.95, Target 2.80	WILAB208

① WS02/151 8/19/2020

QA Release of Blend: Dawn Miller Date: 8-19-20

Work Order Number: 102105B



APS Labs QC Certificate of Analysis

Product description	No More Pills Headache Man
WO #	106705B
Part #	LB-NMPHM02
Lot #	2023001
MBR	679, Revision 0
Equipment Line	B-13
Purpose	Finished Blend Product Analysis

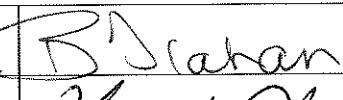
Sample ID	Analysis	Specification	Result	Lab Notebook Reference
Beginning Middle End	Appearance/Color	For Information Only* Tentative specification: Colorless to light brown, clear to slight opaque viscous liquid	B: Conforms M: Conforms E: Conforms	LN502/151
Beginning Middle End	pH @ 25°C	For Information Only* Tentative Specification: 2.70-2.95 (Target 2.80)	B: 2.85 M: 2.84 E: 2.84	LN502/151
Beginning Middle End	Specific Gravity	For Information Only*	B: 1.091 M: 1.092 E: 1.093	LN502/151
Beginning Middle End	Acetaminophen Assay	12.4 – 13.7 mg/mL 95% - 105% (LC)	B: 98.2% M: 97.8% E: 99.5%	LN509/77 LN497/105-106
Beginning Middle End	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.	B: Conforms M: Conforms E: Conforms	LN497/105-106
Beginning Middle End	API ID B	The RF value of each principal spot in the chromatogram of the Modified test solution corresponds to the principal spot in the chromatogram obtained from each relevant Standard Solution as appropriate for the active ingredient or ingredients specified on the label.	B: Conforms M: Conforms E: Conforms	LN514/44-45

*For Information Only

APS Labs QC Certificate of Analysis

Product description	No More Pills Headache Man
WO #	106705B
Part #	LB-NMPHM02
Lot #	2023001
MBR	679, Revision 0
Equipment Line	B-13
Purpose	Finished Blend Product Analysis

 Meets Specifications Does Not Meet Specifications

Prepared By		Date	8-19-20
Reviewed By		Date	8-19-20

Aphena Pharma Solutions

Master Batch Record for the Manufacturing No More Pills,²
Headache Man 3.785 kg Blend (LB-NMPHM01) 650mg/50mL
Acetaminophen Solution in Aphena Work Center B13

Document ID	MBR679	Revision	0
Effective	FOR USE WITH	Page	36 of 37

MICROBIOLOGICAL TESTING OF NO MORE PILLS HEADACHE MAN SOLUTION FLAVOR

Aphena Laboratory Microbiologist will obtain End of discharge sample for conducting the tests noted in the table below, which are being performed by Aphena. Results for the sample to be reported on an Aphena Laboratory Certificate of Analysis.

Test Parameter	Specification	Aphena Test Method
	Total Aerobic Microbial Count (TAMC): Not More Than 10^2 CFU/g	WILAB69 and USP <61>
	Total Yeasts and Molds Count (TYMC): Not More Than 10^1 CFU/g	
Microbial Enumeration Test and Tests for Specified Microorganisms	<i>Staphylococcus aureus</i> : Absent <i>Pseudomonas aeruginosa</i> : Absent <i>Salmonella</i> : Absent <i>Escherichia coli</i> : Absent <i>Burkholderia cepacia complex</i> *	WILAB69 and USP <62>
Test to be completed on the first validation batch only		USP <60>

Work Order Number: 1053

CERTIFICATE OF ANALYSIS



Prepared For:

No More Pills – Finished Blend

WO#: 106705B

Part #: LB-NMPHM01

Lot#: 2023001

Lab Notebook Reference: LN 510 / 152-153

Test Method:

Microbial Limits Test – USP <61> and <62>

Microbial Procedure for Raw Material, Blend and Finished Goods

Test Performed	Test Date	Specification	Result
Total Aerobic Microbial Count	8/18/20	<100 CFU/g	<10 CFU/g
Total Yeast and Mold Count	8/18/20	<10 CFU/g	<10 CFU/g
Absence for Enterobacter per 1g		NA LB 8/24/20	
Absence for Pseudomonas aeruginosa per 1g	8/18/20	Absent	Absent
Absence for Staphylococcus aureus per 1g	8/18/20	Absent	Absent
Absence for Escherichia coli per 1g	8/18/20	Absent	Absent
Absence for Salmonella species per 10g	8/18/20	Absent	Absent

Test Performed by: LB

Date: 8/24/20

Review by: JL

Date: 8-24-20

Aphena Pharma Solutions

Master Batch Record for the Manufacturing No More Pills' Headache Man 3,785 kg Blend (LB-NMPHM01) 650mg/50mL Acetaminophen Solution in Aphena Work Center B13	Document ID MBR679	Revision 0
	Effective FOR USE WITH PPQ2020-007 ONLY	Page 37 of 37

REVISION HISTORY LOG

Revision 0 – Per DCC # 20-737 and CC # 19-037

- 1) New Issue

Work Order Number: 106705B

Daily Time Sheet

SECTION 1

Date: 8-17-20 Machine: B-13 Clocked Cycles: 0
Product: LB-NMPHM01 Supervisor: Serry P
WO#: 106705B Operator: 2
Start Time: 12:00 p.m. Packers: 0
End Time: 5:00 AM Units Produced: 3785 U/M: Kg

SECTION 2:

SECTION 3:

**Number of Cases Started
Cases Produced (Tally)**

0
—
—
—
—
—

Total
Daily
Waste:

Total
Set-Up
Material:

Total Hours

Total Projects
Set Up

Set. up

Total Produced:

3785

Meter: Lot #2023001

SECTION 4: Comments:

SECTION 4: Comments:
Set up for new Blend, start Blend

Daily Time Sheet

SECTION 1

Date: 8-18-20 Machine: B13 Clocked Cycles: _____
Product: LB-NMPhMO1 Supervisor: Jerry P.
WO#: 106705B Operator: 2
Start Time: 5:00 AM Packers: 0
End Time: 7:00 AM Units Produced: 3785.0 U/M: kg

SECTION 2:

SECTION 3:

Number of Cases Started	<u>0</u>	Total Daily Waste:	Total Set-Up Material:	Total Hours:
Cases Produced (Tally)	<u>-</u>			Set-Up _____
	<u>-</u>	Gross: _____		Packer _____
	<u>-</u>	Tare: <u>45</u>	<u>GP 8-18-20</u>	Operator _____
	<u>-</u>	Net: _____		
Total Produced:	<u>0</u>	Meter: <u>2023001</u>		

SECTION 4: Comments:

Tote off, take samples, finish paperwork, line clearance

EXCEPTION REQUISITION

Date: 8/17/20

Work order #: 106705B

Requested by: CP

Date needed: 8/17/20

Delivery to: B B

Filled by: L.L. 8-17-20

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

Daily Time Sheet

SECTION 1

Date: 8/18/20 Machine: B13 Clocked Cycles: 0
Product: LB-NM PHMO Supervisor: J. Rogers
WO#: 10667053 Operator: 3
Start Time: 5:00 AM Packers: 0
End Time: 8:00 AM Units Produced: 3785 U/M: Kg

SECTION 2:

SECTION 3:

**Number of Cases Started
Cases Produced (Tally)**

10

Total Daily Waste: Total Set-Up Material:

Total Hours:
Set-Up _____
Packer _____
Operator _____

Total Produced: 3785 Meter: 2023001

SECTION 4: Comments:

SECTION 4: Comments
Complete ~~note off~~ reconcile batch record, return components

EXCEPTION REQUISITION

Date: 8-17-20
Work order #: 106705 B
Requested by: LL
Date needed: 8-17-20
Delivery to: B13
Filled by: LL 8-17-20

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

Aphena Pharma Solutions
Chain of Custody Form for Laboratory Analysis per LC 008

<u>Product Information</u>	MBR #: 679	Revision #: 8
Work Order or Study #: 106705B	Cleaning Document #: N/A	Revision #: 348-18-20
Part #: LB-NAP1HM01	Equipment Line ID: B13	
Lot #: 2023001	Line Supervisor or Designated Contact: Jerry P	

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: MA 8:18:20 Other: N/A 8:18:20

Sample Release

- Analytical Chemistry Laboratory Microbiological Laboratory External Laboratory: ✓ ~~DA~~

Ambient Temperature Keep Refrigerated Other: A ~~8-18-20~~

Relinquished by: E.P. 18 Date: 8-18-20 Time: 6:33am

For Laboratory Use Only

Received by: BUT Date: 8-18-20 Time: 0700

Comments: _____

① 25mL subsample was taken from each Relein
F1535 Revision 9 for shipment to customer MK 09/02/202
Effective Date: 08/13/2013

LOT CONTROL RETRIEVE - 'LOTEDT'

PART NUMBER: LB-NMPHM01 QUANTITY: 0.0
DESCRIPTION: 1LB SOL:NO MORE PILLS HEADACHE MAN

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

New lot 2023001
Cew 8-14-20

LOT CONTROL RETRIEVE - "LOTEDT"

PART NUMBER: LB-NMPHM01 QUANTITY: 0.0
DESCRIPTION: 1LB SOL:NO MORE PILLS HEADACHE MAN

New lot 2023001
AT 8-14-20

NO LOTS EXIST FOR PART NUMBER LB-NMPHM01

<CR> TO CONTINUE?

ISSUE OR RETURN LISTING DATE 11:28:23 14 AUG 2020

JOB NUMBER - W0106705B

DESCRIPTION - 1LB SOL:NO MORE PILLS HEADACHE MAN

REFERENCE PART NUMBER - LB-NMPHMO1

DATE OPENED - 14AUG20

JOB QUANTITY - 3785.0 KG QTY RECEIVED - 0.0 KG

START DATE - 17AUG20 COMPLETION DATE - 19AUG20

DATE REQUIRED _____

PICKED COMPLETE (Y/N) _____

ISSUED COMPLETE (Y/N) _____

LOCATION OF ISSUE BALANCE _____

ORDER PICKED BY - _____

LB-NMPHMO1
W0106705B
Lot 2023001
NYA Exp

PART NUMBER	DESCRIPTION	U/M	MIN REQ'D TO ISSUE	INV QTY	LOCATION	LOC QTY	ISSUED	TOTAL/PN
CP2442	FINE CITRIC ACID, ANHYDROUS USP	LB	20.8	21.8904	100.0	311-022	50.0	LOT# A518E241BF 47.28118 AEIAHT18ICF
CP2462	SODIUM BENZOATE NF/FCC POWDER ~ NBT	KG	3.5	3.6488	124.0	311-031	98.0	LOT# KASBD7N206 KASBD7N206 (9.500KG)
CP2533	SUCROSE, NF, BIOMAO	KG	406.5	426.8586	2067.1	313-043	2067.1	LOT# 49476 54200KG
CP2647	HYDROXYPROPYL BETA CYCLODEXTRIN, US	KG	499.6	524.5538	1760.0	312-000	720.0	LOT# HH20191223 84.186KG *****SHORT*****
CP2648	ACETAMINOPHEN	KG	46.7	49.0497	127.4	313-011	127.4	LOT# 1950041 33.01 KG Zai990
CP2649	ORGANIC LEMON FLAVOR	KG	43.6	45.8073	132.7	315-031	2.7	LOT# 28154 130.0 *****SHORT***** (2.48KG Zai990)
CP2650	NATURAL BITTERNESS BLOCKER	KG	9.3	9.7293	32.4	315-031	2.4	LOT# 28155 30.0 *****SHORT***** 8.450KG Zai990
CP2651	GELLAN GUM, KELCO GEL CG-LA	KG	0.4	0.4053	24.7	315-035	24.7	LOT# 9J4342A 23.8296KG
LB100PUR	WATER, PURIFIED, USP	LB	6306.6	6621.9	26343.7	B13	14423.3	----- : ----- :

DATE: 8/17/20

PN#: LB-NMPHM01

MBR# 679 Rev# 0

WO# 106705B

LOT# 2023001

Monday 1st Blend

Thanks! Jerry

ISSUE DR RETURN LISTING DATE 07:06:11 14 AUG 2020

DESCRIPTION - 1LB SOL-NO MORE PILLS HEADACHE MAN

WORK CENTER - B13

JOB NUMBER - W0106705A

DATE OPENED - 13AUG20

REFERENCE PART NUMBER - LB-NMPHMD1

JOB QUANTITY - 3785.0 KG QTY RECEIVED - 0.0 KG

START DATE - 14AUG20 COMPLETION DATE - 18AUG20

DATE REQUIRED 8/14/20 TIME REQUIRED 3:30 PM PICKED COMPLETE (Y/N) _____

ISSUED COMPLETE (Y/N) _____

LOCATION OF ISSUE BALANCE

ORDER PICKED BY - _____

PART NUMBER	DESCRIPTION	U/M	MIN REQ'D TO ISSUE	INV QTY	LOCATION	LOC QTY	ISSUED	TOTAL/PN
CP2442 ✓	FINE CITRIC ACID, ANHYDROUS USP	LB	20.8	21.8899	100.0	311-022	50.0	100.0 LOT# A5B6E24455 AFIGH181CF
CP2452 ✓	SODIUM BENZOATE, NF/FCC POWDER - NBT	KG	3.5	3.6483	124.0	311-031	98.0	124.0 LOT# KASBD7N206 17.925 KASBD7N206 23.0 KG
CP2533 ✓	SUCROSE, NF, BIOPRANO	KG	406.5	426.8586	2067.1	313-043	2067.11	406.5 LOT# 49476 933.11 (4102268)
CP2647 ✓	HYDROXYPROPYL BETA CYCLODEXTRIN US	KG	499.6	524.5537	1760.0	312-060	720.0	499.6 LOT# HH20191223 ****SHORT**** 10 KG 14154H 550.0 KG (55010 KG)
CP2648 ✓	ACETAMINOPHEN	KG	46.7	49.0504	127.4	313-011	127.4	46.7 LOT# 1930041 77.4 KG (1000 27.4)
CP2649 ✓	ORGANIC LEMON FLAVOR	KG	43.6	45.8069	132.7	315-031	130.0	43.6 LOT# 280154 2.69 KG 130.0 ****SHORT**** 291996 52.0 KG (4013.0 KG)
CP2650 ✓	NATURAL BITTERNESS BLOCKER	KG	9.3	9.7285	32.4	315-031	32.4	9.3 LOT# 280155 2.42 KG 30.0 ****SHORT**** 291991 15.0 KG
CP2661 ✓	CELLAN GUM, KELCO GEL CG-LA	KG	0.4	0.4058	24.7	315-035	24.69	0.4 LOT# 814342A 24.685 KG
LB100PUR	WATER, PURIFIED, USP	LB	6306.6	6621.9	28463.1	B13	14423.3	6306.6 -----

REV DATE 5JUN20

'JOBADD' PAGE 1

BILL OF MATERIAL FOR LB-NMPHM01
 LABOR IN HOURS PER UNIT 1LB SOL:NO MORE PILLS HEADACHE MAN
 JOB NUMBER - W0106705B

JOB QUANTITY -

3785 JOB COMPLETION DATE - 17AUG20

REVISION 1	ECN # N/A	ECN IMPLEMENTATION DATE 13AUG20	IMPL SERIAL NUMBER R0JM	U/M	REV	QTY	REQ'D	QOH	L/T	STD COST	EXT COST
PART NUMBER	DESCRIPTION										
CODE 1MB CODE B13	LABOR MANUFACTURING, BLENDER LDC - PRD LABOR BLENDING TANK - 1,000 GALLON LDC - PRD		HRS HRS	38.622 38.622		0 0		25.000 0.000		965.554 0.000	
CP2442	CHP FINE CITRIC ACID, ANHYDROUS USP		LB	2	20.848	350	30	1.404	29.268		
CP2462	CHP SODIUM BENZOATE NF/FC C POWDER - NBTY	MELATONIN	KG	2	3.475	177	30	4.852	16.859		
CP2533	CHP SUCROSE, NF, BIORAMO		KG	5	40.6.532	2.067	30	2.139	869.368		
CP2647	CON HYDROXYPROPYL BETA CYCLODEXTRIN, USP		KG	1	49.9.575	1.760	30	0.000	0.000		
CP2648	CHP ACETAMINOPHEN		KG	1	46.714	127	30	8.200	383.059		
CP2649	CHL ORGANIC LEMON FLAVOR		KG	1	43.626	133	30	19.850	865.974		
CP2650	CHL NATURAL BITTERNESS BLOCKER		KG	1	9.266	32	30	12.500	115.821		
CP2651	CHP GELLAN GUM, KELCO GEL CG-LA		KG	1	0.386	25	30	103.660	40.020		
LB100UR	CHL WATER, PURIFIED, USP		LB	3	6.306.556	26.344	2	0.025	160.187		
V0HD LC PRD	VARIABLE OVERHEAD - LDC - PRD		HR	19.311	0	0	0	0.000	1.206.942		
V0HD LC PRD	VARIABLE OVERHEAD - LDC - PRD		HR	38.622	0	0	0	31.250			
<hr/>											
MATERIAL COST											
MATERIAL BURDEN COST											
LABOR COST				0.000	965.554						
SETUP COST				0.000							
FIXED OVERHEAD COST				0.000							
VARIABLE OVERHEAD COST				1,206.942							
VALUE ADDED COST				0.000							
STANDARD COST FOR	3785 LB-NMPHM01 IS			4,653.051							

ROUTE SHEET

PRINT DATE 11:28:23 14 AUG 2020

PAGE 1

JOB NUMBER - W0106705B

START DATE - 17AUG20

JOB QUANTITY - 3785.0 UM - KG

COMPLETION DATE - 19AUG20 QTY COMPLETE - 0.0

SALES ORDER REF -

DESCRIPTION: 1LB SOL: NO MORE PILLS HEADACHE MAN
REVISION 1 IMPLEMENTED ON 13AUG20SPEC REVISION COMMENT: PER CC#19-037 & DCC# 20-1075
UPDATE THE MBR TO ACCOMMODATE COMMERCIAL SIZE

MSDS DOCUMENT CONTROL NO:

CONTROLLED DOCUMENT NUMBER - NEEDED

REFERENCE SPECIFICATIONS:

X2964 (ACETAMINOPHEN SHOT FORMULA NO MORE PILLS REV 0)

X2965 (ACETAMINOPHEN SHOT MANUFACTURING NO MORE PILLS REV 0)

SPECIFIC GRAVITY:

LOT CODE:

LOT CODE FORMAT PER BATCH RECORD.

APPLICABLE PROCEDURES AND WORK INSTRUCTIONS:

MBR679 (LB-NMPH01 MFG OF NMP ACETAMINOPHEN REV 0)

BATCH SIZE: 3780KG

ANALYTICAL TESTING: PER MBR

PRODUCTION NOTES: USE CP6063R REUSABLE COLLAPSABLE TOTE

BILL OF MATERIALS:

ITEM PART NUMBER	REV	DESCRIPTION	U/M	QUANTITY	OP #
LE100PUR	3	WATER, PURIFIED, USP	LB	1.6662	100
CR2651	1	GELLAN GUM, KELCO GEL CG-LA	KG	0.0001	
CR2650	1	NATURAL BITTERNESS BLOCKER (SG=1.034)	KG	0.0024	100
CP2649	1	ORGANIC LEMON FLAVOR (SG=0.8108)	KG	0.0115	
CP2648	1	ACETAMINOPHEN	KG	0.0123	
CP2647	1	HYDROXYPROPYL BETA CYCLODEXTRIN, USP	KG	0.1320	
CR2533	5	SUCROSE, NF, BIORANO	KG	0.1074	
CP2462	2	SODIUM BENZOATE NF/FCC POWDER - NBTY MELATONIN	KG	0.0009	
CP2442	2	FINE CITRIC ACID, ANHYDROUS USP	LB	0.0055	

ROUTING :

OP #	L/C	RESOURCE	DESCRIPTION	QUANTITY	STD HRS
100	PRD	B13	BLENDING TANK - 1.00 MANUFACTURING, BLEND	3785.00	19.31 38.62

Aphena Pharma Solutions
Chain of Custody Form for Laboratory Analysis per LC-008

Cleaning & Sanitization Log – No More Pills	Document ID	REV
	F2429	0
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Work Center: B13

LB- NMP HM01 Rx - Sanitization

WO 104705B

lot 2023001

JUL 8 2020

APPROVED BY:

Aphena Approvals				
Department	Print Name	Title	Signature	Date
Author	Megan Kunkowski	Technical Services Specialist	/s/Megan Kunkowski/s/	8/13/20
Reviewer	Rafeh Raza	Sr. Tech. Services Specialist	/s/Rafeh Raza/s/	8/13/20
Reviewer	Amanda Jenkins	Laboratory Manager	/s/Amanda Jenkins/s/	8/13/20
Reviewer	Julie Curie	Microbiology Supervisor	/s/Julie Curie/s/	8/13/20
Reviewer	Jerry Pappas	Blending Supervisor	/s/Jerry Pappas/s/	8/13/20
Approver	Sanjay Nimkar	Director, Q/RA	/s/Sanjay Nimkar/s/	8/13/20

Revision History:

Rev 0: New issue, Per DCC# 20-830

Cleaning & Sanitization Log – No More Pills	Document ID	REV
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Work Center: B13

Cleaning Confirmation:

- Less than 24 hrs from last clean/sanitization and no other activity in area:**
 - Proceed with blend.
- Greater than 24 hrs from last clean/sanitization and no other activity in area:**
 - Sanitize per F2368, starting with step 20 (TOC and Conductivity from previous clean must be passing)
- Any blending or cleaning activity in area after previous tank clean, clean and sanitize per F2368.**

Resource Requirements: Verify all resources are available to perform necessary cleaning and sanitization steps

- Contrad 100 (PX818)*
- Hot Water (UT2)
- 70% Isopropyl Alcohol (LB181)
- Required PPE (Heat resistant gauntlet gloves, safety glasses, splash shield, apron, water repellent boots, and protective coat hood)
- Disposable vinyl, rubber or nitrile gloves
- Lint free wipes
- Jars (conductivity) or dual use conductivity and TOC vial
- TOC vials or dual use conductivity and TOC vial
- Micro Swabs (sterile)
- Sterile Micro Sampling bottles
- Labels
- F1535 – Chain of Custody Form
- Tags to Mark Equipment Cleaning Required
- Tyvek sheeting to cover hose ends during the drying process
- PX961 Honeywell Chart recorder chart

Verified by Blender or Blending Supervisor (initial and date):


8-17-20

*Note: Mix Contrad 100 and Water for Clean In Place Solution (CIP Solution)

Cleaning & Sanitization Log – No More Pills	Document ID	REV
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Work Center: B13

SAMPLE LABELING and CHAIN OF CUSTODY Requirements:

All samples to be labeled with M023 labels and submitted with Chain of Custody F1535.

Labels and Chain of Custody must include:

Sample Description (ex: Blank, Final Rinse, ...including Hot designation for water)

Tote # (if applicable)

Date sample taken (MM-DD-YY) + Step # + Sample Type #

Example: TOC for LB100PUR/LB101PUR Final Rinse
on 11-4-15, step 55

LB100PUR/LB101PUR Final Rinse
11-4-15+55+1

(Date + Step # + Sample type#)

Sample	Type #	Limits
TOC WILAB15	1	
Conductivity WILAB08	2	$\leq 9.91 \mu\text{S}/\text{cm}$
Micro WILAB36	3	Alert = 30 cfu/mL Action = 100 cfu/mL
API WILAB200	4	$\leq 2058.7 \mu\text{g}/\text{mL}$
Micro Swab WILAB109	Swab	$\leq 2 \text{ CFU}/\text{cm}^2$

Chain of Custody: Include this page with Chain of Custody:

All analytical and micro test results (F1749) must be included as part of the final executed cleaning and sanitization record.

**Cleaning & Sanitization Log –
No More Pills**

Work center: B13

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To be performed by Blender and Verified by Supervisor or Second Qualified Person

Steps	Parameters	Performed By	Verified By
Fitting, Utensils not Cleaned in Place			
1. All ports, caps, elbows, fittings and utensils cleaned and sanitized per WILAB003.		MK 8-17-20	ES 8-17-20
TANK CLEANING			
2. Collect a blank sample from the UT2 POU for TOC, Conductivity and BIO for comparison testing.			
3. Confirm that chart recorder is operational and install a new PX961 chart			
4. Maintain temperature at the chart recorder at 160-180°F thru the remainder of this cleaning step			
5. Fill with 946 Kg (~ 250 gallons) of UT2 Hot Water.			
6. Using a hand sprayer containing Contrad 100 solution, spray all product contact surfaces in tank. (i.e. tank side wall, mixer blades, etc.)		MK 8-17-20	
7. Start agitator and side sweep on slow speeds and add 2 gallons of Contrad 100 to B13			
8. Connect together the infeed and discharge hoses used in the blend process to join infeed and discharge pump lines			
9. With both pumps shut down, direct the 3-way discharge/recirculation valve to the discharge position.			

Cleaning & Sanitization Log –
No More Pills

Work center: B13

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Steps	Parameters	Performed By	Verified By
10.	Run the infeed pump at 30 Hz and discharge/ recirculation pump at 40 Hz to recirculate the Hot CIP Solution throughout all infeed and discharge piping for 10 min. Start Time: _____ am/pm Stop Time: _____ am/pm		
11.	Shut down both pumps. Direct the 3-way discharge/ recirculation valve to the recirculation position. Start the discharge/ recirculation pump and run it at 106.8Hz; start agitator running at low speed settings.		
12.	Mix and Recirculate the Hot CIP Solution thru recirculation line for 10 minutes. Start Time: _____ am/pm Stop Time: _____ am/pm While the system is recirculating, move the 3-way valve handle no more than 45° toward the discharge position, and then immediately turn it back to the recirculation position. Cycle the valve three (3) times.	<i>W</i>	<i>WL</i>
13.	Shut down agitator and side sweeps.		
14.	Stop the recirculation pump, and then momentarily run it in reverse at 80 Hz to clear the contents of the B13 recirculation piping. Do not run the pump dry.		
15.	Direct the 3-way discharge/ recirculation valve to the discharge position		
16.	If discharging to disposable totes, contents must be <110° F. If discharging to stainless steel totes, cooling is not required.		
17.	Separate the infeed and discharge hoses. Connect the discharge hose to the tote. Cap the infeed hose.		
18.	Discharge the waste Hot CIP Solution to totes.		

Cleaning & Sanitization Log –Document ID
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Work center: B13

<u>Steps</u>	<u>Parameters</u>	<u>Performed By</u>	<u>Verified By</u>
19.	While discharging into totes, using a spray hose connected to the UT2 drop loop, spray all product contact surfaces thoroughly.	<i>ME</i> 8-17-20	<i>ES</i> 8-17-20
	1st Rinse/Sanitization		
20.	If this is a re-sanitization only, collect a blank sample from the UT2 POU for TOC, Conductivity and BLO for comparison testing otherwise N/A this step.	<i>ME</i> 8-17-20	<i>ES</i> 8-17-20
21.	Add 3785 Kg (~ 1000 gallons) of hot water (UT2) B13.	<i>ME</i> 8-17-20	<i>ES</i> 8-17-20
22.	Maintain temperature at the chart recorder at 180°F throughout the remainder of this sanitization step.	<i>ME</i> 8-17-20	<i>ES</i> 8-17-20
23.	Connect together the infeed and discharge hoses used in the blend process to join infeed and discharge pump lines	<i>ME</i> 8-17-20	<i>ES</i> 8-17-20
24.	Start agitator and side sweeps at low speed.	<i>ME</i> 8-17-20	<i>ES</i> 8-17-20
25.	With both pumps shut down, direct the 3-way discharge/recirculation valve to the discharge position.	<i>ME</i> 8-17-20	<i>ES</i> 8-17-20
26.	Run the infeed pump at 30 Hz and discharge/ recirculation pump at 40 Hz to recirculate the Hot Water rinse throughout all infeed and discharge piping for 20 min. Start Time: <u>7:06</u> am Stop Time: <u>7:26</u> am	<i>ME</i> 8-17-20	<i>ES</i> 8-17-20
27.	Shut down both pumps. Direct the 3-way discharge/ recirculation valve to the recirculation position. Start the discharge/ recirculation pump and run it at 106.8Hz; start agitator running at low speed settings.	<i>ME</i> 8-17-20	<i>ES</i> 8-17-20

Cleaning & Sanitization Log –
No More Pills

Work center: B13

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Steps	Parameters	Performed By	Verified By
28.	Mix and Recirculate the Hot Water thru the recirculation line for 10 minutes. Start Time: <u>7:28</u> am/pm Stop Time: <u>7:39</u> am/pm While the system is recirculating, move the 3-way valve handle no more than 45° toward the discharge position, and then immediately turn it back to the recirculation position. Cycle the valve three (3) times.	<u>ME</u> 8-17-20	<u>ES</u> 8-17-20
29.	Stop the recirculation pump, and then momentarily run it in reverse at 80 Hz to clear the contents of the recirculation piping. Do not run the pump dry.	<u>ME</u> 8-17-20	<u>ES</u> 8-17-20
30.	Shut down agitator and side sweeps.	<u>ME</u> 8-17-20	<u>ES</u> 8-17-20
31.	Direct the 3-way discharge/ recirculation valve to the discharge position.	<u>ME</u> 8-17-20	<u>ES</u> 8-17-20
32.	If discharging to disposable totes, contents must be <110° F. If discharging to stainless steel totes, cooling is not required.	<u>ME</u> 8-17-20	<u>ES</u> 8-17-20
33.	Collect a Bio rinse sample from discharge hose at the end of the discharge process.	<u>ME</u> 8-17-20	<u>ES</u> 8-17-20
34.	Discharge remaining rinse water to totes.	<u>ME</u> 8-17-20	<u>ES</u> 8-17-20
Note: If this is a re-sanitization only N/A steps 35 thru 44.			
Final Rinse			
35.	Add 3785 kg (~1000 gallons) of LB100PUR from UT2 to B13.		
36.	Connect together the infeed and discharge hoses used in the blend process to join infeed and discharge pump lines.	<u>KH</u> 8-17-20	
37.	With both pumps shut down, direct the 3-way discharge/recirculation valve to the discharge position.	<u>ME</u> 8-17-20	

Cleaning & Sanitization Log –
No More Pills

Work center: B13

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Steps	Parameters	Performed By	Verified By
38.	Run the infeed pump at 30 Hz and discharge/ recirculation pump at 40 Hz to recirculate the Hot Water rinse throughout all infeed and discharge piping for 10 minutes. Start Time: _____ am/pm Stop Time: _____ am/pm		
39.	Shut down both pumps. Direct the 3-way discharge/ recirculation valve to the recirculation position. Start the discharge/ recirculation pump and run it at 106.8 Hz;		
40.	Mix and Recirculate the Hot Water through the recirculation line for 10 minutes. Start Time: _____ am/pm Stop Time: _____ am/pm While the system is recirculating, move the 3-way valve handle no more than 45° toward the discharge position, and then immediately turn it back to the recirculation position. Cycle the valve three (3) times.	<i>11 8-17-20</i>	
41.	Stop the recirculation pump, and then momentarily run it in reverse at 80 Hz to clear the contents of the recirculation piping. Do not run the pump dry.		
42.	Direct the 3-way discharge/ recirculation valve to the discharge position.		
43.	If discharging to disposable totes, contents must be <110° F. If discharging to stainless steel totes, cooling is not required.		
44.	Collect rinse sample from discharge hose at the end of the discharge process for Conductivity testing.		

**Cleaning & Sanitization Log –
No More Pills**

Work center: B13

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Steps	Parameters	Performed By	Verified By
45.	MICRO SWAB SAMPLING - Using a microbial swab, swab an area (4 x 4 inch) for micro testing. Label all samples. Note Micro: if a 4 x 4 area cannot be reached, document the area swabbed in the "performed by" column before initial and dating	ME 8-17-20	ES 8-17-20
46.	Swab Lid of tank	ME 8-17-20	ES 8-17-20
47.	Swab bottom of side sweep cross bar, left side.	ME 8-17-20	ES 8-17-20
48.	Swab midway down T bar agitator.	ME 8-17-20	ES 8-17-20
49.	Swab behind lower backside of baffle.	ME 8-17-20	ES 8-17-20
50.	Swab inside B13 side of wall.	ME 8-17-20	ES 8-17-20
51.	Swab inside the end of the discharge hose.	ME 8-17-20	ES 8-17-20
52.	Swab inside infeed hose.	ME 8-17-20	ES 8-17-20
53.	Swab inside 3-way discharge valve.	ME 8-17-20	ES 8-17-20
MARKING and CLOSE OUT ACTIVITIES			
54.	Disconnect B13 drop to UT2 system	ME 8-17-20	ES 8-17-20
55.	Place a tag indicating status of equipment work center. Tag to include date of listed status, use by date or requirement prior to use. Note: Sanitization is only for 24 hrs.	ME 8-17-20	ES 8-17-20
56.	Marking of tank verified by Supervisor	Q221120	
57.	Cleaning and Sanitization Activities verified by Supervisor	Q221120	8/17/20

Aphena Pharma Solutions Work Instruction

No More Pills Test Method for Determination of pH of Headache Man	Document ID WILAB208	Revision 0
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Signatures

Name	Title	Signature	Date
Bridget Trahan	Stability Program Coordinator	/s/Bridget Trahan/s/	6/25/20
Amanda L. Jenkins	Laboratory Manager	/s/Amanda L. Jenkins/s/	6/25/20
Sanjay Nimkar	Director QA, Aphena	/s/Sanjay Nimkar/s/	6/25/20

1 PURPOSE

This method is used to determine the pH of No More Pills Headache Man.

2 SCOPE

This method applies to No More Pills Headache Man samples submitted for pH testing.

3 PERSONNEL TRAINING AND QUALIFICATIONS

An analyst who has demonstrated proficiency in use of pH meters; proficiency in physical testing is demonstrated by training record documentation and/or experience.

4 REAGENTS AND STANDARDS

- pH Buffer 2.00, ISO Certified, purchased from Fisher Scientific, Ricca Catalog #1493-16, or equivalent
- pH Buffer 4.00, ISO Certified, purchased from Fisher Scientific, Ricca Catalog #1501-16, or equivalent
- pH Buffer 5.00, ISO Certified, purchased from Fisher Scientific, Ricca Catalog #1505-16, or equivalent
- pH Buffer 7.00, ISO Certified, purchased from Fisher Scientific, Ricca Catalog #1551-16, or equivalent

5 APPARATUS AND EQUIPMENT

- Calibrated digital thermometer capable of reading to 0.1°C
- Calibrated pH meter with suitable electrode
- Beaker
- Volumetric pipette, graduated cylinder or equivalent

6 SAFETY PRECAUTIONS AND WASTE HANDLING

- Follow all general laboratory procedures. Wear all appropriate Personal Protective Equipment (PPE) including safety glasses, gloves, and lab coats. Read all Safety Data Sheets (SDS) for all reagents and test samples.
- All laboratory waste is accumulated, managed, and disposed of in accordance with all federal, state, and local laws and regulations.

7 PROCEDURE

7.1 No More Pills Headache Man

7.1.1 pH Standardization

Aphena Pharma Solutions Work Instruction

No More Pills Test Method for Determination of pH of Headache Man	DocumentID WILAB208	Revision 0
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- If pH meter standardization to cover the range of 2.00 to 7.00 has not been completed for the day, standardize the pH meter according to WILAB08, ensuring that buffer pH 2.00 (section 4.1) has been included in the standardization procedure
- Perform a system suitability check by analyzing pH buffer 5.00. Result must be within ± 0.05 pH units of the theoretical value in order to continue to sample.

7.1.2 Solution Analysis

- Follow 7.1.1 for pH Standardization.
- Transfer an aliquot of approximately 10 mL of the Headache Man solution to a glass container. Add 20mL of distilled water to the container with the solution. Place a small stir bar in the container. Place the container with stir bar on a stir plate and then submerge the probe in the stirring liquid for measurement.
- Test the solution using a suitable pH meter. Equilibrate the sample at 23-25°C prior to reading the pH. Sample solutions are stirred during pH readings.

8 DATA ANALYSIS

Report the result to one decimal place.

9 REVISION HISTORY

9.1 Revision 0 – per DCC# 20-760

- New Document.

WIIAB199-Acetaminophen Assay

WO# 106705B

Part# LB-NMPHM01

Lot# FB- Lot#2023001-B-M-E

LN497/105-106 and LN509-77

Acetaminophen

Std Areas	
Standard-Injection-1	320380
Standard-Injection-2	320694
Standard-Injection-3	320561
Standard-Injection-4	320489
Standard-Injection-5	320408
Average	320506
RSD (%)	0.040

Bracket Std Area		% Recovery Bracket Std:	
319742		99.8	

Acetaminophen Assay

Sample ID	Sample Area	Nominal (mg/mL)	Results (mg/mL)	Results (%-Recovery)
Reference Standard-USP-Lot#K2M244-Calibration Standard	321651	13.0	13.0	100.0
Reference Standard-USP-Lot#K2M244-Check Standard	322424	13.0	13.0	100.0
FB-No more pills headache-Lot# 2023001-Beginning	311778	13.0	12.5	98.2
FB-No more pills headache-Lot# 2023001-Middle	310502	13.0	12.7	97.8
FB-No more pills headache-Lot# 2023001-End	310601	13.0	12.9	99.5

Weight/Volume	Methanol/Diluent	Final Concentration	Corrected Concentration
Sample and standard preparation	(g/mL)	(mL)	(mg/mL)
Reference Standard-USP-Lot#K2M244-Calibration Standard	0.010101	100.0	0.0101
Reference Standard-USP-Lot#K2M244-Check Standard	0.010101	100.0	0.0101
FB-No more pills headache-Lot# 2023001-Beginning	0.770	100.0	0.01001
FB-No more pills headache-Lot# 2023001-Middle	0.770	100.0	0.01001
FB-No more pills headache-Lot# 2023001-End	0.770	100.0	0.01001

Reference standard was prepared in Methanol and diluted in diluent (1:3 Methanol : DI water) by 10X

No more pills headache man product samples were prepared in methanol and further diluted in diluent (1:3 Methanol : DI water) by 10X

Reference standard Acetaminophen Lot# K2M244-purity is 99.8%

no more pills headache man product concentrations is 13.0 mg/mL (650mg/50mL)

Results=(ru/rs)x(cs/cu)x100

ru=peak area of Acetaminophen from the sample

rs=peak area of Acetaminophen from the standard

cs= concentration of USP Acetaminophen RS in the standard solution (mg/mL)

cu= concentration of Acetaminophen in the sample solution (mg/mL)

Note: The Check standard solution was prepared using Calibration stock solution since there is no requirement for this in the system suitability.

8/19/2020 9:06 AM

081820_SS_Acetaminophen in Acetaminophen on EMPOWER3 as abul22/Analyst - Alter Sample Set

Vial	Inj Vol (uL)	# of Injs	Label	SampleName	Sample Type	Level	Function	Method Set / Report or Export Method	Label Reference
1	51	10.0	1	a priming	Unknown		Inject Samples	081820_MS_Acetaminophen	
2	50	10.0	1	a Diluent	Unknown		Inject Samples	081820_MS_Acetaminophen	
3	51	10.0	5	a Standard	Unknown		Inject Samples	081820_MS_Acetaminophen	
4	50	10.0	1	a Diluent	Unknown		Inject Samples	081820_MS_Acetaminophen	
5	52	10.0	1	a Check-Std	Unknown		Inject Samples	081820_MS_Acetaminophen	
6	52	10.0	1	a Check-Std	Unknown		Inject Samples	081820_MS_Acetaminophen	
7	50	10.0	1	a Diluent	Unknown		Inject Samples	081820_MS_Acetaminophen	
8	53	10.0	1	a Finished Blend Lot 2023001 Beg	Unknown		Inject Samples	081820_MS_Acetaminophen	
9	54	10.0	1	a Finished Blend Lot 2023001 Midd	Unknown		Inject Samples	081820_MS_Acetaminophen	
10	55	10.0	1	a Finished Blend Lot 2023001 End	Unknown		Inject Samples	081820_MS_Acetaminophen	
11	56	10.0	1	a Standard	Unknown		Inject Samples	081820_MS_Acetaminophen	
12							Condition Column	Wash_2998_PDA	
13							Condition Column	Shut Down MS	
14							Clear Calibration	081820_MS_Acetaminophen	
15							Quantitate	081820_MS_Acetaminophen	a*

	Processing	SampleWeight	Dilution	Altered
1	Normal	1.0000	1.0000	<input checked="" type="checkbox"/>
2	Don't Process or Report	1.0000	1.0000	<input checked="" type="checkbox"/>
3	Don't Process or Report	1.0000	1.0000	<input checked="" type="checkbox"/>
4	Don't Process or Report	1.0000	1.0000	<input checked="" type="checkbox"/>
5	Don't Process or Report	1.0000	1.0000	<input checked="" type="checkbox"/>
6	Don't Process or Report	1.0000	1.0000	<input checked="" type="checkbox"/>
7	Don't Process or Report	1.0000	1.0000	<input checked="" type="checkbox"/>
8	Don't Process or Report	1.0000	1.0000	<input checked="" type="checkbox"/>
9	Don't Process or Report	1.0000	1.0000	<input checked="" type="checkbox"/>
10	Don't Process or Report	1.0000	1.0000	<input checked="" type="checkbox"/>
11	Don't Process or Report	1.0000	1.0000	<input checked="" type="checkbox"/>
12				<input type="checkbox"/>
13				<input type="checkbox"/>
14	Normal			<input type="checkbox"/>
15	Normal			<input type="checkbox"/>

08-19-20

WILAB199-Acetaminophen Assay		
WO#	106705B	LN497/105-106 and LN509-77
Part#	LB-NMPhM01	
Lot#	FB- Lot#2023001-B-M-E	

SAMPLE INFORMATION

Sample Type: Unknown
 Vial: 50, 55, 56, 52, 53, 51, 54

Acquired By: alex15
 Sample Set Name: 081820_SS_Acetaminophen
 Acq. Method Set: 081820_MS_Acetaminophen
 Run Time: 25.0 Minutes

Area Summarized by Name
Channel: 2998 Ch1 230nm@4.8nm

	SampleName	Inj	Channel	Vial	Acetaminophen
1	priming	1	2998 Ch1 230nm@4.8nm	51	320865
2	Standard	1	2998 Ch1 230nm@4.8nm	56	319742
3	Standard	1	2998 Ch1 230nm@4.8nm	51	320380
4	Standard	2	2998 Ch1 230nm@4.8nm	51	320694
5	Standard	3	2998 Ch1 230nm@4.8nm	51	320561
6	Standard	4	2998 Ch1 230nm@4.8nm	51	320489
7	Standard	5	2998 Ch1 230nm@4.8nm	51	320408
8	Diluent	1	2998 Ch1 230nm@4.8nm	50	
9	Check-Std	1	2998 Ch1 230nm@4.8nm	52	321651
10	Check-Std	1	2998 Ch1 230nm@4.8nm	52	322424
11	Diluent	1	2998 Ch1 230nm@4.8nm	50	
12	Finished Blend Lot 2023001 Beg	1	2998 Ch1 230nm@4.8nm	53	311778
13	Finished Blend Lot 2023001 Midd	1	2998 Ch1 230nm@4.8nm	54	310502
14	Finished Blend Lot 2023001 End	1	2998 Ch1 230nm@4.8nm	55	316061
15	Diluent	1	2998 Ch1 230nm@4.8nm	50	
Mean					318796
Std. Dev.					3893
% RSD					1.2

Sample Set: 081820_SS_Acetaminophen*Arc 08-19-20*General Information

Sample Set Name 081820_SS_Acetaminophen
 Sample Set Method 081820_SS_Acetaminophen
 Sample Set Start Date 8/18/2020 8:01:00 PM EDT
 Sample Set Finish Date 8/19/2020 3:20:07 AM EDT
 Sample Set Id 3291
 Sample Set Acquired By alex15
 Sample Set Altered Yes
 Sample Set Acquiring No
 Sample Set Type Acquired
 Sample Set Current Id 3291

WILAB199-Acetaminophen Assay		
WO#	106705B	LN497/105-106 and LN509-77
Part#	LB-NMPHM01	
Lot#	FB- Lot#2023001-B-M-E	

Reported by User: Abul Siddiqui (abul22)

Project Name: Acetaminophen

Report Method: Area Summary Report

Date Printed:

Report Method ID 1248

8/19/2020

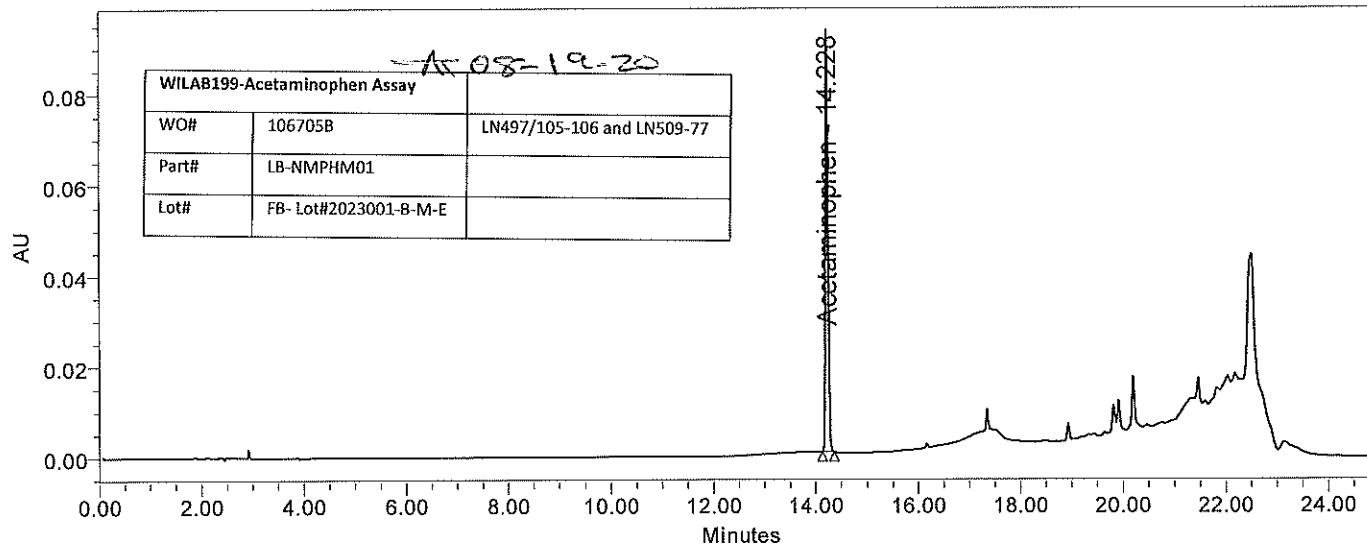
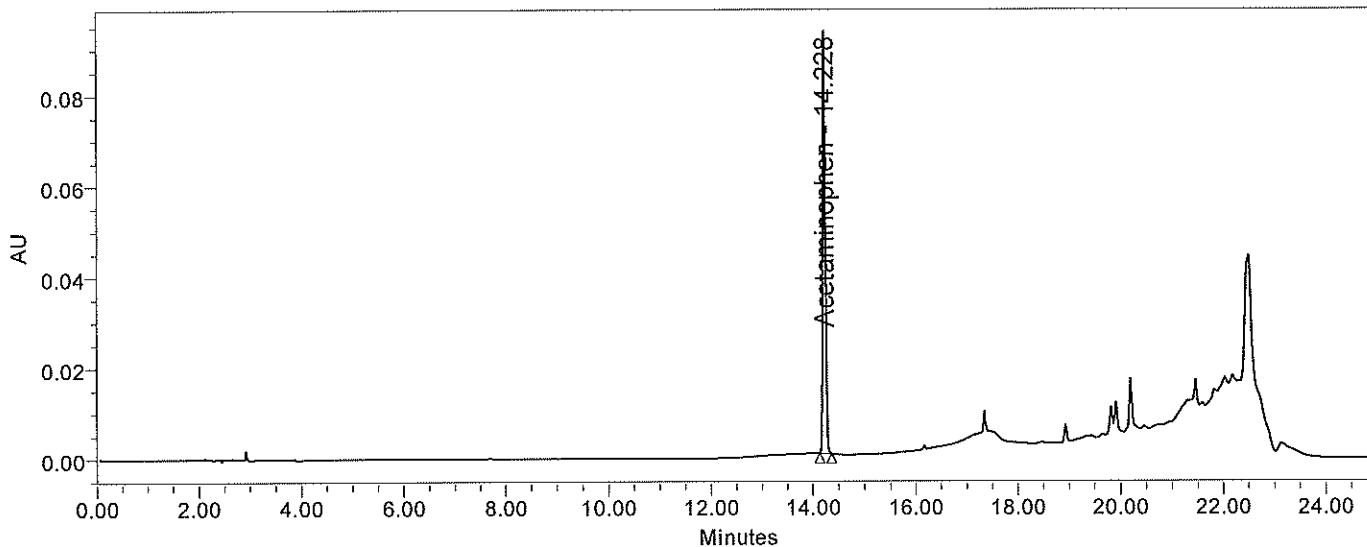
Page: 1 of 2

8:32:16 AM US/Eastern

SAMPLE INFORMATION

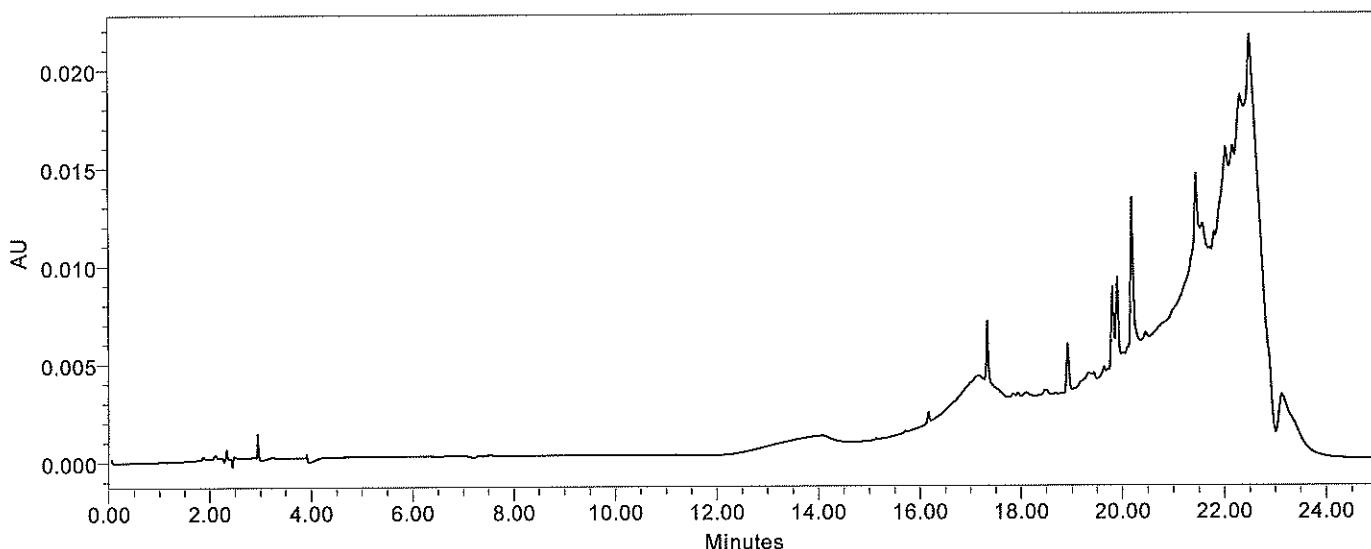
Sample Name: priming Acquired By: alex15
 Sample Type: Unknown Sample Set Name: 081820_SS_Acetaminophen
 Vial: 51 Acq. Method Set: 081820_MS_Acetaminophen
 Injection #: 1 Processing Method: 081820_PM_Acetaminophen
 Injection Volume: 10.00 ul Channel Name: 2998 Ch1 230nm@4.8nm
 Run Time: 25.0 Minutes Proc. Chnl. Descr.: 2998 Ch1 230nm@4.8nm

 Date Acquired: 8/18/2020 8:01:50 PM EDT
 Date Processed: 8/19/2020 8:31:52 AM EDT, 8/19/2020 8:31:53 AM EDT



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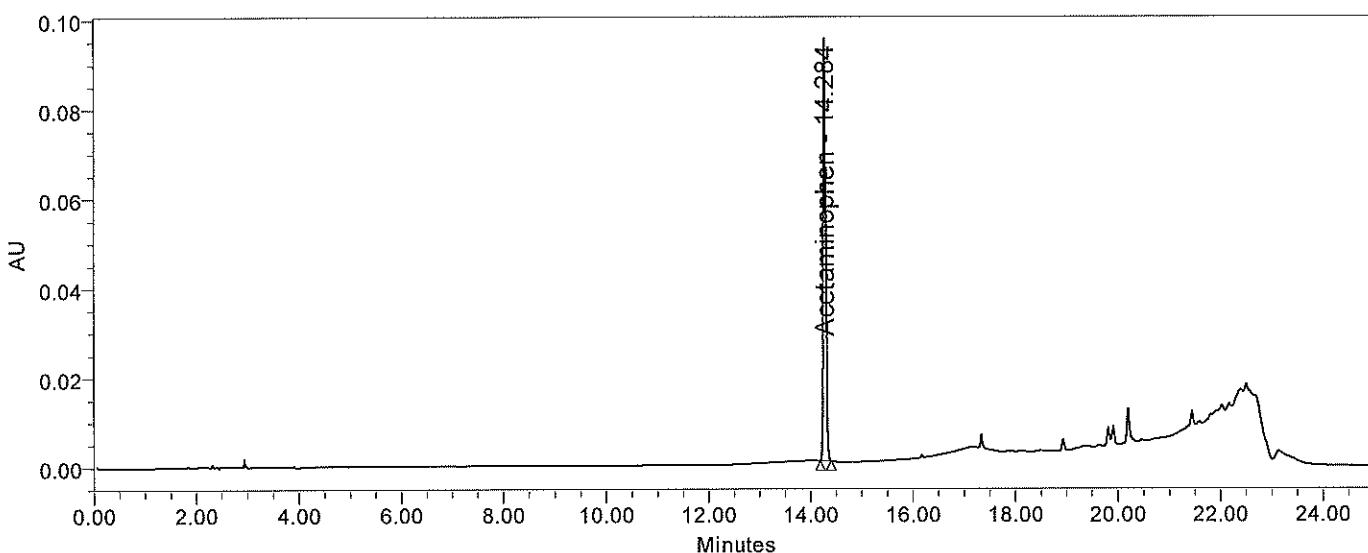
Sample Name:	Diluent	Acquired By:	alex15
Sample Type:	Unknown	Sample Set Name:	081820_SS_Acetaminophen
Vial:	50	Acq. Method Set:	081820_MS_Acetaminophen
Injection #:	1	Processing Method	081820_PM_Acetaminophen
Injection Volume:	10.00 ul	Channel Name:	2998 Ch1 230nm@4.8nm
Run Time:	25.0 Minutes	Proc. Chnl. Descr.:	2998 Ch1 230nm@4.8nm
Date Acquired:	8/18/2020 8:27:51 PM EDT		
Date Processed:	8/19/2020 8:31:54 AM EDT		



	Peak Name	RT
1	Acetaminophen	14.200

SAMPLE INFORMATION

Sample Name:	Standard	Acquired By:	alex15
Sample Type:	Unknown	Sample Set Name:	081820_SS_Acetaminophen
Vial:	51	Acq. Method Set:	081820_MS_Acetaminophen
Injection #:	2	Processing Method	081820_PM_Acetaminophen
Injection Volume:	10.00 ul	Channel Name:	2998 Ch1 230nm@4.8nm
Run Time:	25.0 Minutes	Proc. Chnl. Descr.:	2998 Ch1 230nm@4.8nm
Date Acquired:	8/18/2020 9:19:39 PM EDT		
Date Processed:	8/19/2020 8:31:55 AM EDT		

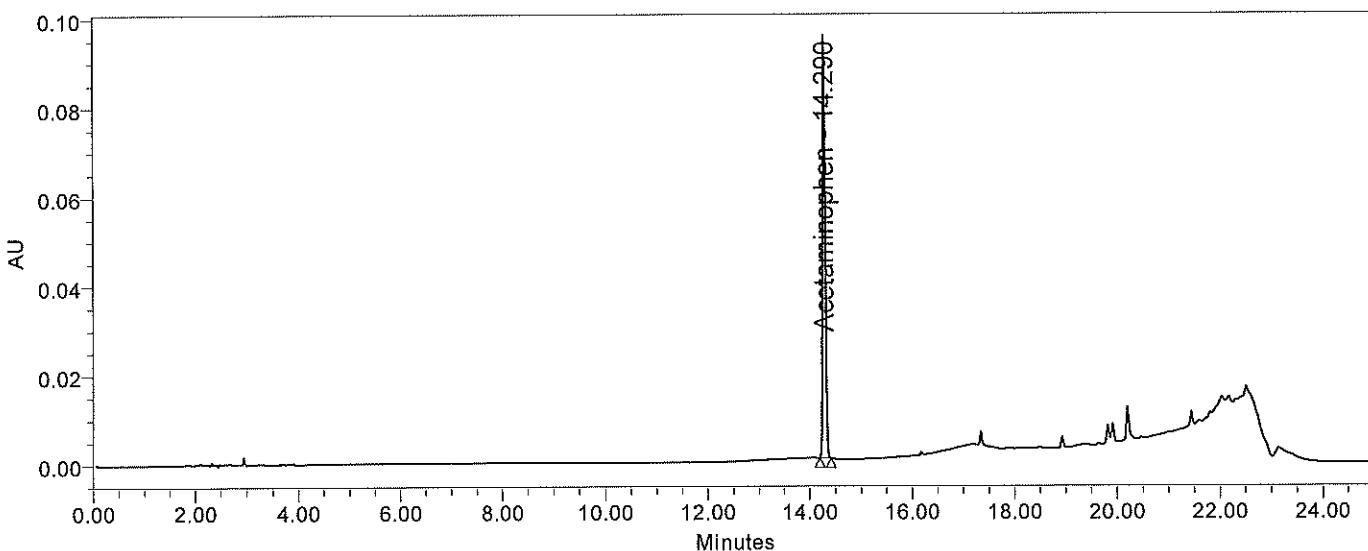


	Peak Name	RT	Area	% Area	Height	USP s/n	USP Tailing
1	Acetaminophen	14.284	320694	100.00	94537	0.92	1.0

	USP Plate Count
1	407283.9

SAMPLE INFORMATION

Sample Name:	Standard	Acquired By:	alex15
Sample Type:	Unknown	Sample Set Name:	081820_SS_Acetaminophen
Vial:	51	Acq. Method Set:	081820_MS_Acetaminophen
Injection #:	4	Processing Method	081820_PM_Acetaminophen
Injection Volume:	10.00 ul	Channel Name:	2998 Ch1 230nm@4.8nm
Run Time:	25.0 Minutes	Proc. Chnl. Descr.:	2998 Ch1 230nm@4.8nm
Date Acquired:	8/18/2020 10:11:27 PM EDT		
Date Processed:	8/19/2020 8:31:55 AM EDT		

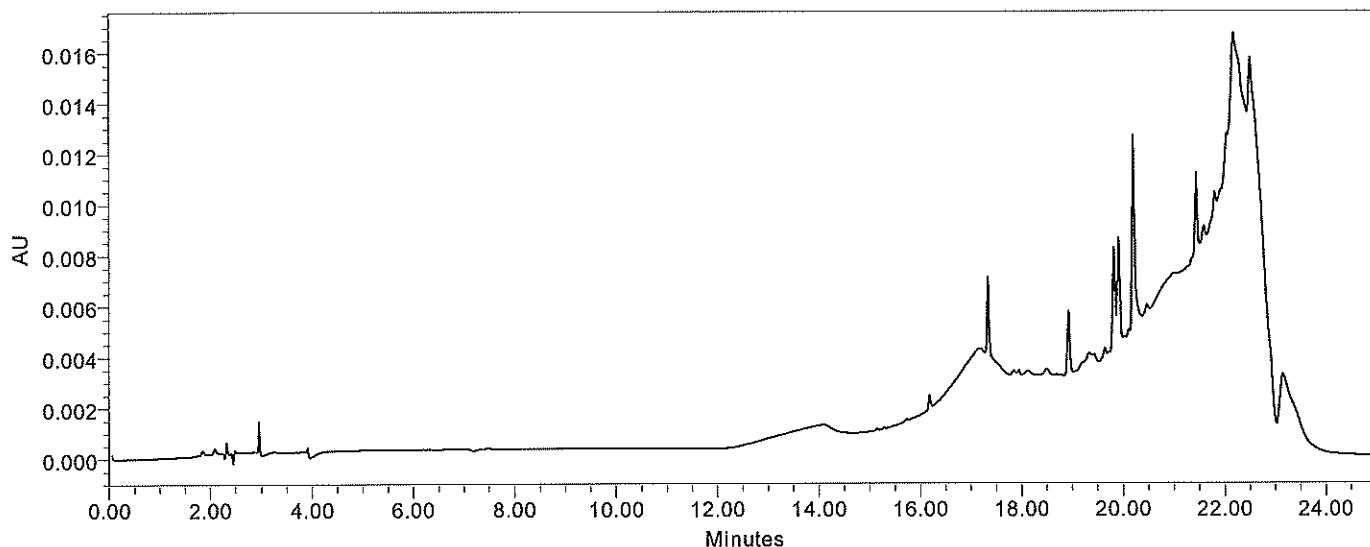


	Peak Name	RT	Area	% Area	Height	USP s/n	USP Tailing
1	Acetaminophen	14.290	320489	100.00	94690	0.92	1.0

	USP Plate Count
1	409651.2

SAMPLE INFORMATION

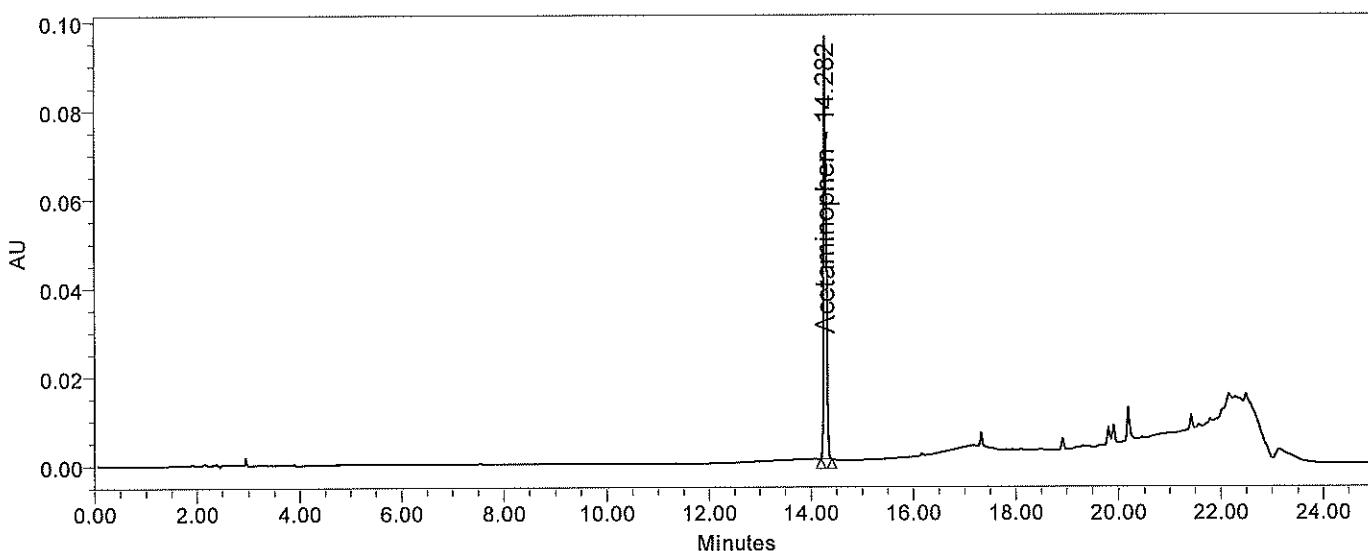
Sample Name:	Diluent	Acquired By:	alex15
Sample Type:	Unknown	Sample Set Name:	081820_SS_Acetaminophen
Vial:	50	Acq. Method Set:	081820_MS_Acetaminophen
Injection #:	1	Processing Method	081820_PM_Acetaminophen
Injection Volume:	10.00 ul	Channel Name:	2998 Ch1 230nm@4.8nm
Run Time:	25.0 Minutes	Proc. Chnl. Descr.:	2998 Ch1 230nm@4.8nm
Date Acquired:	8/18/2020 11:03:22 PM EDT		
Date Processed:	8/19/2020 8:31:56 AM EDT		



	Peak Name	RT
1	Acetaminophen	14.200

SAMPLE INFORMATION

Sample Name:	Check-Std	Acquired By:	alex15
Sample Type:	Unknown	Sample Set Name:	081820_SS_Acetaminophen
Vial:	52	Acq. Method Set:	081820_MS_Acetaminophen
Injection #:	1	Processing Method	081820_PM_Acetaminophen
Injection Volume:	10.00 ul	Channel Name:	2998 Ch1 230nm@4.8nm
Run Time:	25.0 Minutes	Proc. Chnl. Descr.:	2998 Ch1 230nm@4.8nm
Date Acquired:	8/18/2020 11:55:12 PM EDT		
Date Processed:	8/19/2020 8:31:57 AM EDT		

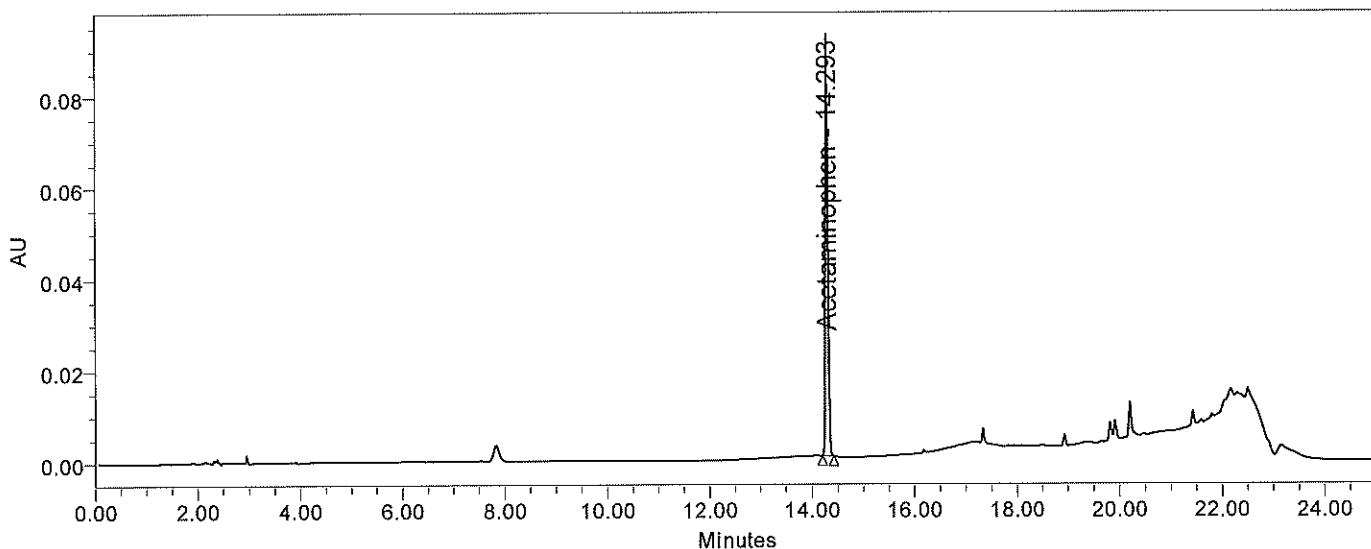


	Peak Name	RT	Area	% Area	Height	USP s/n	USP Tailing
1	Acetaminophen	14.282	322424	100.00	95205	0.92	1.0

	USP Plate Count
1	408694.1

SAMPLE INFORMATION

Sample Name:	Finished Blend Lot 2023001 Beg	Acquired By:	alex15
Sample Type:	Unknown	Sample Set Name:	081820_SS_Acetaminophen
Vial:	53	Acq. Method Set:	081820_MS_Acetaminophen
Injection #:	1	Processing Method	081820_PM_Acetaminophen
Injection Volume:	10.00 ul	Channel Name:	2998 Ch1 230nm@4.8nm
Run Time:	25.0 Minutes	Proc. Chnl. Descr.:	2998 Ch1 230nm@4.8nm
Date Acquired:	8/19/2020 12:47:00 AM EDT		
Date Processed:	8/19/2020 8:31:57 AM EDT		

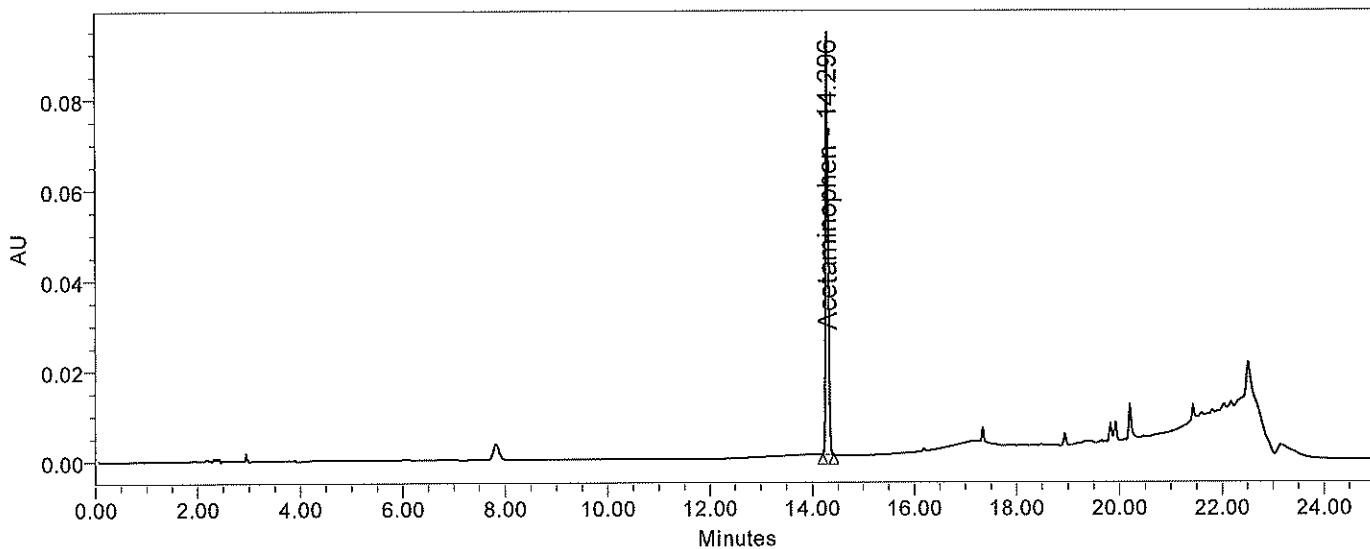


	Peak Name	RT	Area	% Area	Height	USP s/n	USP Tailing
1	Acetaminophen	14.293	311778	100.00	92346	0.92	1.0

	USP Plate Count
1	411878.6

SAMPLE INFORMATION

Sample Name:	Finished Blend Lot 2023001 End	Acquired By:	alex15
Sample Type:	Unknown	Sample Set Name:	081820_SS_Acetaminophen
Vial:	55	Acq. Method Set:	081820_MS_Acetaminophen
Injection #:	1	Processing Method	081820_PM_Acetaminophen
Injection Volume:	10.00 ul	Channel Name:	2998 Ch1 230nm@4.8nm
Run Time:	25.0 Minutes	Proc. Chnl. Descr.:	2998 Ch1 230nm@4.8nm
Date Acquired:	8/19/2020 1:38:44 AM EDT		
Date Processed:	8/19/2020 8:31:58 AM EDT		



	Peak Name	RT	Area	% Area	Height	USP s/n	USP Tailing
1	Acetaminophen	14.296	316061	100.00	93475	0.92	1.0

	USP Plate Count
1	410808.4

Vial: 51, Sample Name: primingVial Information

Vial	51	Original Vial Id	3292	Dilution	1.0000
Sample Type	Unknown	Comments	run	Sample Matrix	
Level		Blank	No	SampleName	priming
Label	a	Peak Ratio Reference	No	SampleWeight	1.0000
Vial Id	3334	Column Name			
Altered	Yes	Column Serial Number			

Sample History

User: abul22 Date: 8/19/2020 8:29:22 AM EDT Reason: update

Modified Vial(Label): <No Value> -> a

Acquisition Log

Acquired By	alex15
Injection	1
Date Acquired	8/18/2020 8:01:50 PM EDT
Run Time	25.00(Minutes)
Acq Method Set	081820_MS_Acetaminophen
Injection Volume	10.00(uL)
Barcode / BCD	
Auto Additions	
Injection Id	3293
Instrument Method Id	3289
Instrument Method Name	IM_Acetomin 081820 B_2998 PDA
Superseded	No
# of Process Only Sample Sets	0
Injection Status	Complete
eCord Name	
eCord Serial Number	
eCord Injection Count (Lifetime to Date)	
eCord Sample Count (Lifetime to Date)	
eCord Maximum Pressure (Lifetime to Date)	(psi)
eCord Maximum Temperature (Lifetime to Date)	(°C)
Use Syringe Settings	
Syringe Size A (uL)	
Nanoliter Adapter A	
Syringe Size B (uL)	
Nanoliter Adapter B	

WILAB199-Acetaminophen Assay		
WO#	106705B	LN497/105-106 and LN509-77
Part#	LB-NMPHM01	
Lot#	FB- Lot#2023001-B-M-E	

Vial: 51, Sample Name: Standard

Vial Information

Vial	51	Peak Ratio Reference	No
Sample Type	Unknown	Column Name	XTerra C18 4.6x250mm, 5μ
Level		Column Serial Number	
Label	a	Dilution	1.0000
Vial Id	3336	Sample Matrix	
Altered	Yes	SampleName	Standard
Original Vial Id	3298	SampleWeight	1.0000
Comments	run		
Blank	No		

Sample History

User: abul22 Date: 8/19/2020 8:29:22 AM EDT Reason: update
Modified Vial(Label): <No Value> -> a

Acquisition Log

Acquired By	alex15
Injection	1
Date Acquired	8/18/2020 8:53:45 PM EDT
Run Time	25.00(Minutes)
Acq Method Set	081820_MS_Acetaminophen
Injection Volume	10.00(µL)
Barcode / BCD	
Auto Additions	
Injection Id	3299
Instrument Method Id	3289
Instrument Method Name	IM_Acetomin 081820 B_2998 PDA
Superseded	No
# of Process Only Sample Sets	0
Injection Status	Complete
eCord Name	
eCord Serial Number	
eCord Injection Count (Lifetime to Date)	
eCord Sample Count (Lifetime to Date)	
eCord Maximum Pressure (Lifetime to Date) (psi)	
eCord Maximum Temperature (Lifetime to Date) (°C)	
Use Syringe Settings	
Syringe Size A (µL)	
Nanoliter Adapter A	
Syringe Size B (µL)	
Nanoliter Adapter B	

Vial: 51, Sample Name: Standard

Vial Information

Vial	51	Peak Ratio Reference	No
Sample Type	Unknown	Column Name	XTerra C18 4.6x250mm, 5μ
Level		Column Serial Number	
Label	a	Dilution	1.0000
Vial Id	3336	Sample Matrix	
Altered	Yes	SampleName	Standard
Original Vial Id	3298	SampleWeight	1.0000
Comments	run		
Blank	No		

Sample History

User: abul22 Date: 8/19/2020 8:29:22 AM EDT Reason: update
Modified Vial(Label): <No Value> -> a

Acquisition Log

Acquired By	alex15
Injection	3
Date Acquired	8/18/2020 9:45:33 PM EDT
Run Time	25.00(Minutes)
Acq Method Set	081820_MS_Acetaminophen
Injection Volume	10.00(µL)
Barcode / BCD	
Auto Additions	
Injection Id	3303
Instrument Method Id	3289
Instrument Method Name	IM_Acetomin 081820 B_2998 PDA
Superseded	No
# of Process Only Sample Sets	0
Injection Status	Complete
eCord Name	
eCord Serial Number	
eCord Injection Count (Lifetime to Date)	
eCord Sample Count (Lifetime to Date)	
eCord Maximum Pressure (Lifetime to Date) (psi)	
eCord Maximum Temperature (Lifetime to Date) (°C)	
Use Syringe Settings	
Syringe Size A (µL)	
Nanoliter Adapter A	
Syringe Size B (µL)	
Nanoliter Adapter B	

Vial: 51, Sample Name: Standard

Vial Information

Vial	51	Peak Ratio Reference	No
Sample Type	Unknown	Column Name	XTerra C18 4.6x250mm, 5μ
Level		Column Serial Number	
Label	a	Dilution	1.0000
Vial Id	3336	Sample Matrix	
Altered	Yes	SampleName	Standard
Original Vial Id	3298	SampleWeight	1.0000
Comments	run		
Blank	No		

Sample History

User: abul22 Date: 8/19/2020 8:29:22 AM EDT Reason: update
Modified Vial(Label): <No Value> -> a

Acquisition Log

Acquired By	alex15
Injection	5
Date Acquired	8/18/2020 10:37:22 PM EDT
Run Time	25.00(Minutes)
Acq Method Set	081820_MS_Aacetaminophen
Injection Volume	10.00(µL)
Barcode / BCD	
Auto Additions	
Injection Id	3307
Instrument Method Id	3289
Instrument Method Name	IM_Aacetomin 081820 B_2998 PDA
Superseded	No
# of Process Only Sample Sets	0
Injection Status	Complete
eCord Name	
eCord Serial Number	
eCord Injection Count (Lifetime to Date)	
eCord Sample Count (Lifetime to Date)	
eCord Maximum Pressure (Lifetime to Date) (psi)	
eCord Maximum Temperature (Lifetime to Date) (°C)	
Use Syringe Settings	
Syringe Size A (µL)	
Nanoliter Adapter A	
Syringe Size B (µL)	
Nanoliter Adapter B	

Vial: 52, Sample Name: Check-Std

Vial Information

Vial	52	Peak Ratio Reference	No
Sample Type	Unknown	Column Name	XTerra C18 4.6x250mm, 5μ
Level		Column Serial Number	
Label	a	Dilution	1.0000
Vial Id	3338	Sample Matrix	
Altered	Yes	SampleName	Check-Std
Original Vial Id	3312	SampleWeight	1.0000
Comments	run		
Blank	No		

Sample History

User: abul22 Date: 8/19/2020 8:29:22 AM EDT Reason: update
Modified Vial(Label): <No Value> -> a

Acquisition Log

Acquired By	alex15
Injection	1
Date Acquired	8/18/2020 11:29:17 PM EDT
Run Time	25.00(Minutes)
Acq Method Set	081820_MS_Acetaminophen
Injection Volume	10.00(µL)
Barcode / BCD	
Auto Additions	
Injection Id	3313
Instrument Method Id	3289
Instrument Method Name	IM_Acetomin 081820 B_2998 PDA
Superseded	No
# of Process Only Sample Sets	0
Injection Status	Complete
eCord Name	
eCord Serial Number	
eCord Injection Count (Lifetime to Date)	
eCord Sample Count (Lifetime to Date)	
eCord Maximum Pressure (Lifetime to Date) (psi)	
eCord Maximum Temperature (Lifetime to Date) (°C)	
Use Syringe Settings	
Syringe Size A (µL)	
Nanoliter Adapter A	
Syringe Size B (µL)	
Nanoliter Adapter B	

Vial: 50, Sample Name: Diluent

Vial Information

Vial	50	Peak Ratio Reference	No
Sample Type	Unknown	Column Name	XTerra C18 4.6x250mm, 5μ
Level		Column Serial Number	
Label	a	Dilution	1.0000
Vial Id	3340	Sample Matrix	
Altered	Yes	SampleName	Diluent
Original Vial Id	3318	SampleWeight	1.0000
Comments	run		
Blank	No		

Sample History

User: abul22 Date: 8/19/2020 8:29:22 AM EDT Reason: update

Modified Vial(Label): <No Value> -> a

Acquisition Log

Acquired By	alex15
Injection	1
Date Acquired	8/19/2020 12:21:05 AM EDT
Run Time	25.00(Minutes)
Acq Method Set	081820_MS_Acetaminophen
Injection Volume	10.00(uL)
Barcode / BCD	
Auto Additions	
Injection Id	3319
Instrument Method Id	3289
Instrument Method Name	IM_Acetomin 081820 B_2998 PDA
Superseded	No
# of Process Only Sample Sets	0
Injection Status	Complete
eCord Name	
eCord Serial Number	
eCord Injection Count (Lifetime to Date)	
eCord Sample Count (Lifetime to Date)	
eCord Maximum Pressure (Lifetime to Date) (psi)	
eCord Maximum Temperature (Lifetime to Date) (°C)	
Use Syringe Settings	
Syringe Size A (uL)	
Nanoliter Adapter A	
Syringe Size B (uL)	
Nanoliter Adapter B	

Vial: 54, Sample Name: Finished Blend Lot 2023001 Midd**Vial Information**

Vial 54
 Sample Type Unknown
 Level
 Label a
 Vial Id 3342
 Altered Yes
 Original Vial Id 3324
 Comments run
 Blank No
 Peak Ratio Reference No
 Column Name Xterra C18 4.6x250mm, 5 μ
 Column Serial Number
 Dilution 1.0000
 Sample Matrix
 SampleName Finished Blend Lot 2023001 Midd
 SampleWeight 1.0000

Sample History

User: abul22 Date: 8/19/2020 8:29:22 AM EDT Reason: update
 Modified Vial(Label): <No Value> -> a

Acquisition Log

Acquired By alex15
 Injection 1
 Date Acquired 8/19/2020 1:12:55 AM EDT
 Run Time 25.00(Minutes)
 Acq Method Set 081820_MS_Acetaminophen
 Injection Volume 10.00(μ L)
 Barcode / BCD
 Auto Additions
 Injection Id 3325
 Instrument Method Id 3289
 Instrument Method Name IM_Acetomin 081820 B_2998 PDA
 Superseded No
 # of Process Only Sample Sets 0
 Injection Status Complete
 eCord Name
 eCord Serial Number
 eCord Injection Count (Lifetime to Date)
 eCord Sample Count (Lifetime to Date)
 eCord Maximum Pressure (Lifetime to Date) (psi)

Waters Column Calculator

Original Method

Column Dimensions: 4.6 mm x 100 mm, 3 µm

Injection Volume: 10.0 µL

Temperature: 35 °C

Run Time: 15.00 min

Dwell Volume: 1.000 mL

Pressure: 2,291 psi

Time (min)	Flow Rate (mL/min)	%A	%B	Column Volumes
0.00	1.000	99.0	1.0	0.00
3.00	1.000	99.0	1.0	2.74
7.00	1.000	19.0	81.0	3.65
7.10	1.000	99.0	1.0	0.09
15.00	1.000	99.0	1.0	7.20

Target Method

Column Dimensions: 4.6 mm x 250 mm, 5 µm

Injection Volume: 25.0 µL

Dwell Volume: 1.000 mL

Pressure: 1,856 psi

Run Time: 41.67 min

Suggested Hold: 0 µL

Pre-injection Volume: 0 µL

Time (min)	Flow Rate (mL/min)	%A	%B	Column Volumes
0.00	0.900	99.0	1.0	0.00
8.33	0.900	99.0	1.0	2.74
19.44	0.900	19.0	81.0	3.65
19.72	0.900	99.0	1.0	0.09
41.67	0.900	99.0	1.0	7.20

AA 08/18/20

Aphena Pharma Solutions

Cleaning & Sanitization Log – No More Pills	Document ID	REV
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L3-NM0PHM01 Post Clean
W0106705B
Lot 2023001

APPROVED BY:

Aphena Approvals				
Department	Print Name	Title	Signature	Date
Author	Megan Kunkowski	Technical Services Specialist	/s/Megan Kunkowski/s/	8/13/20
Reviewer	Rafeh Raza	Sr. Tech. Services Specialist	/s/Rafeh Raza/s/	8/13/20
Reviewer	Amanda Jenkins	Laboratory Manager	/s/Amanda Jenkins/s/	8/13/20
Reviewer	Julie Curie	Microbiology Supervisor	/s/Julie Curie/s/	8/13/20
Reviewer	Jerry Pappas	Blending Supervisor	/s/Jerry Pappas/s/	8/13/20
Approver	Sanjay Nimkar	Director, Q/RA	/s/Sanjay Nimkar/s/	8/13/20

Revision History:

Rev 0: New issue, Per DCC# 20-830

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Cleaning Confirmation:

- Less than 24 hrs from last clean/sanitization and no other activity in area:**
- Proceed with blend.
- Greater than 24 hrs from last clean/sanitization and no other activity in area:**
- Sanitize per F2368, starting with step 20 (TOC and Conductivity from previous clean must be passing)
- Any blending or cleaning activity in area after previous tank clean, clean and sanitize per F2368.**

Resource Requirements: Verify all resources are available to perform necessary cleaning and sanitization steps

- Contrad 100 (PX818)*
- Hot Water (UT2)
- 70% Isopropyl Alcohol (LB181)
- Required PPE (Heat resistant gauntlet gloves, safety glasses, splash shield, apron, water repellent boots, and protective coat hood)
- Disposable vinyl, rubber or nitrile gloves
- Lint free wipes
- Jars (conductivity) or dual use conductivity and TOC vial
- TOC vials or dual use conductivity and TOC vial
- Micro Swabs (sterile)
- Sterile Micro Sampling bottles
- Labels
- F1535 – Chain of Custody Form
- Tags to Mark Equipment Cleaning Required
- Tyvek sheeting to cover hose ends during the drying process
- PX961 Honeywell Chart recorder chart

Verified by Blender or Blending Supervisor (initial and date):

LL 8-19-20

*Note: Mix Contrad 100 and Water for Clean In Place Solution (CIP Solution)

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Work center: B13

To be performed by Blender and Verified by Supervisor or Second Qualified Person

Steps	Parameters	Performed By	Verified By
	Fitting, Utensils not Cleaned in Place		
1.	All ports, caps, elbows, fittings and utensils cleaned and sanitized per WILAB003.	RLH 8-19-20	ES 8-19-20
	TANK CLEANING		
2.	Collect a blank sample from the UT2 POU for TOC, conductivity and BIO for comparison testing.	LL 8-19-20	ES 8-19-20
3.	Confirm that chart recorder is operational and install a new PX961 chart	LL 8-19-20	ES 8-19-20
4.	Maintain temperature at the chart recorder at 160-180°F thru the remainder of this cleaning step	LL 8-19-20	ES 8-19-20
5.	Fill with 946 Kg (~ 250 gallons) of UT2 Hot Water.	LL 8-19-20	ES 8-19-20
6.	Using a hand sprayer containing Contrad 100 solution, spray all product contact surfaces in tank. (i.e. tank side wall, mixer blades, etc.)	LL 8-19-20	ES 8-19-20
7.	Start agitator and side sweep on slow speeds and add 2 gallons of Contrad 100 to B13	LL 8-19-20	ES 8-19-20
8.	Connect together the infeed and discharge hoses used in the blend process to join infeed and discharge pump lines	LL 8-19-20	ES 8-19-20
9.	With both pumps shut down, direct the 3-way discharge/recirculation valve to the discharge position.	LL 8-19-20	ES 8-19-20

Cleaning & Sanitization Log –

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Work center: B13

Steps	Parameters	Performed By	Verified By
10.	Run the infeed pump at 30 Hz and discharge/ recirculation pump at 40 Hz to recirculate the Hot CIP Solution throughout all infeed and discharge piping for 10 min. Start Time: <u>8:28</u> <u>am</u> /pm Stop Time: <u>8:38</u> <u>am</u> /pm	L 8-19-20	ES 8-19-20
11.	Shut down both pumps. Direct the 3-way discharge/ recirculation valve to the recirculation position. Start the discharge/ recirculation pump and run it at 106.8Hz; start agitator running at low speed settings.	L 8-19-20	ES 8-19-20
12.	Mix and Recirculate the Hot CIP Solution thru recirculation line for 10 minutes. Start Time: <u>8:42</u> <u>am</u> /pm Stop Time: <u>8:52</u> <u>am</u> /pm While the system is recirculating, move the 3-way valve handle no more than 45° toward the discharge position, and then immediately turn it back to the recirculation position. Cycle the valve three (3) times.	L 8-19-20	ES 8-19-20
13.	Shut down agitator and side sweeps.	L 8-19-20	ES 8-19-20
14.	Stop the recirculation pump, and then momentarily run it in reverse at 80 Hz to clear the contents of the B13 recirculation piping. Do not run the pump dry.	L 8-19-20	ES 8-19-20
15.	Direct the 3-way discharge/ recirculation valve to the discharge position	L 8-19-20	ES 8-19-20
16.	If discharging to disposable totes, contents must be <110° F. If discharging to stainless steel totes, cooling is not required.	L 8-19-20	ES 8-19-20
17.	Separate the infeed and discharge hoses. Connect the discharge hose to the tote. Cap the infeed hose.	L 8-19-20	ES 8-19-20
18.	Discharge the waste Hot CIP Solution to totes.	L 8-19-20	ES 8-19-20

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Work center: B13

Steps	Parameters	Performed By	Verified By
19.	While discharging into totes, using a spray hose connected to the UT2 drop loop, spray all product contact surfaces thoroughly.	LL 8-19-20	ES 8-19-20
1st Rinse/Sanitization			
20.	If this is a re-sanitization only, collect a blank sample from the UT2 POU for TOC, Conductivity and Bio for comparison testing otherwise N/A this step.	LL 8-19-20	ES 8-19-20
21.	Add 3785 Kg (~ 1000 gallons) of hot water (UT2) B13.	LL 8-19-20	ES 8-19-20
22.	Maintain temperature at the chart recorder at 180°F throughout the remainder of this sanitization step.	LL 8-19-20	ES 8-19-20
23.	Connect together the infeed and discharge hoses used in the blend process to join infeed and discharge pump lines	LL 8-19-20	ES 8-19-20
24.	Start agitator and side sweeps at low speed.	LL 8-19-20	ES 8-19-20
25.	With both pumps shut down, direct the 3-way discharge/recirculation valve to the discharge position.	LL 8-19-20	ES 8-19-20
26.	Run the infeed pump at 30 Hz and discharge/ recirculation pump at 40 Hz to recirculate the Hot Water rinse throughout all infeed and discharge piping for 20 min.	LL 8-19-20	ES 8-19-20
	Start Time: <u>11:18</u> am/pm	LL 8-19-20	ES 8-19-20
	Stop Time: <u>11:38</u> am/pm	LL 8-19-20	ES 8-19-20
27.	Shut down both pumps. Direct the 3-way discharge/ recirculation valve to the recirculation position. Start the discharge/ recirculation pump and run it at 106.8Hz; start agitator running at low speed settings.	LL 8-19-20	ES 8-19-20

**Cleaning & Sanitization Log –
No More Pills**

Work center: B13

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Steps	Parameters	Performed By	Verified By
28.	Mix and Recirculate the Hot Water thru the recirculation line for 10 minutes. Start Time: 11:40 am/pm Stop Time: 11:50 am/pm While the system is recirculating, move the 3-way valve handle no more than 45° toward the discharge position, and then immediately turn it back to the recirculation position. Cycle the valve three (3) times.	LL 8-19-20	ES 8-19-20
29.	Stop the recirculation pump, and then momentarily run it in reverse at 80 Hz to clear the contents of the recirculation piping. Do not run the pump dry.	LL 8-19-20	ES 8-19-20
30.	Shut down agitator and side sweeps.	LL 8-19-20	ES 8-19-20
31.	Direct the 3-way discharge/ recirculation valve to the discharge position.	LL 8-19-20	ES 8-19-20
32.	If discharging to disposable totes, contents must be <110° F. If discharging to stainless steel totes, cooling is not required.	LL 8-19-20	ES 8-19-20
33.	Collect a Bio rinse sample from discharge hose at the end of the discharge process.	LL 8-19-20	ES 8-19-20
34.	Discharge remaining rinse water to totes. Note: If this is a re-sanitization only N/A steps 35 thru 44.	LL 8-19-20	ES 8-19-20
Final Rinse			
35.	Add 3785 kg (~1000 gallons) of LB100PUR from UT2 to B13.	LL 8-19-20	ES 8-19-20
36.	Connect together the infeed and discharge hoses used in the blend process to join infeed and discharge pump lines.	LL 8-19-20	ES 8-19-20
37.	With both pumps shut down, direct the 3-way discharge/recirculation valve to the discharge position.	LL 8-19-20	ES 8-19-20

**Cleaning & Sanitization Log –
No More Pills**

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Steps	Parameters	Performed By	Verified By
38.	Run the infeed pump at 30 Hz and discharge/ recirculation pump at 40 Hz to recirculate the Hot Water rinse throughout all infeed and discharge piping for 10 minutes. Start Time: <u>1:39</u> am Stop Time: <u>1:49</u> am	<u>LL</u> 8-19-20	ES 8-19-20
39.	Shut down both pumps. Direct the 3-way discharge/ recirculation valve to the recirculation position. Start the discharge/ recirculation pump and run it at 106.8 Hz;	<u>LL</u> 8-19-20	ES 8-19-20
40.	Mix and Recirculate the Hot Water through the recirculation line for 10 minutes. Start Time: <u>1:51</u> am Stop Time: <u>2:01</u> am While the system is recirculating, move the 3-way valve handle no more than 45° toward the discharge position, and then immediately turn it back to the recirculation position. Cycle the valve three (3) times.	<u>LL</u> 8-19-20	ES 8-19-20
41.	Stop the recirculation pump, and then momentarily run it in reverse at 80 Hz to clear the contents of the recirculation piping. Do not run the pump dry.	<u>LL</u> 8-19-20	ES 8-19-20
42.	Direct the 3-way discharge/ recirculation valve to the discharge position.	<u>LL</u> 8-19-20	ES 8-19-20
43.	If discharging to disposable totes, contents must be <110° F. If discharging to stainless steel totes, cooling is not required.	<u>LL</u> 8-19-20	ES 8-19-20
44.	Collect rinse sample from discharge hose at the end of the discharge process for Conductivity testing.	<u>LL</u> 8-19-20	ES 8-19-20

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Work center: B13		

Steps	Parameters	Performed By	Verified By
	MICRO SWAB SAMPLING - Using a microbial swab, swab an area (4 x 4 inch) for micro testing. Label all samples. Note Micro: if a 4 x 4 area cannot be reached, document the area swabbed in the “performed by” column before initial and dating		
45.	Swab Lid of tank	LL 8-19-20	ES 8-19-20
46.	Swab agitator shaft.	LL 8-19-20	ES 8-19-20
47.	Swab bottom of side sweep cross bar, left side.	LL 8-19-20	ES 8-19-20
48.	Swab midway down T bar agitator.	LL 8-19-20	ES 8-19-20
49.	Swab behind lower backside of baffle.	LL 8-19-20	ES 8-19-20
50.	Swab inside B13 side of wall.	LL 8-19-20	ES 8-19-20
51.	Swab inside the end of the discharge hose.	LL 8-19-20	ES 8-19-20
52.	Swab inside infeed hose.	LL 8-19-20	ES 8-19-20
53.	Swab inside 3-way discharge valve.	LL 8-19-20	ES 8-19-20
MARKING and CLOSE OUT ACTIVITIES			
54.	Disconnect B13 drop to UT2 system	LL 8-19-20	ES 8-19-20
55.	Place a tag indicating status of equipment work center. Tag to include date of listed status, use by date or requirement prior to use. Note: Sanitization is only for 24 hrs.	LL 8-19-20	ES 8-19-20
56.	Marking of tank verified by Supervisor	QQQ(19)120	QQQ(19)120
57.	Cleaning and Sanitization Activities verified by Supervisor		

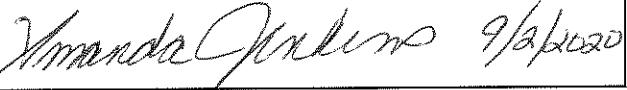


ANALYTICAL TESTING REPORT

Title	Determination of Organic Impurities in No More Pills Headache Man Bulk Material using the USP Monograph for Acetaminophen Oral Suspension	
Product	No More Pills Headache Man	
Product Number	LB-NMPHM01	WO# 106705B Lot # FB-2023001

APPROVALS

The following signatures indicate approval of the content of this report:

Analyst: Abul Siddiqui Senior Analytical Chemist	 09-02-20
Reviewed by: Amanda Jenkins Laboratory Manager	 9/3/2020

1. Summary

The purpose of this document is to provide the experimental data/results of testing for the organic impurity content in No More Pills Headache Man Part #LB-NMPHM01, WO# 106705B, Lot # FB-2023001 following the method described in the USP Monograph for Acetaminophen Oral Suspension.

2. Analytical Method Summary: Organic Impurities

Solution A: 0.2% trifluoroacetic acid in water

Solution B: 0.2% trifluoroacetic acid in acetonitrile

Mobile phase: See Table 2.

Table 2

Time (min)	Solution A (%)	Solution B (%)
0.0	98	2
1.0	98	2
8.0	80	20
9.0	5	95
10.0	5	95
10.5	98	2
15.0	98	2

Buffer: 10 mM sodium citrate dihydrate, with a pH of 4.0, prepared by adding 1.1 g of sodium citrate dihydrate and 1.3 g of citric acid monohydrate to a 1-L volumetric flask, dissolving, and diluting with water to volume. Adjust with sodium citrate dihydrate to increase the pH or with citric acid monohydrate to decrease the pH, if necessary, to achieve a pH of 4.0.

Diluent: Acetonitrile and *Buffer* (10:90)

Sensitivity solution: 0.16 µg/mL of USP Acetaminophen RS and 0.08 µg/mL of USP 4-Aminophenol RS in *Diluent*

Standard solution: 1.6 µg/mL each of USP Acetaminophen RS and USP 4-Aminophenol RS in *Diluent*

Sample solution: Nominally 1.6 mg/mL of acetaminophen in *Diluent* prepared as follows. Transfer a quantity equivalent to about 1.23mL of No More Pills Headache Man (13mg/mL acetaminophen) from a volume of Oral Suspension, well shaken, to a 10-mL volumetric flask. Add 6 mL of *Diluent* and mix well. Dilute with *Diluent* to volume. Mix well. Pass a

portion of this solution through a suitable filter. (Volumes have been adjusted from the USP to support the concentrations in the Headache Man product).

Chromatographic system

Mode: LC

Detector: UV 272 nm

Column: Kinetex 2.6 μ m C18 100A° 150x4.6mm

Column temperature: 40°

Flow rate: 1.0 mL/min

Injection volume: 10 μ L

Flow rate was increased from 0.5mL/min to 1.0mL/min and the injection volume increased from 2.5 μ L to 10 μ L allow acceptable chromatography. This will be captured in the No More Pills Impurity Testing WILAB206 for use in subsequent batches.

System suitability

Samples:

Sensitivity solution and Standard solution [Note— See Table 3 for relative retention times.]

Suitability requirements

Tailing factor: NMT 2.0 for acetaminophen and 4-aminophenol, *Standard solution*

Relative standard deviation: NMT 5.0% for acetaminophen and 4-aminophenol, *Standard solution*

Signal-to-noise ratio: NLT 10 for acetaminophen and 4-aminophenol, *Sensitivity solution*
Analysis

Samples:

Standard solution and Sample solution

Calculate the percentage of 4-aminophenol in the portion of Oral Suspension taken:

$$\text{Result} = (rU/rS) \times (CS/CU) \times 100$$

rU = peak response of 4-aminophenol from the *Sample solution*

rS = peak response of 4-aminophenol from the *Standard solution*

CS = concentration of USP 4-Aminophenol RS in the *Standard solution* (mg/mL)

CU = nominal concentration of acetaminophen in the *Sample solution* (mg/mL)

Calculate the percentage of acetaminophen dimer or any unspecified impurity in the portion of Oral Suspension taken:

$$\text{Result} = (rU/rS) \times (CS/CU) \times 100$$

- rU = peak response of acetaminophen dimer or any unspecified impurity from the *Sample solution*
 rS = peak response of acetaminophen from the *Standard solution*
 CS = concentration of USP Acetaminophen RS in the *Standard solution* (mg/mL)
 CU = nominal concentration of acetaminophen in the *Sample solution* (mg/mL)

Acceptance criteria: See Table 3. The reporting threshold is 0.05% for any impurities.

Table 3

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
4-Aminophenol	0.36	0.15
Acetaminophen	1.0	—
Acetaminophen dimer ^a	~1.57	0.15
Any unspecified impurity	—	0.15
Total impurities	—	2.0

^a *N,N'*-(6,6'-Dihydroxy-[1,1'-biphenyl]-3,3'-diyl)di-acetamide.

3. Results

3.1 System Suitability

Test Attribute	Specification	Result
Tailing Factor: Acetaminophen	NMT 2.0	1.0
Tailing Factor: 4-aminophenol	NMT 2.0	0.9
Relative standard deviation: Acetaminophen	NMT 5.0%	1.6
Relative standard deviation: 4-aminophenol	NMT 5.0%	2.1
Signal to Noise Ratio: Acetaminophen	NLT 10	177
Signal to Noise Ratio: 4-aminophenol	NLT 10	407

3.2 Acceptance Criteria

Test Attribute	Relative Retention Time	Acceptance Criteria, NMT (%)	Result
4-Aminophenol	0.28	0.15	B: 0.00 M: 0.00 E: 0.00
Acetaminophen	1.0	—	—
Acetaminophen dimer ^a	~1.57	0.15	B: 0.00 M: 0.00 E: 0.00
Any unspecified impurity	—	0.15	B: 0.00 M: 0.00 E: 0.00
Total impurities	—	2.0	B: 0.00 M: 0.00 E: 0.00

4. References

- USP Test Method for Acetaminophen Oral Suspension
- WILAB33 Basic Operating Procedures for HPLC 2695 with PDA Detector 2996

5. Conclusions

Impurities Testing for No More Pills Headache Man bulk solution Part Number LB-NMPHM01 Work Order 106705B, Lot # FB-2023001 was within specifications. No impurities were detected in the solution.

WO 106705B
Part LB-NMPHM01
LN497/117,119

Project
Sequence
USP-Acetaminophen Oral Suspension
Organic Impurities

ES-31-20

Peak Areas									
	RRT 0.37	Blank Avg	RRT 1	RRT 0.60	RRT 0.82	RRT 1.34	RRT 1.52	RRT 1.86	
Sample	4-Aminophenol	Blank Subtracted	Acetaminophen	Impurity 1	Impurity 2	Impurity 3	Impurity 4	Impurity 5	
Diluent	1.482	35	0	0	0	0	0	0	
Sensitivity Solution	2.281	834	1907	0	0	0	0	0	
Standard 1	12733	11286	15224	0	0	0	0	0	
Standard 2	12761	11314	15221	0	0	0	0	0	
Standard 3	13107	11660	15711	0	0	0	0	0	
Standard 4	13007	11560	15604	0	0	0	0	0	
Standard 5	13016	11569	15612	0	0	0	0	0	
Standard 6	12451	11014	15155	0	0	0	0	0	
Diluent	1412	-35	0	0	0	0	0	0	
Finished Blend Lot 2023001 B	11938	10491	1236980	2428	2634	1630	694	1880	
Finished Blend Lot 2023001 M	14166	12719	12331438	3787	4414	1619	737	1852	
Finished Blend Lot 2023001 E	16717	15270	12734482	6215	6814	1670	781	1953	
Standard	12287	10840	17271	0	0	0	0	0	
Standard 1-6 Avg		11400.50	15421.17						
Std Dev		241.31	246.43						
%RSD		2.12	1.60						

% 4-aminophenol $(R_u / R_s) * (C_s / C_u) * 100$
Ru peak response of 4-aminophenol in Sample solution
Rs peak response of 4-aminophenol in Standard solution
Cs Concentration of 4-Aminophenol in Standard solution (mg/mL)
Cu nominal concentration acetaminophen in Sample solution (mg/mL)

% Acetaminophen Dimer / Unspecified impurity $(R_u / R_s) * (C_s / C_u) * 100$
Ru peak response acetaminophen dimer or unspecified impurity from sample solution
Rs peak response of acetaminophen from Standard solution
Cs concentration of Acetaminophen in Standard solution (mg/mL)
Cu nominal concentration acetaminophen in Sample solution (mg/mL)

% Impurity (threshold for reporting is 0.05%)									
	RRT 0.37	Blank (Averaged)	RRT 1	RRT 0.60	RRT 0.82	RRT 1.34	RRT 1.52	RRT 1.86	SUM IMPURITIES
Sample	4-Aminophenol	Blank Subtracted	Acetaminophen	Impurity 1	Impurity 2	Impurity 3	Impurity 4	Impurity 5	
Finished Blend Lot 2023001 B	0.00076	92.95170475	1236980	0.0000200	0.0000216	0.000134	0.0000570	0.0000155	0.0000762
Finished Blend Lot 2023001 M	0.00093	112.6920916	1233138	0.0000312	0.0000364	0.000133	0.0000608	0.0000153	0.000102
Finished Blend Lot 2023001 E	0.00111	135.2943029	12734482	0.0000496	0.0000544	0.000133	0.0000624	0.0000156	0.000139

Specification Result	NMT 2%
Conformity	PASS
no impurity is more than 0.15%	NMT 2%
no impurity is more than 0.15%	NMT 2%

082820_SS_Acetaminophen_Ol in Acetaminophen-Oral-Solution on EMPOWER3 as abul22/Analyst - Alter Sample Set

	Vial	Inj Vol (uL)	# of Injs	Label	SampleName	Sample Type	Level	Function	Method Set / Report or Export-Method	Label Reference
1	1	10.0	2	a	Priming	Unknown		Inject Samples	082620_MS_Acetaminophen_Ol	
2	2	10.0	1	a	Diluent	Unknown		Inject Samples	082620_MS_Acetaminophen_Ol	
3	3	10.0	1	a	Sensitivity Solution	Unknown		Inject Samples	082620_MS_Acetaminophen_Ol	
4	1	10.0	6	a	Standard	Unknown		Inject Samples	082620_MS_Acetaminophen_Ol	
5	2	10.0	1	a	Diluent	Unknown		Inject Samples	082620_MS_Acetaminophen_Ol	
6	4	10.0	1	a	Finished Blend Lot 2023001 B	Unknown		Inject Samples	082620_MS_Acetaminophen_Ol	
7	5	10.0	1	a	Finished Blend Lot 2023001 M	Unknown		Inject Samples	082620_MS_Acetaminophen_Ol	
8	6	10.0	1	a	Finished Blend Lot 2023001 E	Unknown		Inject Samples	082620_MS_Acetaminophen_Ol	
9	1	10.0	1	a	Standard	Unknown		Inject Samples	082620_MS_Acetaminophen_Ol	
10								Condition Column	Wash_2998_PDA	
11								Condition Column	Shut Down MS	
12								Clear Calibration	082620_MS_Acetaminophen_Ol	
13								Quantitate	082620_MS_Acetaminophen_Ol	a*

	Processing	SampleWeight	Dilution	Altered
1	Normal	1.0000	1.0000	<input checked="" type="checkbox"/>
2	Don't Process or Report	1.0000	1.0000	<input checked="" type="checkbox"/>
3	Don't Process or Report	1.0000	1.0000	<input checked="" type="checkbox"/>
4	Don't Process or Report	1.0000	1.0000	<input checked="" type="checkbox"/>
5	Don't Process or Report	1.0000	1.0000	<input checked="" type="checkbox"/>
6	Don't Process or Report	1.0000	1.0000	<input checked="" type="checkbox"/>
7	Don't Process or Report	1.0000	1.0000	<input checked="" type="checkbox"/>
8	Don't Process or Report	1.0000	1.0000	<input checked="" type="checkbox"/>
9	Don't Process or Report	1.0000	1.0000	<input checked="" type="checkbox"/>
10				<input type="checkbox"/>
11				<input type="checkbox"/>
12	Normal			<input type="checkbox"/>
13	Normal			<input type="checkbox"/>

WO	106705B	Project	USP-Acetaminophen Oral Suspension
Part	LB-NMPHM01	Sequence	Organic Impurities
	LN497/117, 119		

SAMPLE INFORMATION

Sample Type: Unknown
 Vial: 2, 5, 6, 1, 3, 4

Acquired By: abul22
 Sample Set Name: 082820_SS_Acetaminophen_OI
 Acq. Method Set: 082620_MS_Acetaminophen_OI
 Run Time: 15.0 Minutes

Area Summarized by Name Channel: 2998 Ch1 272nm@4.8nm

	SampleName	Inj	Channel	Vial	4-Aminophenol	Impurity-1	Impurity-2
1	Finished Blend Lot 2023001 E	1	2998 Ch1 272nm@4.8nm	6	16717	6215	6814
2	Standard	1	2998 Ch1 272nm@4.8nm	1	12287		
3	Priming	1	2998 Ch1 272nm@4.8nm	1	12054		
4	Priming	2	2998 Ch1 272nm@4.8nm	1	13124		
5	Diluent	1	2998 Ch1 272nm@4.8nm	2	1482		
6	Sensitivity Solution	1	2998 Ch1 272nm@4.8nm	3	2281		
7	Standard	1	2998 Ch1 272nm@4.8nm	1	12733		
8	Standard	2	2998 Ch1 272nm@4.8nm	1	12761		
9	Standard	3	2998 Ch1 272nm@4.8nm	1	13107		
10	Standard	4	2998 Ch1 272nm@4.8nm	1	13007		
11	Standard	5	2998 Ch1 272nm@4.8nm	1	13016		
12	Standard	6	2998 Ch1 272nm@4.8nm	1	12461		
13	Diluent	1	2998 Ch1 272nm@4.8nm	2	1412		
14	Finished Blend Lot 2023001 B	1	2998 Ch1 272nm@4.8nm	4	11938	2428	2634
15	Finished Blend Lot 2023001 M	1	2998 Ch1 272nm@4.8nm	5	14166	3787	4414
Mean					10836	4143	4620
Std. Dev.					4853	1919	2097
% RSD					44.8	46.3	45.4

Area Summarized by Name Channel: 2998 Ch1 272nm@4.8nm

W/O	Project	USP-Acetaminophen Oral Suspension	Organic Impurities
	Sequence		
	Part	LB-NMPHM01	
LN497/117, 119			

	Acetaminophen	Impurity-3	Impurity-4	Impurity-5
1	12734482	1670	781	1953
2	17271			
3	14980			
4	15808			
5				
6	1907			
7	15224			
8	15221			

	Acetaminophen	Impurity-3	Impurity-4	Impurity-5
9	15711			
10	15604			
11	15612			
12	15155			
13				
14	12369980	1630	694	1880
15	12331438	1619	737	1852
Mean	2890646	1640	738	1895

Reported by User: Abul Siddiqui (abul22)

Report Method: Area Summary Report

Report Method ID 1052

Page: 1 of 2

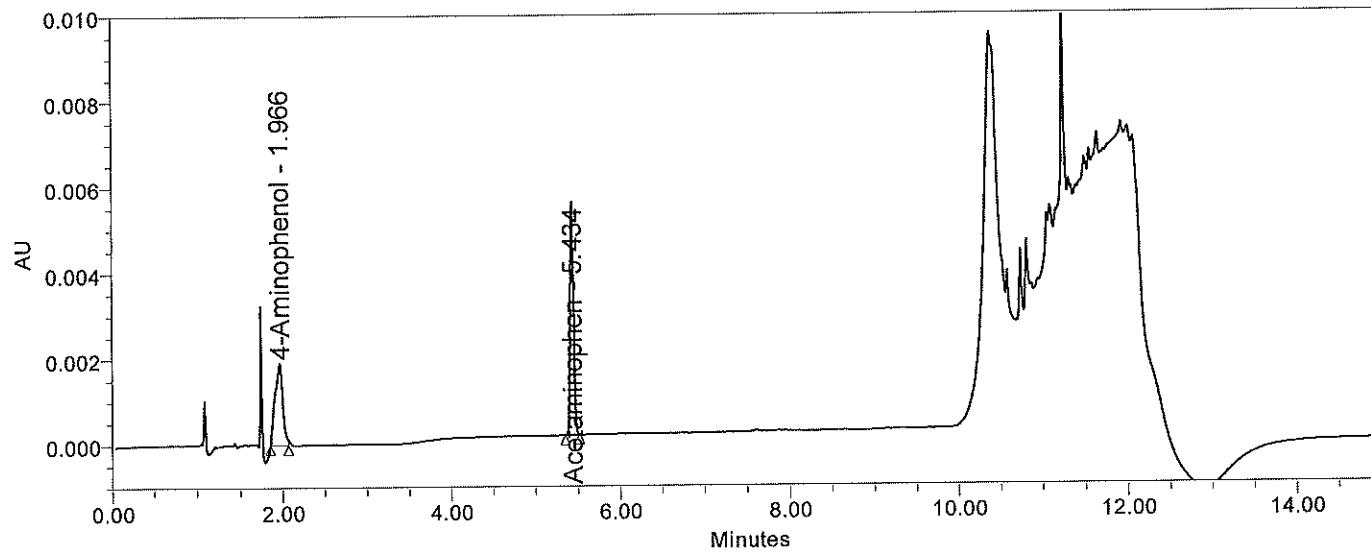
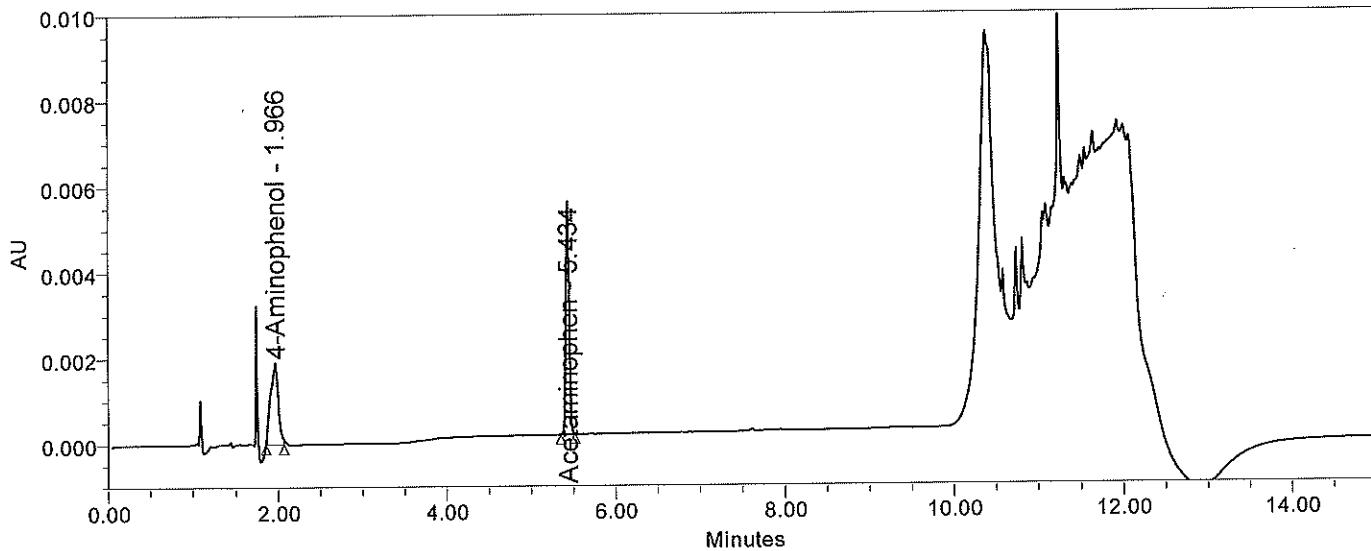
Project Name: Acetaminophen-Oral-Solution

Date Printed:

8/27/2020

9:25:28 AM US/Eastern

SAMPLE INFORMATION			
Sample Name:	Priming	Acquired By:	abul22
Sample Type:	Unknown	Sample Set Name:	082820_SS_Acetaminophen_OI
Vial:	1	Acq. Method Set:	082620_MS_Acetaminophen_OI
Injection #:	1	Processing Method	082620_PM_Acetaminophen_OI
Injection Volume:	10.00 ul	Channel Name:	2998 Ch1 272nm@4.8nm
Run Time:	15.0 Minutes	Proc. Chnl. Descr.:	2998 Ch1 272nm@4.8nm
Date Acquired:	8/26/2020 4:35:28 PM EDT		
Date Processed:	8/27/2020 9:22:43 AM EDT, 8/27/2020 9:22:44 AM EDT		



Reported by User: Abul Siddiqui (abul22)

Project Name: Acetaminophen-Oral-Solution

Report Method: Multi Sample Summary_AIS

Date Printed:

Report Method ID 1802

8/27/2020

Page: 1 of 28

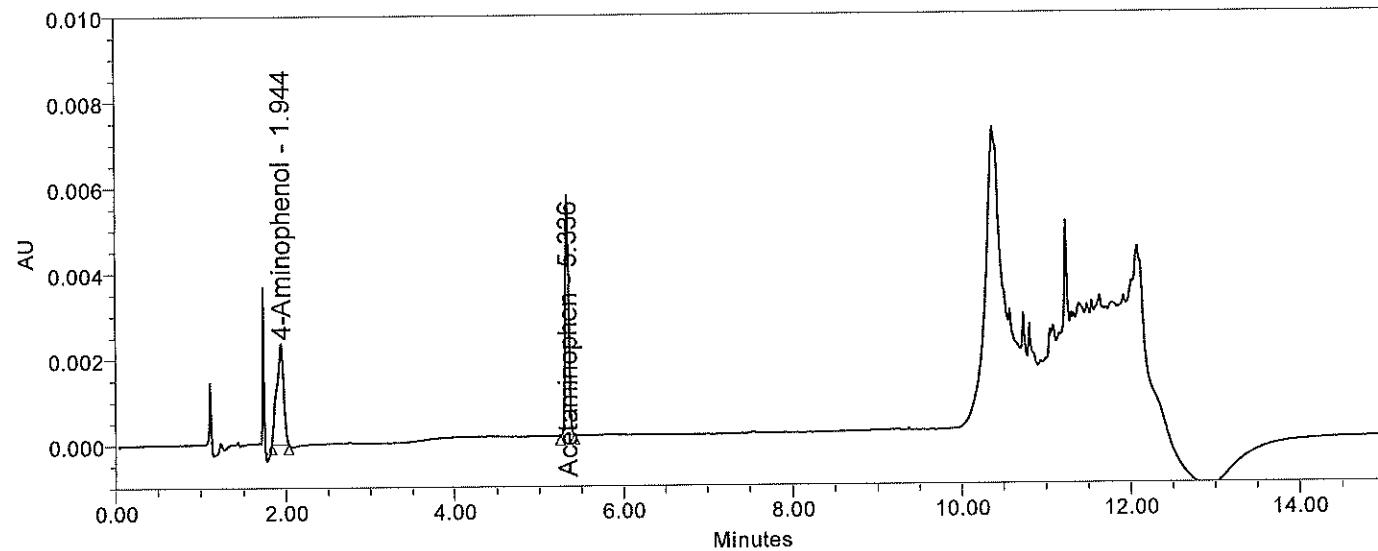
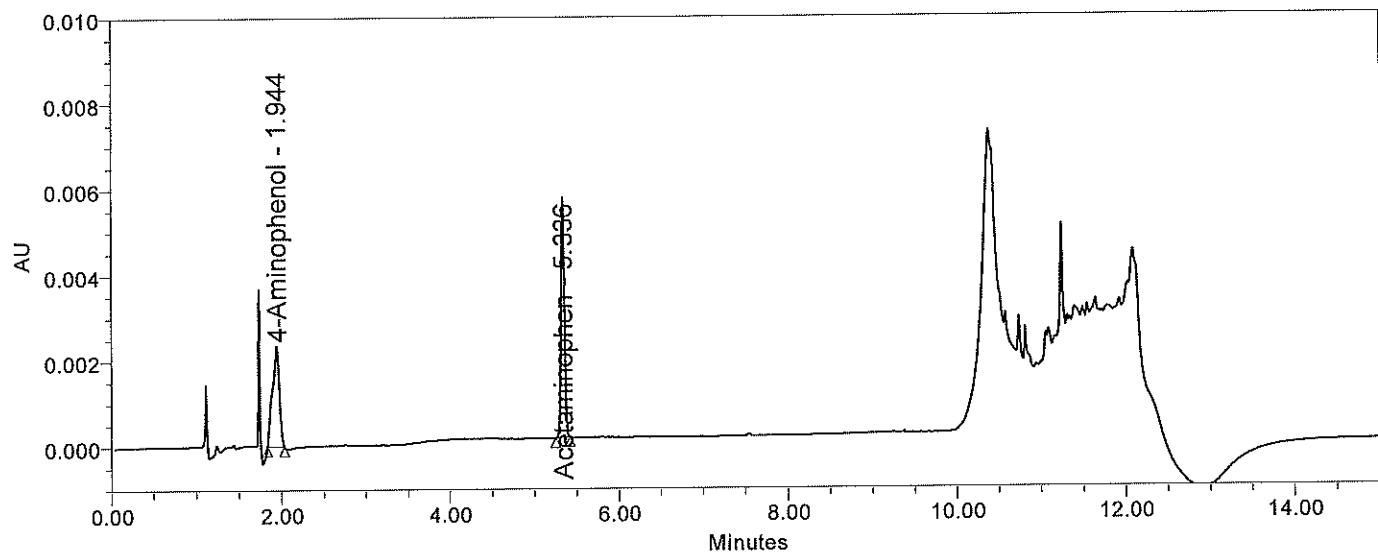
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WO	106705B	Project	USP-Acetaminophen Oral Suspension
Part	LB-NMPHM01	Sequence	Organic Impurities
	LN497/117, 119		

SAMPLE INFORMATION

Sample Name:	Priming	Acquired By:	abul22
Sample Type:	Unknown	Sample Set Name:	082820_SS_Acetaminophen_OI
Vial:	1	Acq. Method Set:	082620_MS_Acetaminophen_OI
Injection #:	2	Processing Method	082620_PM_Acetaminophen_OI
Injection Volume:	10.00 ul	Channel Name:	2998 Ch1 272nm@4.8nm
Run Time:	15.0 Minutes	Proc. Chnl. Descr.:	2998 Ch1 272nm@4.8nm

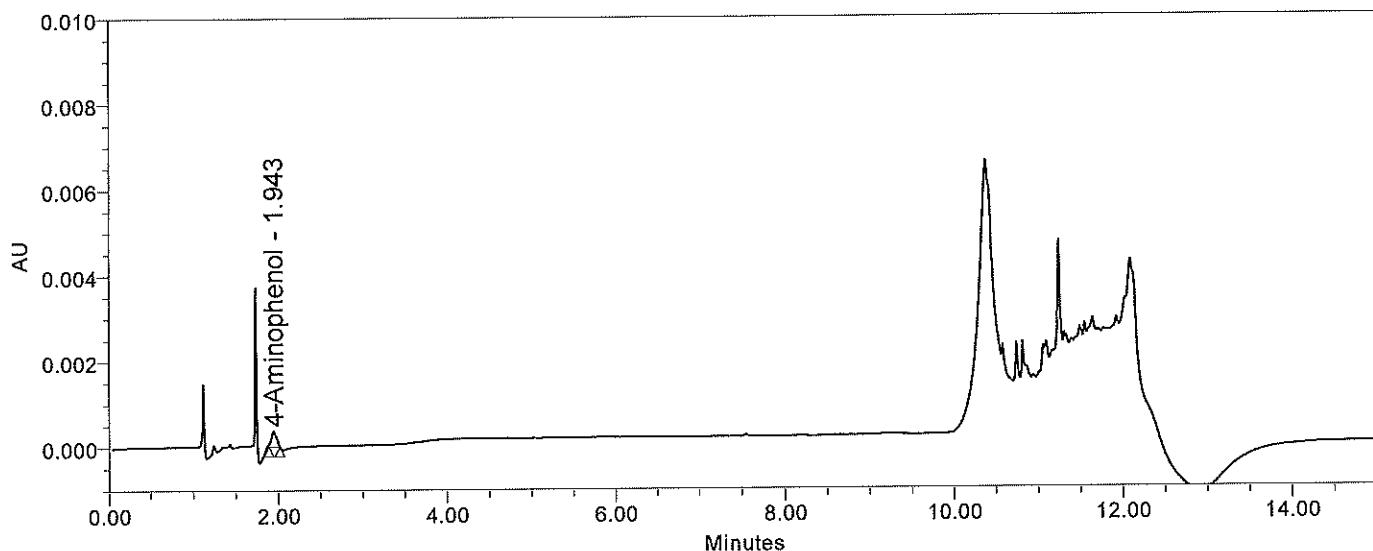
Date Acquired: 8/26/2020 4:51:18 PM EDT
 Date Processed: 8/27/2020 9:22:44 AM EDT, 8/27/2020 9:22:45 AM EDT



SAMPLE INFORMATION

Sample Name:	Diluent	Acquired By:	abul22
Sample Type:	Unknown	Sample Set Name:	082820_SS_Acetaminophen_OI
Vial:	2	Acq. Method Set:	082620_MS_Acetaminophen_OI
Injection #:	1	Processing Method	082620_PM_Acetaminophen_OI
Injection Volume:	10.00 ul	Channel Name:	2998 Ch1 272nm@4.8nm
Run Time:	15.0 Minutes	Proc. Chnl. Descr.:	2998 Ch1 272nm@4.8nm

Date Acquired: 8/26/2020 5:07:07 PM EDT
 Date Processed: 8/27/2020 9:22:45 AM EDT



	Peak Name	RT	Area	% Area	Height	USP s/n	USP Tailing
1	4-Aminophenol	1.943	1482	100.00	359	25.11	1.3
2	Impurity-1	3.169					
3	Impurity-2	4.362					
4	Acetaminophen	5.396					
5	Impurity-3	7.105					
6	Impurity-4	8.048					
7	Impurity-5	9.865					

	USP Plate Count
1	3550.0
2	
3	

	USP Plate Count
4	
5	
6	

	USP Plate Count
7	

Reported by User: Abul Siddiqui (abul22)

Report Method: Multi Sample Summary_Alt

Report Method ID 1802

Page: 5 of 28

Project Name: Acetaminophen-Oral-Solution

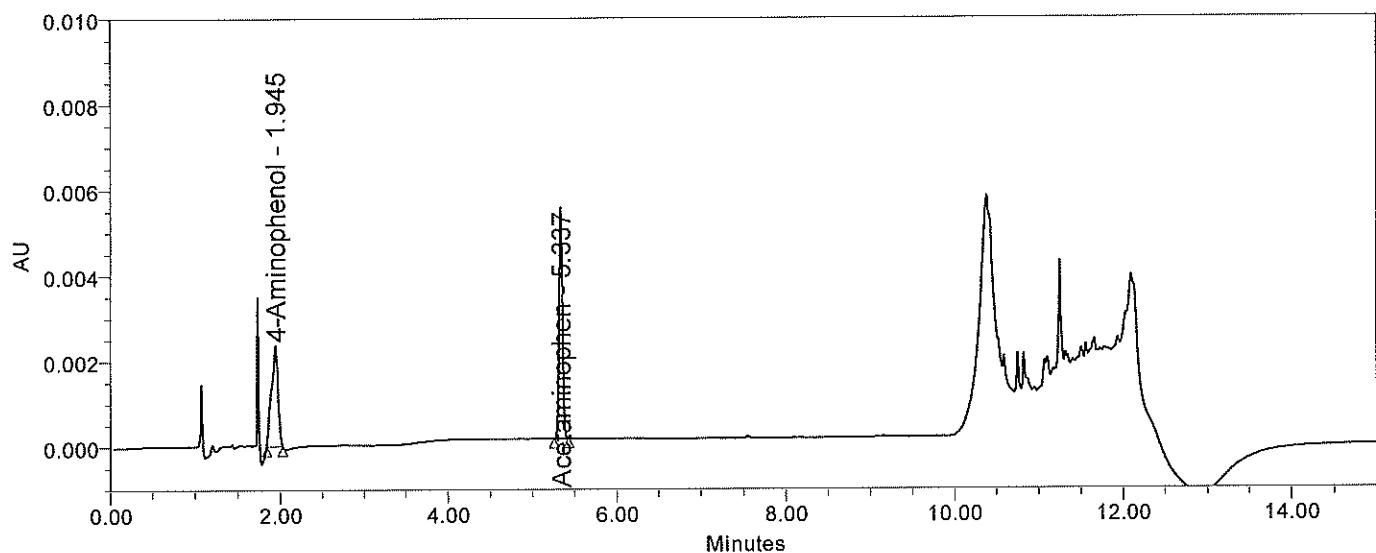
Date Printed:

8/27/2020

9:30:09 AM US/Eastern

SAMPLE INFORMATION

Sample Name:	Standard	Acquired By:	abul22
Sample Type:	Unknown	Sample Set Name:	082820_SS_Acetaminophen_OI
Vial:	1	Acq. Method Set:	082620_MS_Acetaminophen_OI
Injection #:	1	Processing Method	082620_PM_Acetaminophen_OI
Injection Volume:	10.00 ul	Channel Name:	2998 Ch1 272nm@4.8nm
Run Time:	15.0 Minutes	Proc. Chnl. Descr.:	2998 Ch1 272nm@4.8nm
Date Acquired:	8/26/2020 5:38:52 PM EDT		
Date Processed:	8/27/2020 9:22:46 AM EDT		



	Peak Name	RT	Area	% Area	Height	USP s/n	USP Tailing
1	4-Aminophenol	1.945	12733	45.54	2351	176.93	0.8
2	Impurity-1	3.169					
3	Impurity-2	4.362					
4	Acetaminophen	5.337	15224	54.46	5393	407.18	1.0
5	Impurity-3	7.105					
6	Impurity-4	8.048					
7	Impurity-5	9.865					

	USP Plate Count	USP Resolution
1	1421.1	
2		
3		

	USP Plate Count	USP Resolution
4	82208.1	2.621348e+01
5		
6		

Reported by User: Abul Siddiqui (abul22)

Project Name: Acetaminophen-Oral-Solution

Report Method: Multi Sample Summary_AI

Date Printed:

Report Method ID 1802

8/27/2020

Page: 8 of 28

9:30:09 AM US/Eastern

	USP Plate Count	USP Resolution
7		

Reported by User: Abul Siddiqui (abul22)
Report Method: Multi Sample Summary_Alt
Report Method ID 1802
Page: 9 of 28

Project Name: Acetaminophen-Oral-Solution
Date Printed: 8/27/2020
9:30:09 AM US/Eastern

	USP Plate Count	USP Resolution
7		

Reported by User: Abul Siddiqui (abul22)
Report Method: Multi Sample Summary_Alt
Report Method ID 1802
Page: 11 of 28

Project Name: Acetaminophen-Oral-Solution
Date Printed: 8/27/2020
9:30:09 AM US/Eastern

	USP-Plate-Count	USP-Resolution
7		

Reported by User: Abul Siddiqui (abul22)
Report Method: Multi Sample Summary_Alt
Report Method ID 1802
Page: 13 of 28

Project Name: Acetaminophen-Oral-Solution
Date Printed: 8/27/2020
9:30:09 AM US/Eastern

	USP Plate Count	USP Resolution
7		

Reported by User: Abul Siddiqui (abul22)
Report Method: Multi Sample Summary_Alt
Report Method ID 1802
Page: 15 of 28

Project Name: Acetaminophen-Oral-Solution
Date Printed: 8/27/2020
9:30:09 AM US/Eastern

	USP-Plate-Count	USP-Resolution
7		

Reported by User: Abul Siddiqui (abul22)
Report Method: Multi Sample Summary_AI
Report Method ID 1802
Page: 17 of 28

Project Name: Acetaminophen-Oral-Solution
Date Printed: 8/27/2020
9:30:09 AM US/Eastern

	USP Plate Count	USP Resolution
7		

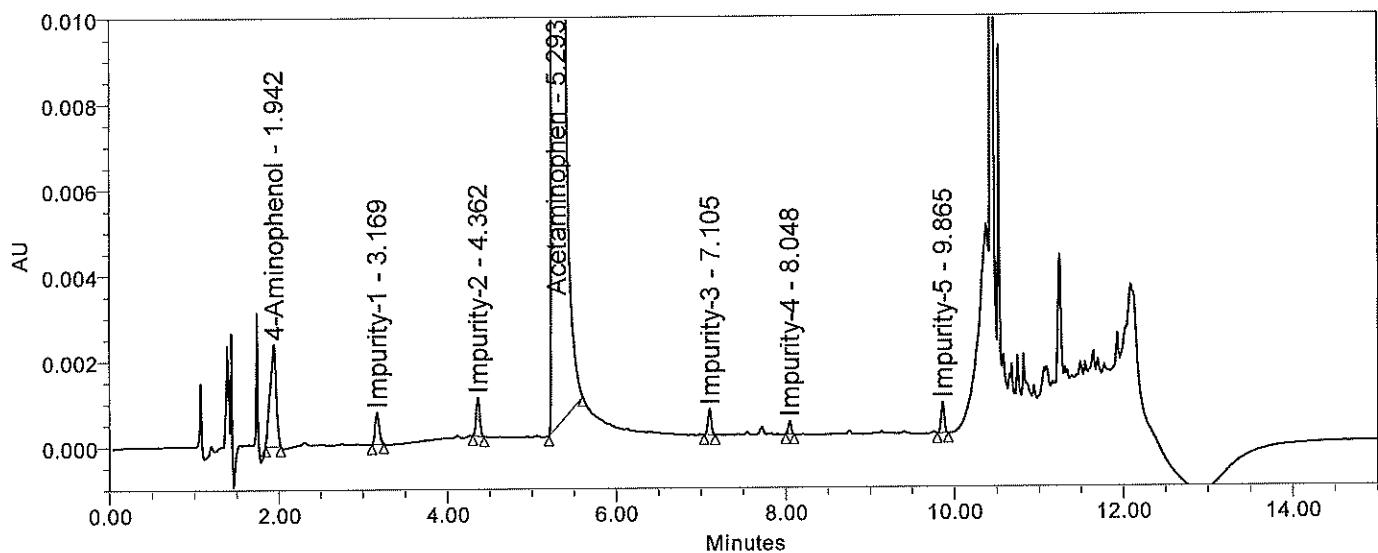
Reported by User: Abul Siddiqui (abul22)
Report Method: Multi Sample Summary_Alt
Report Method ID 1802
Page: 19 of 28

Project Name: Acetaminophen-Oral-Solution
Date Printed: 8/27/2020
9:30:09 AM US/Eastern

SAMPLE INFORMATION

Sample Name: Finished Blend Lot 2023001 B Acquired By: abul22
 Sample Type: Unknown Sample Set Name: 082820_SS_Acetaminophen_OI
 Vial: 4 Acq. Method Set: 082620_MS_Acetaminophen_OI
 Injection #: 1 Processing Method: 082620_PM_Acetaminophen_OI
 Injection Volume: 10.00 ul Channel Name: 2998 Ch1 272nm@4.8nm
 Run Time: 15.0 Minutes Proc. Chnl. Descr.: 2998 Ch1 272nm@4.8nm

Date Acquired: 8/26/2020 7:29:57 PM EDT
 Date Processed: 8/27/2020 9:22:48 AM EDT



	Peak Name	RT	Area	% Area	Height	USP s/n	USP Tailing
1	4-Aminophenol	1.942	11938	0.10	2379	169.07	0.9
2	Impurity-1	3.169	2428	0.02	730	51.20	1.1
3	Impurity-2	4.362	2634	0.02	893	62.86	1.1
4	Acetaminophen	5.293	12369980	99.83	3049060	217941.79	1.5
5	Impurity-3	7.105	1630	0.01	593	41.36	1.0
6	Impurity-4	8.048	694	0.01	299	20.34	1.0
7	Impurity-5	9.865	1880	0.02	714	50.01	1.0

	USP Plate Count	USP Resolution
1	2164.0	
2	20003.7	9.875709e+00
3	49711.0	1.391097e+01

	USP Plate Count	USP Resolution
4	42235.7	1.009756e+01
5	151842.1	2.032841e+01
6	263964.2	1.367119e+01

Reported by User: Abul Siddiqui (abul22)

Report Method: Multi Sample Summary_AI

Report Method ID 1802

Page: 21 of 28

Project Name: Acetaminophen-Oral-Solution

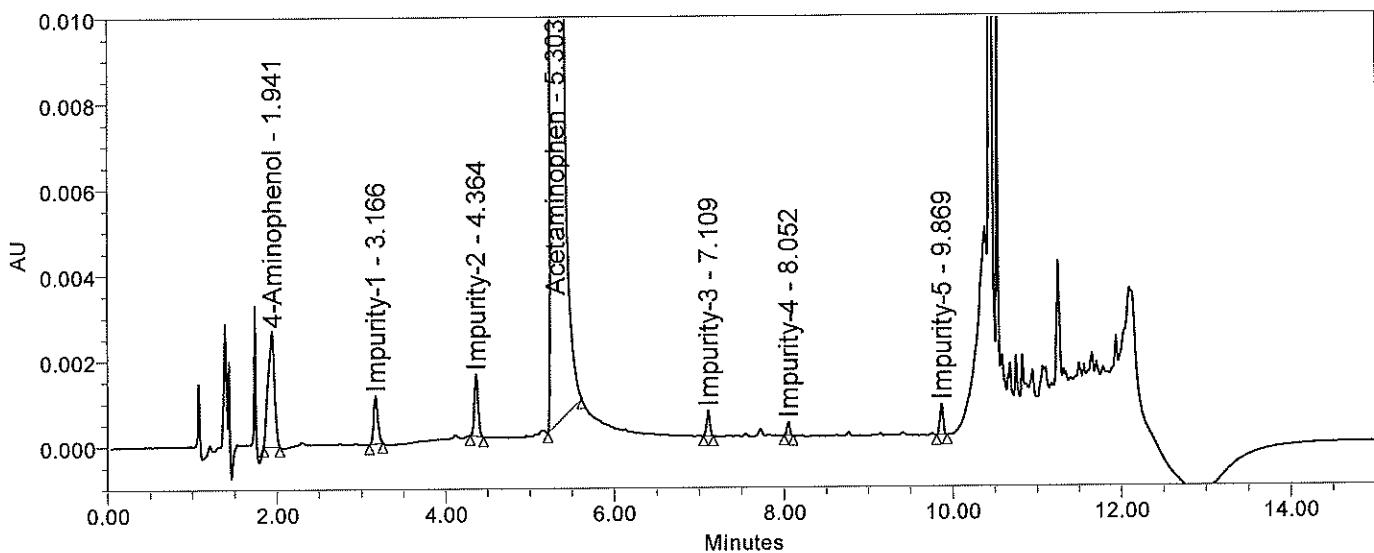
Date Printed:

8/27/2020

9:30:09 AM US/Eastern

SAMPLE INFORMATION

Sample Name:	Finished Blend Lot 2023001 M	Acquired By:	abul22
Sample Type:	Unknown	Sample Set Name:	082820_SS_Acetaminophen_OI
Vial:	5	Acq. Method Set:	082620_MS_Acetaminophen_OI
Injection #:	1	Processing Method	082620_PM_Acetaminophen_OI
Injection Volume:	10.00 ul	Channel Name:	2998 Ch1 272nm@4.8nm
Run Time:	15.0 Minutes	Proc. Chnl. Descr.:	2998 Ch1 272nm@4.8nm
Date Acquired:	8/26/2020 7:45:52 PM EDT		
Date Processed:	8/27/2020 9:22:48 AM EDT		



	Peak Name	RT	Area	% Area	Height	USP s/n	USP Tailing
1	4-Aminophenol	1.941	14166	0.11	2676	176.30	0.9
2	Impurity-1	3.166	3787	0.03	1113	72.72	1.2
3	Impurity-2	4.364	4414	0.04	1438	94.27	1.1
4	Acetaminophen	5.303	12331438	99.78	3042115	201526.24	1.5
5	Impurity-3	7.109	1619	0.01	587	37.92	1.0
6	Impurity-4	8.052	737	0.01	310	19.56	1.0
7	Impurity-5	9.869	1852	0.01	710	46.03	0.9

	USP Plate Count	USP Resolution
1	2052.3	
2	19678.6	9.854986e+00
3	46168.7	1.370917e+01

	USP Plate Count	USP Resolution
4	42150.6	1.002097e+01
5	151441.8	2.013579e+01
6	269560.2	1.361668e+01

Reported by User: Abul Siddiqui (abul22)

Report Method: Multi Sample Summary_AI

Report Method ID 1802

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Project Name: Acetaminophen-Oral-Solution

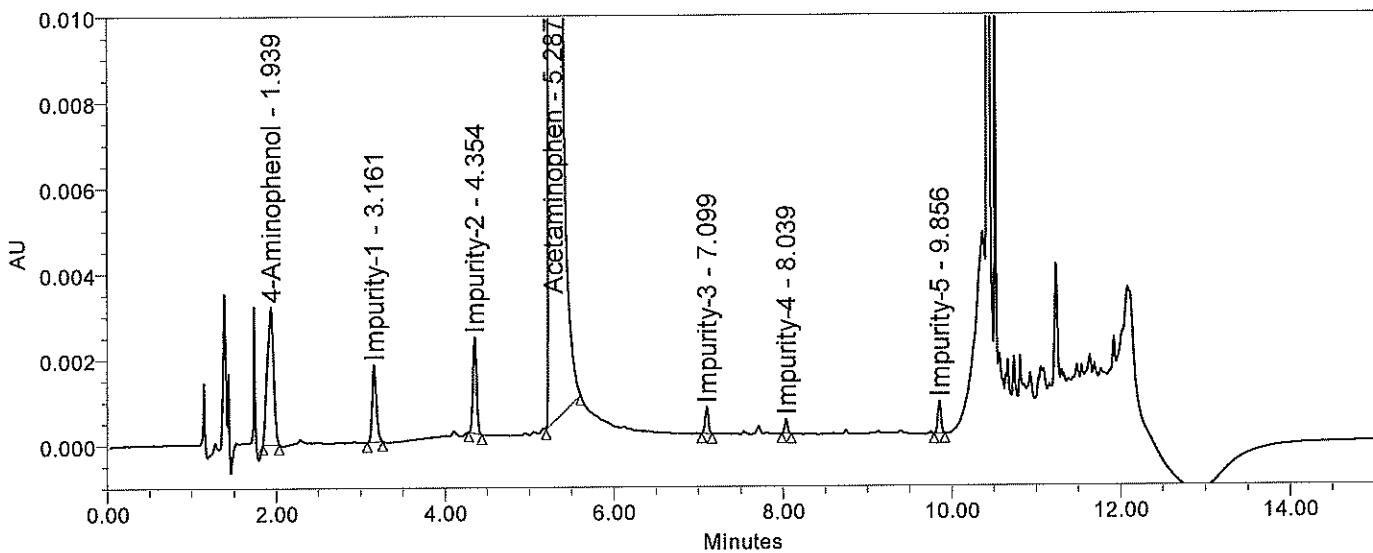
Date Printed:

8/27/2020

9:30:09 AM US/Eastern

SAMPLE INFORMATION

Sample Name:	Finished Blend Lot 2023001 E	Acquired By:	abul22
Sample Type:	Unknown	Sample Set Name:	082820_SS_Acetaminophen_OI
Vial:	6	Acq. Method Set:	082620_MS_Acetaminophen_OI
Injection #:	1	Processing Method	082620_PM_Acetaminophen_OI
Injection Volume:	10.00 ul	Channel Name:	2998 Ch1 272nm@4.8nm
Run Time:	15.0 Minutes	Proc. Chnl. Descr.:	2998 Ch1 272nm@4.8nm
Date Acquired:	8/26/2020 8:01:42 PM EDT		
Date Processed:	8/27/2020 9:22:49 AM EDT		



	Peak Name	RT	Area	% Area	Height	USP s/n	USP Tailing
1	4-Aminophenol	1.939	16717	0.13	3209	250.61	0.9
2	Impurity-1	3.161	6215	0.05	1795	139.72	1.2
3	Impurity-2	4.354	6814	0.05	2237	174.39	1.1
4	Acetaminophen	5.287	12734482	99.73	3064054	240225.65	1.5
5	Impurity-3	7.099	1670	0.01	613	47.04	1.0
6	Impurity-4	8.039	781	0.01	332	25.05	1.0
7	Impurity-5	9.856	1953	0.02	748	57.62	1.0

	USP Plate Count	USP Resolution
1	2279.6	
2	19769.9	9.957143e+00
3	46771.4	1.363091e+01

	USP Plate Count	USP Resolution
4	40587.0	9.901528e+00
5	156358.3	2.020868e+01
6	263980.4	1.375906e+01

Reported by User: Abul Siddiqui (abul22)

Report Method: Multi Sample Summary_AI

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Project Name: Acetaminophen-Oral-Solution

Date Printed:

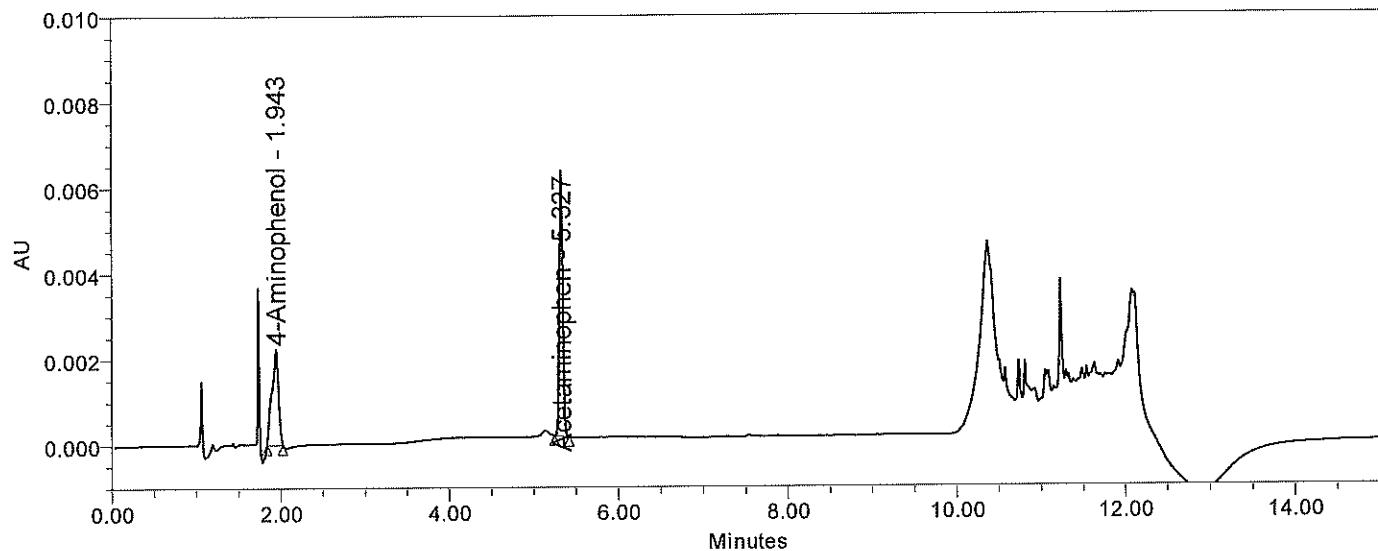
8/27/2020

9:30:09 AM US/Eastern

SAMPLE INFORMATION

Sample Name: Standard
 Sample Type: Unknown
 Vial: 1
 Injection #: 1
 Injection Volume: 10.00 μ l
 Run Time: 15.0 Minutes
 Acquired By: abul22
 Sample Set Name: 082820_SS_Acetaminophen_OI
 Acq. Method Set: 082620_MS_Acetaminophen_OI
 Processing Method: 082620_PM_Acetaminophen_OI
 Channel Name: 2998 Ch1 272nm@4.8nm
 Proc. Chnl. Descr.: 2998 Ch1 272nm@4.8nm

Date Acquired: 8/26/2020 8:17:38 PM EDT
 Date Processed: 8/27/2020 9:22:49 AM EDT



	Peak Name	RT	Area	% Area	Height	USP s/n	USP Tailing
1	4-Aminophenol	1.943	12287	41.57	2224	197.53	0.8
2	Impurity-1	3.169					
3	Impurity-2	4.362					
4	Acetaminophen	5.327	17271	58.43	6195	552.00	1.0
5	Impurity-3	7.105					
6	Impurity-4	8.048					
7	Impurity-5	9.865					

	USP Plate Count	USP Resolution
1	1220.6	
2		
3		

	USP Plate Count	USP Resolution
4	83532.9	2.466834e+01
5		
6		

Reported by User: Abul Siddiqui (abul22)

Report Method: Multi Sample Summary_AI

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Project Name: Acetaminophen-Oral-Solution

Date Printed:

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Vial: 1, Sample Name: Priming

Vial Information

Vial	1	Original Vial Id	1716	Dilution	1.0000
Sample Type	Unknown	Comments	NA	Sample Matrix	
Level		Blank	No	SampleName	Priming
Label	a	Peak Ratio Reference	No	SampleWeight	1.0000
Vial Id	1758	Column Name			
Altered	Yes	Column Serial Number			

Sample History

User: abul22 Date: 8/27/2020 9:21:53 AM EDT Reason: NA
 Modified Vial(Label): <No Value> -> a

Acquisition Log

Acquired By	abul22
Injection	1
Date Acquired	8/26/2020 4:35:28 PM EDT
Run Time	15.00(Minutes)
Acq Method Set	082620_MS_Aacetaminophen_OI
Injection Volume	10.00(uL)
Barcode / BCD	
Auto Additions	
Injection Id	1717
Instrument Method Id	1709
Instrument Method Name	IM_Aacetomin 082620_2998 PDA_OI
Superseded	No
# of Process Only Sample Sets	0
Injection Status	Complete
eCord Name	
eCord Serial Number	
eCord Injection Count (Lifetime to Date)	
eCord Sample Count (Lifetime to Date)	
eCord Maximum Pressure (Lifetime to Date)	(psi)
eCord Maximum Temperature (Lifetime to Date)	(°C)
Use Syringe Settings	
Syringe Size A (uL)	
Nanoliter Adapter A	
Syringe Size B (uL)	
Nanoliter Adapter B	

A-08-31-20			
WO	106705B	Project	USP-Aacetaminophen Oral Suspension
Part	LB-NMPHM01	Sequence	Organic Impurities
	LN497/117, 119		

Sample Type	Unknown	Peak Ratio Reference	No
Level		Column Name	XTerra C18 4.6x250mm, 5μ
Label	a	Column Serial Number	
Vial Id	1759	Dilution	1.0000
Altered	Yes	Sample Matrix	
Original Vial Id	1721	SampleName	Diluent
Comments	NA	SampleWeight	1.0000
Blank	No		

Sample History

User: abul22 Date: 8/27/2020 9:21:53 AM EDT Reason: NA

Modified Vial(Label): <No Value> -> a

Acquisition Log

Acquired By	abul22
Injection	1
Date Acquired	8/26/2020 5:07:07 PM EDT
Run Time	15.00(Minutes)
Acq Method Set	082620_MS_Acetaminophen_OI
Injection Volume	10.00(µL)
Barcode / BCD	
Auto Additions	
Injection Id	1722
Instrument Method Id	1709
Instrument Method Name	IM_Aacetomin 082620_2998 PDA_OI
Superseded	No
# of Process Only Sample Sets	0
Injection Status	Complete
eCord Name	
eCord Serial Number	
eCord Injection Count (Lifetime to Date)	
eCord Sample Count (Lifetime to Date)	
eCord Maximum Pressure (Lifetime to Date) (psi)	
eCord Maximum Temperature (Lifetime to Date) (°C)	
Use Syringe Settings	
Syringe Size A (uL)	
Nanoliter Adapter A	
Syringe Size B (uL)	
Nanoliter Adapter B	

Vial: 3, Sample Name: Sensitivity Solution

Vial Information

Vial	3
Sample Type	Unknown
Level	

Reported by User: Abul Siddiqui (abul22)
 Report Method: Sample Audit Report
 Report Method ID 1065
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Project Name: Acetaminophen-Oral-Solution
 Date Printed: 8/27/2020
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Vial Id	1761	Peak Ratio Reference	No
Altered	Yes	Column Name	XTerra C18 4.6x250mm, 5μ
Original Vial Id	1727	Column Serial Number	
Comments	NA	Dilution	1.0000
Blank	No	Sample Matrix	
		SampleName	Standard
		SampleWeight	1.0000

Sample History

User: abul22 Date: 8/27/2020 9:21:54 AM EDT Reason: NA

Modified Vial(Label): <No Value> -> a

Acquisition Log

Acquired By	abul22
Injection	1
Date Acquired	8/26/2020 5:38:52 PM EDT
Run Time	15.00(Minutes)
Acq Method Set	082620_MS_Acetaminophen_OI
Injection Volume	10.00(µL)
Barcode / BCD	
Auto Additions	
Injection Id	1728
Instrument Method Id	1709
Instrument Method Name	IM_Acetomin 082620_2998 PDA_OI
Superseded	No
# of Process Only Sample Sets	0
Injection Status	Complete
eCord Name	
eCord Serial Number	
eCord Injection Count (Lifetime to Date)	
eCord Sample Count (Lifetime to Date)	
eCord Maximum Pressure (Lifetime to Date) (psi)	
eCord Maximum Temperature (Lifetime to Date) (°C)	
Use Syringe Settings	
Syringe Size A (µL)	
Nanoliter Adapter A	
Syringe Size B (µL)	
Nanoliter Adapter B	

Vial: 1, Sample Name: Standard

Vial Information

Vial	1
Sample Type	Unknown
Level	
Label	a

Reported by User: Abul Siddiqui (abul22)

Project Name: Acetaminophen-Oral-Solution

Report Method: Sample Audit Report

Date Printed:

Report Method ID 1065

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Vial Id	1761	Peak Ratio Reference	No
Altered	Yes	Column Name	XTerra C18-4.6x250mm, 5μ
Original Vial Id	1727	Column Serial Number	
Comments	NA	Dilution	1.0000
Blank	No	Sample Matrix	
		SampleName	Standard
		SampleWeight	1.0000

Sample History

User: abul22 Date: 8/27/2020 9:21:54 AM EDT Reason: NA

Modified Vial(Label): <No Value> -> a

Acquisition Log

Acquired By	abul22
Injection	3
Date Acquired	8/26/2020 6:10:32 PM EDT
Run Time	15.00(Minutes)
Acq Method Set	082620_MS_Acetaminophen_OI
Injection Volume	10.00(uL)
Barcode / BCD	
Auto Additions	
Injection Id	1732
Instrument Method Id	1709
Instrument Method Name	IM_Aacetomin 082620_2998 PDA_OI
Superseded	No
# of Process Only Sample Sets	0
Injection Status	Complete
eCord Name	
eCord Serial Number	
eCord Injection Count (Lifetime to Date)	
eCord Sample Count (Lifetime to Date)	
eCord Maximum Pressure (Lifetime to Date) (psi)	
eCord Maximum Temperature (Lifetime to Date) (°C)	
Use Syringe Settings	
Syringe Size A (uL)	
Nanoliter Adapter A	
Syringe Size B (uL)	
Nanoliter Adapter B	

Vial: 1, Sample Name: Standard

Vial Information

Vial	1
Sample Type	Unknown
Level	
Label	a

Reported by User: Abul Siddiqui (abul22)

Project Name: Acetaminophen-Oral-Solution

Report Method: Sample Audit Report

Date Printed:

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Vial Id	1761	Peak Ratio Reference	No
Altered	Yes	Column Name	XTerra C18 4.6x250mm, 5μ
Original Vial Id	1727	Column Serial Number	
Comments	NA	Dilution	1.0000
Blank	No	Sample Matrix	
		SampleName	Standard
		SampleWeight	1.0000

Sample History

User: abul22 Date: 8/27/2020 9:21:54 AM EDT Reason: NA

Modified Vial(Label): <No Value> -> a

Acquisition Log

Acquired By	abul22
Injection	5
Date Acquired	8/26/2020 6:42:16 PM EDT
Run Time	15.00(Minutes)
Acq Method Set	082620_MS_Aacetaminophen_OI
Injection Volume	10.00(uL)
Barcode / BCD	
Auto Additions	
Injection Id	1736
Instrument Method Id	1709
Instrument Method Name	IM_Aacetomin 082620_2998 PDA_OI
Superseded	No
# of Process Only Sample Sets	0
Injection Status	Complete
eCord Name	
eCord Serial Number	
eCord Injection Count (Lifetime to Date)	
eCord Sample Count (Lifetime to Date)	
eCord Maximum Pressure (Lifetime to Date) (psi)	
eCord Maximum Temperature (Lifetime to Date) (°C)	
Use Syringe Settings	
Syringe Size A (uL)	
Nanoliter Adapter A	
Syringe Size B (uL)	
Nanoliter Adapter B	

Vial: 1, Sample Name: Standard

Vial Information

Vial	1
Sample Type	Unknown
Level	
Label	a

Reported by User: Abul Siddiqui (abul22)

Project Name: Acetaminophen-Oral-Solution

Report Method: Sample Audit Report

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Vial Id	1762	Peak Ratio Reference	No
Altered	Yes	Column Name	XTerra C18 4.6x250mm, 5μ
Original Vial Id	1740	Column Serial Number	
Comments	NA	Dilution	1.0000
Blank	No	Sample Matrix	
		SampleName	Diluent
		SampleWeight	1.0000

Sample History

User: abul22 Date: 8/27/2020 9:21:54 AM EDT Reason: NA

Modified Vial(Label): <No Value> -> a

Acquisition Log

Acquired By	abul22
Injection	1
Date Acquired	8/26/2020 7:14:02 PM EDT
Run Time	15.00(Minutes)
Acq Method Set	082620_MS_Aacetaminophen_OI
Injection Volume	10.00(µL)
Barcode / BCD	
Auto Additions	
Injection Id	1741
Instrument Method Id	1709
Instrument Method Name	IM_Aacetomin 082620_2998 PDA_OI
Superseded	No
# of Process Only Sample Sets	0
Injection Status	Complete
eCord Name	
eCord Serial Number	
eCord Injection Count (Lifetime to Date)	
eCord Sample Count (Lifetime to Date)	
eCord Maximum Pressure (Lifetime to Date) (psi)	
eCord Maximum Temperature (Lifetime to Date) (°C)	
Use Syringe Settings	
Syringe Size A (µL)	
Nanoliter Adapter A	
Syringe Size B (µL)	
Nanoliter Adapter B	

Vial: 4, Sample Name: Finished Blend Lot 2023001 B

Vial Information

Vial	4
Sample Type	Unknown
Level	
Label	a

Reported by User: Abul Siddiqui (abul22)

Project Name: Acetaminophen-Oral-Solution

Report Method: Sample Audit Report

Date Printed:

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Vial Information

Vial	5
Sample Type	Unknown
Level	
Label	a
Vial Id	1764
Altered	Yes
Original Vial Id	1746
Comments	NA
Blank	No
Peak Ratio Reference	No
Column Name	XTerra C18 4.6x250mm, 5μ
Column Serial Number	
Dilution	1.0000
Sample Matrix	
SampleName	Finished Blend Lot 2023001 M
SampleWeight	1.0000

Sample History

User: abul22 Date: 8/27/2020 9:21:54 AM EDT Reason: NA

Modified Vial(Label): <No Value> -> a

Acquisition Log

Acquired By	abul22
Injection	1
Date Acquired	8/26/2020 7:45:52 PM EDT
Run Time	15.00(Minutes)
Acq Method Set	082620_MS_Acetaminophen_OI
Injection Volume	10.00(uL)
Barcode / BCD	
Auto Additions	
Injection Id	1747
Instrument Method Id	1709
Instrument Method Name	IM_Acetomin 082620_2998 PDA_OI
Superseded	No
# of Process Only Sample Sets	0
Injection Status	Complete
eCord Name	
eCord Serial Number	
eCord Injection Count (Lifetime to Date)	
eCord Sample Count (Lifetime to Date)	
eCord Maximum Pressure (Lifetime to Date) (psi)	
eCord Maximum Temperature (Lifetime to Date) (°C)	
Use Syringe Settings	
Syringe Size A (uL)	
Nanoliter Adapter A	
Syringe Size B (uL)	
Nanoliter Adapter B	

Vial: 1, Sample Name: Standard

Vial Information

Vial	1	Peak Ratio Reference	No
Sample Type	Unknown	Column Name	XTerra C18 4.6x250mm, 5μ
Level		Column Serial Number	
Label	a	Dilution	1.0000
Vial Id	1766	Sample Matrix	
Altered	Yes	SampleName	Standard
Original Vial Id	1752	SampleWeight	1.0000
Comments	NA		
Blank	No		

Sample History

User: abul22 Date: 8/27/2020 9:21:54 AM EDT Reason: NA

Modified Vial(Label): <No Value> -> a

Acquisition Log

Acquired By	abul22
Injection	1
Date Acquired	8/26/2020 8:17:38 PM EDT
Run Time	15.00(Minutes)
Acq Method Set	082620_MS_Acetaminophen_OI
Injection Volume	10.00(uL)
Barcode / BCD	
Auto Additions	
Injection Id	1753
Instrument Method Id	1709
Instrument Method Name	IM_Acetomin 082620_2998 PDA_OI
Superseded	No
# of Process Only Sample Sets	0
Injection Status	Complete
eCord Name	
eCord Serial Number	
eCord Injection Count (Lifetime to Date)	
eCord Sample Count (Lifetime to Date)	
eCord Maximum Pressure (Lifetime to Date) (psi)	
eCord Maximum Temperature (Lifetime to Date) (°C)	
Use Syringe Settings	
Syringe Size A (uL)	
Nanoliter Adapter A	
Syringe Size B (uL)	
Nanoliter Adapter B	