

Certificate of QA Approval

Client	University of Oxford
Job Step Number	27547.4
Protocol	PRINCIPLE
Bulk Lot Numbers	9R1AR

Products of Step

Qty. Produced	Part Number	Description
499.000000	HF70215	HYDROXYCHLOROQUINE SULFATE (Plaquenil) 200mg 15 Fill Tablet Labeled Blister, Information Booklet, Patient contact Card, Medication Card Unlabeled Envelope Prt: PRINCIPLE Manufacturing Lot: 27547.4 Customer Lot: 9R1AR
499.000000	HF70216	PAPERWORK ONLY (No Drug) Information Booklet, Patient Contact Card In Envelope Prt: PRINCIPLE Manufacturing Lot: 27547.4 Customer Lot: 27547.4
1.000000	HF70220	RETAIN SAMPLE: HYDROXYCHLOROQUINE SULFATE (Plaquenil) 200mg 15 Fill Tablet Labeled Blister, Information Booklet, Patient contact Card, Medication Card in Unlabeled Envelope Prt: PRINCIPLE Manufacturing Lot: 27547.4 Customer Lot: 9R1AR
1.000000	HF70221	RETAIN SAMPLE: PAPERWORK ONLY (No Drug) Information Booklet, Patient Contact Card In Envelope Prt: PRINCIPLE Manufacturing Lot: 27547.4 Customer Lot: 27547.4

Included Documents

Certificate of Approval	Attachment : Form - Certificate of QA Review	Attachment : Deviations - PR188738
Production Order	Instruction Comments	Line Clearance Log
Personnel Log	In-Process Inspection Summary	Quality Audit Log
Material Accountability	Sample Labels	Destruction of Material
Data Revision History	Attachment : Image - First Printed Medication Card	Attachment : Image - First Printed Patient Contact Card
Attachment : Image - First Set Of Components Entering The Envelope [3]	Attachment : Image - First Completed Envelope [3]	Attachment : Image - First labelled blister
Attachment : Image - First set of components entering the envelope [4]	Attachment : Image - First completed envelope [4]	Required Attachment : Form - Label Proofs
Attachment : Form - Supporting Documentation		

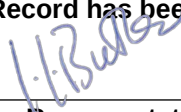
Certificate of QA Approval

This certifies that the material described herein has been packaged in accordance with current Good Manufacturing Practices and the approved Job Step Instructions.

Operations Reviewed By:		Quality Approved By:	
<i>Adshead, Stephen</i>	04/MAY/20 21:59	<i>Hay, Richard</i>	05/MAY/20 17:32

____ Signature below indicates the Batch Record has been reviewed and approved.

____ Signature below indicates the Batch Record has been reviewed/approved and the product is released for shipment.

 _____ Customer Representative Signature	05.05.2020 _____ Date
Christopher C. Butler _____ Customer Representative Name (print)	Professor _____ Title
Clinical Trials Unit, Nuffield Department of Primary Care Health Sciences _____ Customer/Entity Name	

Certificate of QA Review

Product	HYDROXYCHLOROQUINE SULFATE (Plaquenil) 200mg 15 Fill Tablet Labeled Blister, Information Booklet, Patient contact Card, Medication Card Unlabeled Envelope Prt: PRINCIPLE
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Fisher references

Part number:	HF70215
Receive lot number:	FH202688
Job number:	27547.4
Quantity	499

Client references

Customer lot number:	9R1AR
Expiration Date:	04/2022

References for any relevant deviations

PR# 188738

A review of product, samples and batch documentation has been completed by Quality Assurance. All product was produced in compliance with applicable GMP (Directive 2003/94/EC).

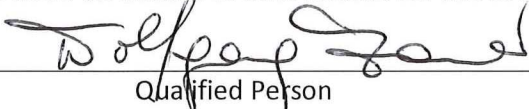
Any deviations have been investigated.

This certificate applies only to the processing carried out under the job number quoted above.

Reviewer:  Date: 05 MAY 2020
Jean Nichols

Quality Assurance

This is not a certificate of final release for use in clinical trials or for sale

Approver:  Date: 05 MAY 2020
Qualified Person

G. Goodban MChem CSci CChem MRSC	☒	H. Berlanga BSc (Hons) CBiol MRSB	
W. Zauner PhD	☒	N. Wilmer BSc (Hons) MRSB	
M. Clevett BSc (Hons) MRSC		M. Shaw PhD	

This Report May Contain Unblinding Information
INVESTIGATION Report

PR ID:	188738	PR State:	Awaiting Client Approval
		Since:	05-May-2020 12:50
Date Created:	04-May-2020 12:29	Site / Project:	Horsham / Investigation

Initiation
General Information

Originator:	Jeffs, Caroline	Investigation Type:	Deviation
Date Opened:	04-May-2020 12:26 pm	Date Due:	01-Jun-2020
Short Description:	Prt: PRINCIPLE: Job# 27547.4 - PASS incorrectly setup with OL numbers		
Investigation Owner:	Duncan, Gareth	Assigned To:	Duncan, Gareth
Reported By:	Jeffs, Caroline	Reported To:	Duncan, Gareth
Reported Date:	04-May-2020	Date of Event:	4-May-2020
Department Head:	Mosley, Ross	Other Sites Impacted:	N/A

Client / Vendor Information

Client Name:	University of Oxford	Client Approval Req:	Yes
Vendor Related?:	No	Date Client Notified:	04-May-2020
Vendor Name:			

Event Information

Description: On 04 May 2020, during the Start-Up of Sub-Step 4 for Job# 27547.4 in Secondary Ambient Packaging Cabin 17, the Senior Operator identified that the Open Label (OL) number on the booklet label barcode did not match that of the Production Assembly Scanning System (PASS) scan setup, Barcode data was set up as OL002 whilst the PASS was setup as OL2.

The job could not start until PASS was disabled, and the labels would subsequently be required to be pre-dispensed as per WI-000004261 (Packaging - Labelling, De-labelling and Replacement Label Procedure). This has no impact, as the labels are open label and PASS is setup to ensure all labels have been processed. It is within packaging processes to dispense labels that do not contain patient numbers.

Current Known Impact: There is no impact as the job could continue once PASS had been disabled.

Immediate Actions Taken: The issue was escalated as per the FCS Horsham escalation procedure SOP-000004048 (Packaging Escalation Procedure) and the Packaging Project Manager (PPM) was informed of the issue.

Impacted Area: Secondary Packaging **Impacted Area II:** Ambient Temperature & Standard light

Impacted Area III: Labelling

Production Batch Record

Error Classification Level I: Documentation Discrepancy

Error Classification Level II: GPM - Job Setup

Error Classification Level III: Incorrect

Accountability Level I: CTD Attributable

Accountability Level II: Horsham

Accountability Level III: Client Services - Packaging

Severity of Event: Level 1

Are Equipment / Tools Affected?: No

Equipment / Tools:

Is Stock Affected?: No

Affected Parts Grid:

<u>Protocol Number</u>	<u>Part Number</u>	<u>Part Description</u>	<u>Lot Number</u>	<u>Receiving Number</u>
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Is Packaging/Manufac. Affected?: Yes

Packaging/Manufacturing Grid:

<u>Protocol Number</u>	<u>Project Name</u>	<u>Job Number</u>	<u>Job Step</u>
PRINCIPLE		27547	4

Is Distribution Affected?: No

Distribution Grid:

<u>Protocol Number:</u>	<u>Distribution Order:</u>	<u>Shipping Site:</u>	<u>Receiving Site:</u>	<u>Shipper Component</u>	<u>Temp Monitor</u>	<u>Shipping Destination</u>	<u>Courrier</u>
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Are Labels Affected?: No

Label Grid:

<u>Protocol Number:</u>	<u>Label ID Number:</u>	<u>Label Description:</u>	<u>Part Number</u>	<u>PDR/CLK Number</u>
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Attachments

Approval Attachments:

Impact Investigation

Impact Investigation

Is There Product Impact?: No

Scope of Product Impact:

Production Batch Record

There is no product impact as a result of this event.

Is There Patient Impact?: No

Patient Impact Details:

There is no patient impact as a result of this event.

Is There Study Impact?: No

Study Impact Details:

There is no study impact as a result of this event.

Is Drug Supply Impacted?: No

Drug Supply Impact Details:

There is no drug supply impact as a result of this event. The detail within the Barcode was for internal PASS use only.

Is There Regulatory Impact?: No

Regulatory Impact Details:

There is no regulatory impact as a result of this event.

Summary of Impact Assessment:

There is no impact to the Safety, Quality, Identity, Potency, or Purity for the client or the end user of this product. However, it is noted that without the additional identity check of the item via the label barcode the labels did need to be pre-dispensed as per WI-000004261 (Packaging - Labelling, De-labelling and Replacement Label Procedure), adding an unexpected step to the process. Labels will still undergo a 100% accountability check.

A review of the Trackwise PR raised in the last 12 months shows this is the first incident of a PR where the used OL (Open Label) material number in GPMS differs from that coded within the barcode itself.

•**Potential Severity:** 1 - This is an Open label study, the Material ranged used within the barcode is for FCS internal accountability checks only. As a result of the PR these were pre-dispensed as per WI-000004261 (Packaging - Labelling, De-labelling and Replacement Label Procedure).

•**Probability of Reoccurrence:** 1 A review of the Trackwise PRs raised in the last 12 months shows this is the only incident of this nature in that time period

•**Detectability:** 1 All labels are scanned as part of accountability checks. Any anomaly such as this would be highlighted prior to job start and escalated accordingly.

The overall risk rating is therefore rated at 1, and as a result no root cause analysis is required.

Final Product Disposition: Approved

Is Error a Reoccurrence?: No

Risk Level Determination

Potential Severity: 1

Probability of Reoccurrence: 1

Detectability: 1

Risk Level Count: 1

Root Cause Investigation

Root Cause Investigation

Data Collection:

PR ID: 188738

**Fisher Clinical Services**

PR State: Awaiting Client Approval Job Step: 27547.4

Since: 05-May-2020 12:50

Date Created: 04-May-2020 12:29

Site / Project: Horsham / Investigation

Production Batch Record

No investigation is deemed necessary due to absence of product impact, low probability of reoccurrence and high detectability. This represents a data entry input PASS error that does not have any hindrance on the production of the stock. There are robust systems in place to prevent any stock being impacted by such an event, as we have witnessed in this example with the issue being flagged before the job starts. This also leads to a high detectability.

Root Cause Summary:

Not Applicable

Contributory Causes:

Not Applicable

Is Root Cause a Reoccurrence?: No

Root Cause Level I: No RCA conducted

Root Cause Level II: No RCA conducted

Root Cause Level III: No RCA conducted

Approvals

Signatures

Submitted By: Jeffs, Caroline

Submitted On: 04-May-2020 14:14

Cancelled By:

Cancelled On:

Level 0 Investigation By:

Level 0 Investigation On:

Initial Quality Review By: Brown, Thomas

Initial Quality Review On: 04-May-2020 15:30

Level 0 Dispo. Confirmed By:

Level 0 Dispo. Confirmed On:

Back to Quality Review By:

Back to Quality Review On:

Investigation Completed By: Duncan, Gareth

Investigation Completed On: 05-May-2020 12:45

External Approval Needed By: Briggs, Choi Wan

External Approval Needed On: 05-May-2020 12:50

Internal Approval Only By:

Internal Approval Only On:

Client Approval Received By:

Client Approval Received On:

Client Approval By:

Date:

Production Order

Customer: University of Oxford
Protocol: PRINCIPLE
Job/Version: 27547.4 v2
Site: Horsham
Step Description: Compilation of non-drug kit and Hydroxychloroquine Kits

Temperature packaging room requirements: 15°C to 25°C
Humidity Requirements: Not Controlled

Production Order**SubStep 1 - Recovery Service****Service Output**

Quantity	Part #	Description
500	S27547.4.1A	PRINTED MEDICATION CARD Prt: PRINCIPLE
		Manufacturers Lot
		27547.4

Service Input

Quantity	Part #	Description
3	HJ10684	HP color choice, A4,250 gsm, laser paper, White (ream 250 sheets) Part No: 297832452 Prt: PRINCIPLE

Station Assignments

Station	Part #	Description
1	HJ10684	HP color choice, A4,250 gsm, laser paper, White (ream 250 sheets) Part No: 297832452 Prt: PRINCIPLE

Image Plan

Quantity	Part #	Description	Instruction
1	S27547.4.1A	PRINTED MEDICATION CARD Prt: PRINCIPLE	Attach all photo(s) to the job and save a copy in the Operations photo files. Ensure the following photo(s) to be taken clearly show label placement and all label variables where appropriate. 1.The first printed Medication Card

Startup Inspection Procedure**Perform Startup Inspections After**

5 Minutes

In-Process Inspection Procedure

In Process Inspection	Interval Type	Quantity
999 Minutes	At Least	1 Units

Startup Instructions:

Due to the nature of inspection which requires 100% check of all stock, no start-up inspection is required.

Please enter Not Required for the Inspect Test "Surface blemishes such as dirt"

Production Order

Note: Please ensure required number of In-Process Inspections are completed before job close out for GPM purposes.

Special In-Process Instructions:

Due to the nature of inspection which requires 100% check of all stock, no start-up inspection is required.

Production Order**Assembly Instructions:**

NOTES:

PR#187792

HCOSHH N/A

Controlled Drug: No

Storage: 15-25°C

Packaging: 15-25°C

Amber Lighting Required: No

Humidity: Not Controlled

NOTE: Comment to be recorded as part of the EPO to confirm printer serial number.

NOTE: 5% overage to be printed for Medication cards. (25 extra Medication cards to be printed)

Sub-step 1

Printing of Medication Card

INSTRUCTIONS:

HJ10684 - Card component - Labelling Station 1

Move HJ10684 to the print room, record via a comment.

Using the card, print Medication Cards as per the attached document.

Note: The Medication card is A5 printed double sided.

Cut card to size once printed.

Record printing on FORM-000004737 (Replacement Label Tracker) and include in batch record documentation.

Move printed cards back into cabin. Record via a comment.

Receive as sub-assembly S27547.4.1A

Production Order
SubStep 2 - Recovery Service
Service Output

Quantity	Part #	Description
1,000	S27547.4.2A	PRINTED PATIENT CONTACT CARD Prt: PRINCIPLE
		Manufacturers Lot
		27547.4

Service Input

Quantity	Part #	Description
3	HJ10684	HP color choice, A4,250 gsm, laser paper, White (ream 250 sheets) Part No: 297832452 Prt: PRINCIPLE

Station Assignments

Station	Part #	Description
1	HJ10684	HP color choice, A4,250 gsm, laser paper, White (ream 250 sheets) Part No: 297832452 Prt: PRINCIPLE

Image Plan

Quantity	Part #	Description	Instruction
1	S27547.4.2A	PRINTED PATIENT CONTACT CARD Prt: PRINCIPLE	Attach all photo(s) to the job and save a copy in the Operations photo files. Ensure the following photo(s) to be taken clearly show label placement and all label variables where appropriate. 1.The first printed Patient Contact Card

Startup Inspection Procedure

Perform Startup Inspections After
5 Minutes

In-Process Inspection Procedure

In Process Inspection	Interval Type	Quantity
999 Minutes	At Least	1 Units

Startup Instructions:

Due to the nature of inspection which requires 100% check of all stock, no start-up inspection is required.

Please enter Not Required for the Inspect Test "Surface blemishes such as dirt"

Production Order

Note: Please ensure required number of In-Process Inspections are completed before job close out for GPM purposes.

Special In-Process Instructions:

Due to the nature of inspection which requires 100% check of all stock, no start-up inspection is required.

Production Order**Assembly Instructions:**

NOTES:

PR#187792

HCOSHH N/A

Controlled Drug: No

Storage: 15-25°C

Packaging: 15-25°C

Amber Lighting Required: No

Humidity: Not Controlled

NOTE: Comment to be recorded as part of the EPO to confirm printer serial number.

NOTE: 5% overage to be printed for Patient Contact cards. (50 extra Patient Contact cards to be printed)

Sub-step 2

Printing of Patient Contact Card

INSTRUCTIONS:

HJ10684 - Card component - Labelling Station 1

Move HJ10684 to the print room, record via a comment.

Using the card, print Patient Contact Cards as per the attached document.

Cut card to size once printed.

Record printing on FORM-000004737 (Replacement Label Tracker) and include in batch record documentation.

Move printed cards back into cabin. Record via a comment.

Receive as sub-assembly S27547.4.2A

Production Order

SubStep 3 - Labeling Service

Service Output

Quantity	Part #	Description
499	HF70216	PAPERWORK ONLY (No Drug) Information Booklet, Patient Contact Card In Envelope Prt: PRINCIPLE
		Manufacturers Lot
		27547.4
1	HF70221	RETAIN SAMPLE: PAPERWORK ONLY (No Drug) Information Booklet, Patient Contact Card In Envelope Prt: PRINCIPLE
		Manufacturers Lot
		27547.4

Service Input

Quantity	Part #	Description
10	HJ10688	Mail Lite® Padded Envelope 336 x 238 mm, AirCap® Self-Adhesive, Kraft Paper, Box of 50, Part 297881821 Prt: PRINCIPLE
500	HL69222	LABEL White 8 1/4 x 11 11/16 inch Placed On Leaflet/Booklet TG Instructions booklet for participants English OXF2501 (HL69221) Prt: PRINCIPLE
500	S27547.4.2A	PRINTED PATIENT CONTACT CARD Prt: PRINCIPLE
		Manufacturers Lot
		27547.4

Station Assignments

Station	Part #	Description
1	HL69222	LABEL White 8 1/4 x 11 11/16 inch Placed On Leaflet/Booklet TG Instructions booklet for participants English OXF2501 (HL69221) Prt: PRINCIPLE
1	S27547.4.2A	PRINTED PATIENT CONTACT CARD Prt: PRINCIPLE
2	HJ10688	Mail Lite® Padded Envelope 336 x 238 mm, AirCap® Self-Adhesive, Kraft Paper, Box of 50, Part 297881821 Prt: PRINCIPLE

Image Plan

Quantity	Part #	Description	Instruction
1	HF70216	PAPERWORK ONLY (No Drug) Information Booklet, Patient Contact Card In Envelope Prt: PRINCIPLE	Attach all photo(s) to the job and save a copy in the Operations photo files. Ensure the following photo(s) to be taken clearly show label placement and all label variables where appropriate. 1. The first set of components entering the envelope. 2. The first completed envelope.

Production Order**Startup Inspection Procedure**

Perform Startup Inspections After
5 Minutes

In-Process Inspection Procedure

In Process Inspection	Interval Type	Quantity
240 Minutes	At Least	1 Units

Startup Instructions:

Verify accuracy of the door sign and Inspect 1 unit at start of sub step (up to + 15 minutes) versus the Production Order, blinding/consistency Images, CADTD, sample label page and CSD (if applicable)

Damaged Product or Component

- Ensure Stock is issued to correct workstation
- Ensure the correct CADTD and blinding/consistency images are at the correct workstation
- Verify accuracy of label text versus the Service Input
- Verify accuracy of label text versus Assembly Instruction notes section
- Verify accuracy of label text versus the sample label page
- Verify any applicable ancillary components are present
- Verify all components are free from damage
- Verify the drug, if visible, is not damaged
- Confirm presence of patient information leaflet (if applicable)
- Inspect the inside of kit prior to closure (if applicable)

Incorrect Label Placement

- Verify the proper adherence of label(s)
- Confirm correct label placement

Production Order

- Confirm correct commercial label placement/coverage(if applicable)
- Confirm correct tamper evident seal placement(if applicable)
- For applicable automated labelling ensure the alignment of the label placement on the unit is correct to the specification

Tamper Evident Seal Missing

- Ensure tamper evident seal is present (if applicable)

Foreign Material

- Verify all components are free from contamination
- Verify the drug, if visible, is free from contamination

Label Print Excessive Fading and/or Smears

- Inspect labels to ensure all text is legible
- Verify text appearance is consistent
- Ensure no text defects are present

Torn Label

- Verify the label is not damaged

Special In-Process Instructions:

Verify accuracy of the door sign and Inspect 1 unit every 240 minutes (+/- 10 minutes) during production, after any machine adjustment/repair and at resume service versus the Production Order, blinding/consistency Images, CADTD, sample label page and CSD (if applicable).

For ALL In Process and End Production IPC follow the inspection criteria as detailed in the Start Up Inspection

Production Order**Assembly Instructions:**

NOTES:

HCOSHH N/A

Controlled Drug: No

Storage: 15-25°C

Packaging: 15-25°C

Amber Lighting Required: No

Humidity: Not Controlled

Attachments:

CADTD07823 Revision 1

CADTD07843 Revision 1

Label Proofs

Consistency Instructions:

Use the photo(s) from Job 27547.4, Sub-step [3] as a reference to ensure consistency in Sub-step [3]

INSTRUCTIONS

WORKSTATION 1

Fold Information Booklet as per CADTD07843.

Place Folded Information Booklet and Patient Contact Card on to shadow board as per CADTD07843.

Transfer to workstation 2.

WORKSTATION 2:

Verify Information Booklet and Patient Contact Card on shadow board as per CADTD07843.

Place Information Booklet and Patient Contact Card into brown envelope as per CADTD07823.

Transfer to workstation 3.

WORKSTATION 3:

Verify presence of Information Booklet and Patient Contact Card in brown envelope as per CADTD07823.

Note: Leave envelope un-sealed.

Pack 250 envelopes in to shipper and seal with tamper tape.

RETAIN SAMPLE: Pack into appropriate ID labelled container(s) and receive into inventory.

STUDY STOCK: Pack into appropriate ID labelled container(s) and receive into inventory.

Reconcile.

Production Order
SubStep 4 - Labeling Service
Service Output

Quantity	Part #	Description
499	HF70215	HYDROXYCHLOROQUINE SULFATE (Plaquenil) 200mg 15 Fill Tablet Labeled Blister, Information Booklet, Patient contact Card, Medication Card Unlabeled Envelope Prt: PRINCIPLE
		Manufacturers Lot
		27547.4
1	HF70220	RETAIN SAMPLE: HYDROXYCHLOROQUINE SULFATE (Plaquenil) 200mg 15 Fill Tablet Labeled Blister, Information Booklet, Patient contact Card, Medication Card in Unlabeled Envelope Prt: PRINCIPLE
		Manufacturers Lot
		27547.4

Service Input

Quantity	Part #	Description
125	HB34790	HYDROXYCHLOROQUINE SULFATE (Plaquenil) 200mg 60 Fill Tablet 15 Fill Blister x 4 in Labeled Carton Marketed Product
		Manufacturers Lot
		9R1AR
10	HJ10672	Mail Lite® Bubble Lined White Mailers 240 x 330 mm (box 50) Prt: PRINCIPLE
500	HL69219	LABEL White Single Panel 2 x 6 inch Placed On Blister Card TG Blister of 15ct Hydroxychloroquine sulphate 200mg tablets English OXF2505 (HL69217) Prt: PRINCIPLE
500	HL69222	LABEL White 8 1/4 x 11 11/16 inch Placed On Leaflet/Booklet TG Instructions booklet for participants English OXF2501 (HL69221) Prt: PRINCIPLE
500	S27547.4.1A	PRINTED MEDICATION CARD Prt: PRINCIPLE
		Manufacturers Lot
		27547.4
500	S27547.4.2A	PRINTED PATIENT CONTACT CARD Prt: PRINCIPLE
		Manufacturers Lot
		27547.4

Station Assignments

Station	Part #	Description
1	HB34790	HYDROXYCHLOROQUINE SULFATE (Plaquenil) 200mg 60 Fill Tablet 15 Fill Blister x 4 in Labeled Carton Marketed Product

Production Order

Station Assignments

Station	Part #	Description
1	HL69219	LABEL White Single Panel 2 x 6 inch Placed On Blister Card TG Blister of 15ct Hydroxychloroquine sulphate 200mg tablets English OXF2505 (HL69217) Prt: PRINCIPLE
2	HJ10672	Mail Lite® Bubble Lined White Mailers 240 x 330 mm (box 50) Prt: PRINCIPLE
2	HL69222	LABEL White 8 1/4 x 11 11/16 inch Placed On Leaflet/Booklet TG Instructions booklet for participants English OXF2501 (HL69221) Prt: PRINCIPLE
2	S27547.4.1A	PRINTED MEDICATION CARD Prt: PRINCIPLE
2	S27547.4.2A	PRINTED PATIENT CONTACT CARD Prt: PRINCIPLE

Image Plan

Quantity	Part #	Description	Instruction
1	HF70215	HYDROXYCHLOROQUINE SULFATE (Plaquenil) 200mg 15 Fill Tablet Labeled Blister, Information Booklet, Patient contact Card, Medication Card Unlabeled Envelope Prt: PRINCIPLE	Attach all photo(s) to the job and save a copy in the Operations photo files. Ensure the following photo(s) to be taken clearly show label placement and all label variables where appropriate. 1. The first labelled blister. 2. The first set of components entering the envelope. 3. The first completed envelope.

Startup Inspection Procedure

Perform Startup Inspections After
5 Minutes

In-Process Inspection Procedure

In Process Inspection	Interval Type	Quantity
240 Minutes	At Least	1 Units

Startup Instructions:

Verify accuracy of the door sign and Inspect 1 unit at start of sub step (up to + 15 minutes) versus the Production Order, blinding/consistency Images, CADTD, sample label page and CSD (if applicable)

Damaged Product or Component

- Ensure Stock is issued to correct workstation
- Ensure the correct CADTD and blinding/consistency images are at the correct workstation

Production Order

- Verify accuracy of label text versus the Service Input
- Verify accuracy of label text versus Assembly Instruction notes section
- Verify accuracy of label text versus the sample label page
- Verify any applicable ancillary components are present
- Verify all components are free from damage
- Verify the drug, if visible, is not damaged
- Confirm presence of patient information leaflet (if applicable)
- Inspect the inside of kit prior to closure (if applicable)

Incorrect Label Placement

- Verify the proper adherence of label(s)
- Confirm correct label placement
- Confirm correct commercial label placement/coverage(if applicable)
- Confirm correct tamper evident seal placement(if applicable)
- For applicable automated labelling ensure the alignment of the label placement on the unit is correct to the specification

Tamper Evident Seal Missing

- Ensure tamper evident seal is present (if applicable)

Foreign Material

- Verify all components are free from contamination
- Verify the drug, if visible, is free from contamination

Label Print Excessive Fading and/or Smears

- Inspect labels to ensure all text is legible

Production Order

- Verify text appearance is consistent
- Ensure no text defects are present

Torn Label

- Verify the label is not damaged

Special In-Process Instructions:

Verify accuracy of the door sign and Inspect 1 unit every 240 minutes (+/- 10 minutes) during production, after any machine adjustment/repair and at resume service versus the Production Order, blinding/consistency Images, CADTD, sample label page and CSD (if applicable).

For ALL In Process and End Production IPC follow the inspection criteria as detailed in the Start Up Inspection

Production Order**Assembly Instructions:**

NOTES:

HCOSHH 526

Controlled Drug: No

Storage: 15-25°C

Packaging: 15-25°C

Amber Lighting Required: No

Humidity: Not Controlled

Attachments:

CADTD07821 Revision 1

CADTD07822 Revision 1

CADTD07844 Revision 1

Label Proofs

Label Variable information:

N/A (Fixed Text)

Sequence/material numbers:

Retain Sample (Sequence number :1) material number :OL1

Study Stock (Sequence number range: 2 to 500) material number range: OL2 to OL500

Material numbers are provided in the label barcodes for PASS scanning purposes only.

Consistency Instructions:

Use the photo(s) from Job 27547.4, Sub-step [4] as a reference to ensure consistency in Sub-step [4]

INSTRUCTIONS

WORKSTATION 1:

Carefully cut tamper seal and remove blisters.

Retain 1 commercial carton within the Batch Record.

Retain 1 Patient Information Leaflet (if present) within the Batch Record.

Discard any remaining PILs and commercial cartons.

Apply label to blister, fold label and wrap it around blister as per CADTD07821.

Transfer to workstation 2

WORKSTATION 2:

Verify application of label to blister as per CADTD0782

Fold Information Booklet as per CADTD07844.

Place Folded Information Booklet, Patient Contact Card, Medication Card and 1 x Labelled Blister on Shadow board as per CADTD07844.

Transfer to workstation 3

WORKSTATION 3:

Verify Information Booklet, Patient Contact Card, Medication Card and 1 x Labelled Blister on Shadow board as per CADTD07844.

Insert Information Booklet, Patient Contact Card, Medication Card and 1 x Labelled Blister on Shadow board into White envelope as per CADTD07822.

NOTE: Scan using PASS.

Production Order

Transfer to workstation 4.

WORKSTATION 4:

Verify presence of Information Booklet, Patient Contact Card, Medication Card and 1 x Labelled Blister in white Envelope as per CADTD07822.

Note: Leave envelope un-sealed

Pack 250 envelopes in to shipper and seal with tamper tape.

RETAIN SAMPLE: Pack into appropriate ID labelled container(s) and receive into inventory.

STUDY STOCK: Pack into appropriate ID labelled container(s) and receive into inventory.

Destroy excess cards from S27547.4.1A and S27547.4.2A

Reconcile.

Production Order

Assigned Author:	Pre-Review Approved By:
<i>Isted, Kerri</i> 29/APR/20 11:13 By signing, I release this EPO for approval.	<i>Short, Graham</i> 29/APR/20 11:41 By signing, I confirm that I have reviewed this EPO and that all the information is complete and correct.

Production Batch Record

Align and apply label centrally to blister as shown.

POCKETS UP

POCKETS UP

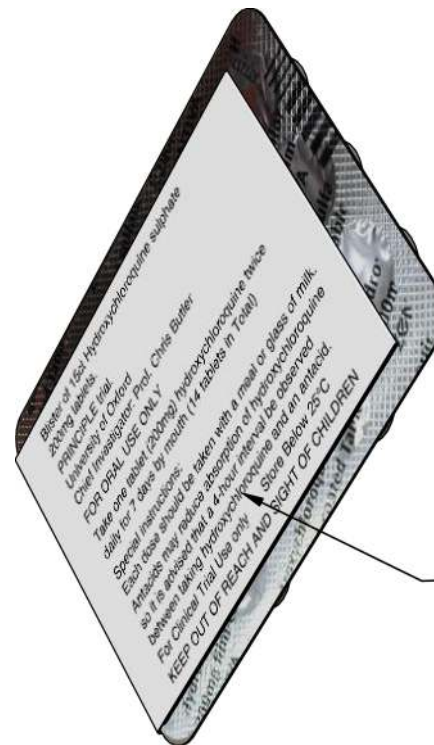
Blister of 15ct Hydroxychloroquine sulphate 200mg tablets.
PRINCIPLE trial.
 University of Oxford
 Chief Investigator: Prof. Chris Butler
FOR ORAL USE ONLY
 Take one tablet (200mg) hydroxychloroquine twice daily for 7 days by mouth (14 tablets in Total)
Special instructions:
 Each dose should be taken with a meal or glass of milk. Antacids may reduce absorption of hydroxychloroquine so it is advised that a 4-hour interval be observed between taking hydroxychloroquine and an antacid. For Clinical Trial Use only Store Below 25°C
KEEP OUT OF REACH AND SIGHT OF CHILDREN
Protocol: PRINCIPLE
Lot: 9R1AR
Expiry Date: 04/2022
Patient Trial Number :
Kit Number
 Sponsor: University of Oxford, Joint Research Office,
 1st floor, Boundary Brook House Churchhill Drive,
 Headington Oxford, OX3 7GB
 Tel: +44 (0)186572224 Fax: +44 (0)186572228
 OXF2505

Expiry Date/Lot No.

POCKETS DOWN

Expiry Date/Lot No.

Protocol: PRINCIPLE
Lot: 9R1AR
Expiry Date: 04/2022
Patient Trial Number :
Kit Number
 Sponsor: University of Oxford, Joint Research Office,
 1st floor, Boundary Brook House Churchhill Drive,
 Headington Oxford, OX3 7GB
 Tel: +44 (0)186572224 Fax: +44 (0)186572228
 OXF2505



Wrap label around blister as shown.

Fold label as shown.
 DO NOT COVER BLISTER EXPIRY/ LOT No.

LABEL TEXT & COMMERCIAL CARTON MAY VARY - DIAGRAM FOR APPLICATION & ASSEMBLY ONLY
 ALL MEASUREMENTS ARE IN MM UNLESS OTHERWISE STATED

TITLE: Operational Assembly Instructions				LABEL SIZE: 2" x 6"	
DRAWN BY: Kscarsbrook		DATE: 22/Apr/20		COMP NO.: N/A	TOOL NO.: N/A
REVISED BY: N/A		SCALE: NTS	REVISION: 1	 fisher clinical services	
DRAWING NO.: CAD007821.dwg					

Production Batch Record

Printed: 05/MAY/20 17:32

Place inside the envelope:
1x Labelled Blister
1x Information Booklet
1x Patient Contact Card
1x Medication Card

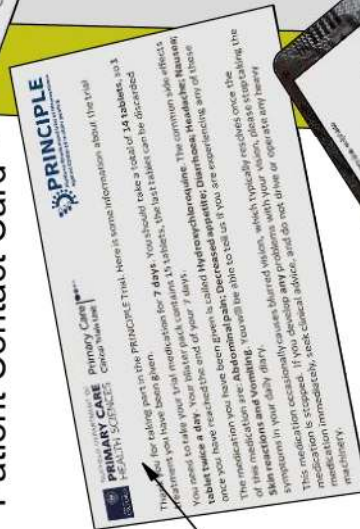
Information booklet



Patient Contact Card



Medication Card



Labelled blister



DO NOT SEAL AND CLOSE ENVELOPE

LABEL TEXT, COMMERCIAL CARTON & COLOURS MAY VARY - DIAGRAM FOR ASSEMBLY ONLY

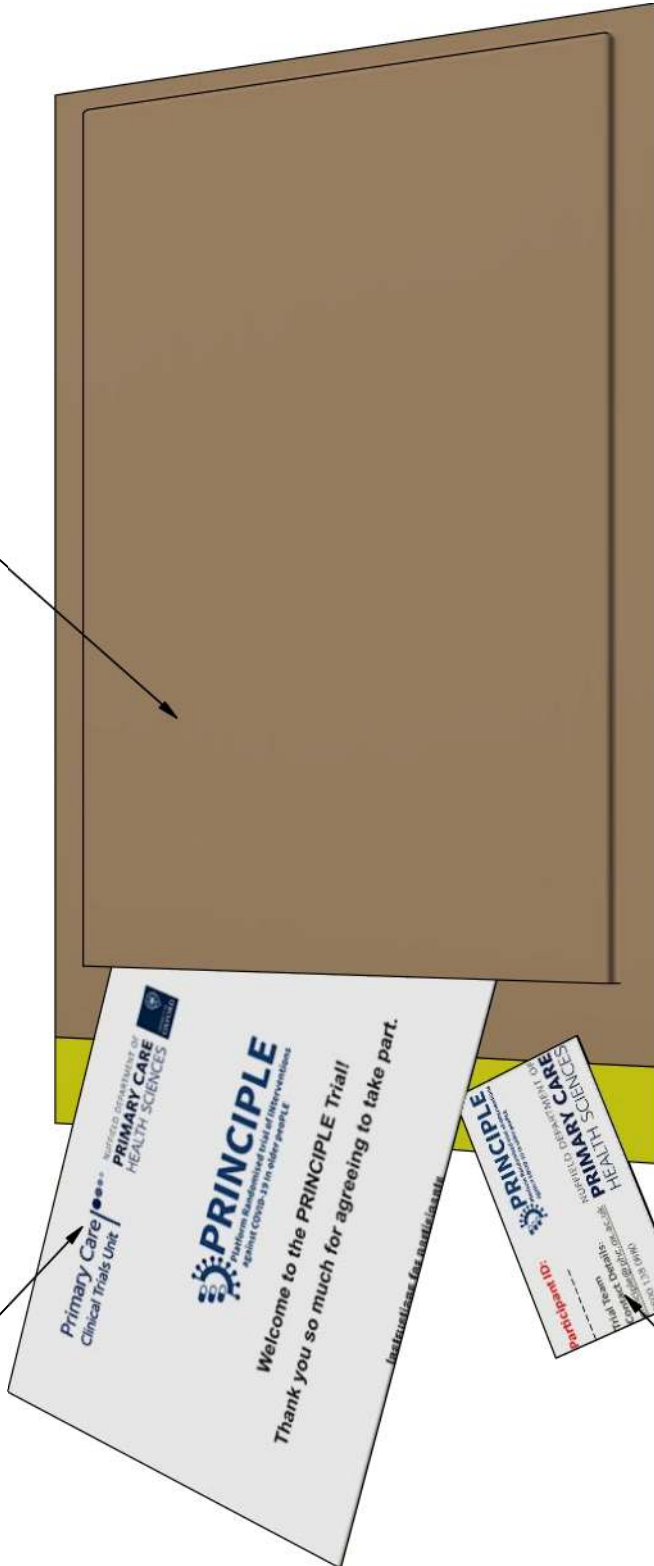
ALL MEASUREMENTS ARE IN MM UNLESS OTHERWISE STATED

TITLE: Operational Assembly Instructions		LABEL SIZE: N/A	
DRAWN BY: Kscarsbrook	DATE: 22/Apr/20	COMP NO.: N/A	TOOL NO.: N/A
REVISION: 1	SCALE: NTS		
DRAWING NO.: CAD007822.dwg	NTS		
		JOB NO: 27547	CLIENT: University of Oxford
		STEP: 27547_4	PROTOCOL: PRINCIPLE

Production Batch Record

Place inside the envelope:
1x Information Booklet
1x Patient Contact Card

Information booklet



Patient Contact Card

DO NOT SEAL AND CLOSE ENVELOPE

LABEL TEXT, COMMERCIAL CARTON & COLOURS MAY VARY - DIAGRAM FOR ASSEMBLY ONLY
ALL MEASUREMENTS ARE IN MM UNLESS OTHERWISE STATED

TITLE: Operational Assembly Instructions		LABEL SIZE: N/A	
DRAWN BY: K. Scarsbrook	DATE: 22/Apr/20	COMP NO.: N/A	TOOL NO.: N/A
REVISION: 1	SCALE: NTS		
DRAWING NO.: CAD007823.dwg			
		JOB NO.: 27547	CLIENT: University of Oxford
		STEP: 27547_4	PROTOCOL: PRINCIPLE



Patient Information Booklet (OXF2501)
(Folded in half)



Patient Contact Card

TITLE: Shadow Board				LABEL TEXT & COMMERCIAL CARTON MAY VARY - DIAGRAM FOR APPLICATION & ASSEMBLY ONLY ALL MEASUREMENTS ARE IN MM UNLESS OTHERWISE STATED					
DRAWN BY: kscarsbrook		DATE: 24/Apr/20	COMP NO.: N/A					TOOL NO.: N/A	
REVISED BY: N/A		SCALE: NTS	REVISION: 1						
DRAWING NO.: CADTD07843.dwg									
JOB NO: 27547		CLIENT: University of Oxford		STEP: 27547.4		PROTOCOL: PRINCIPLE			

CAD-1547/04

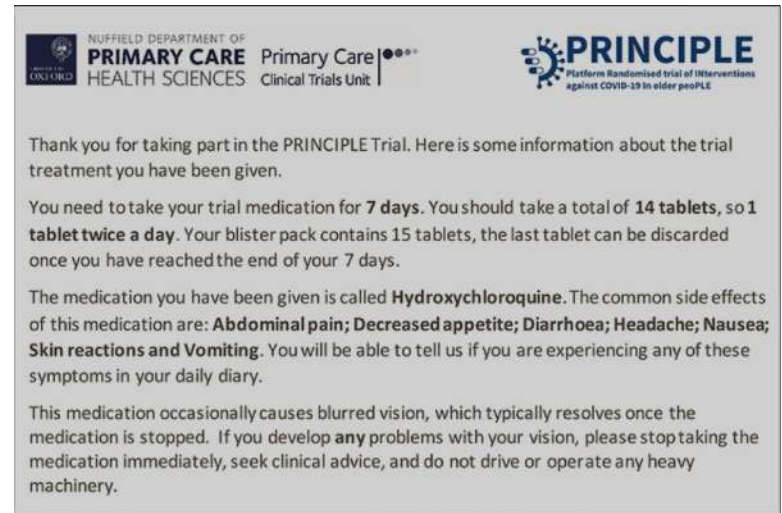
Page 1 of 1



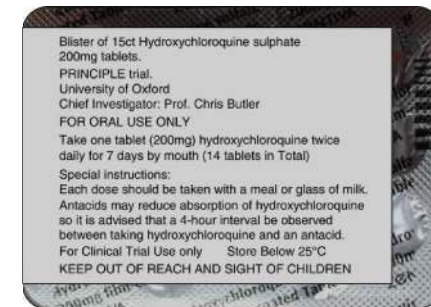
**Patient Information Booklet (OXF2501)
(Folded in half)**



Patient Contact Card



Medication Card



Labelled HYDROXYCHLOROQUINE Blister

TITLE: Shadow Board				LABEL TEXT & COMMERCIAL CARTON MAY VARY - DIAGRAM FOR APPLICATION & ASSEMBLY ONLY ALL MEASUREMENTS ARE IN MM UNLESS OTHERWISE STATED			
DRAWN BY: kscarsbrook	DATE: 24/Apr/20	COMP NO.: N/A	TOOL NO.: N/A	JOB NO: 27547	CLIENT: University of Oxford		
REVISED BY: N/A	SCALE: NTS	REVISION: 1		STEP: 27547_4	PROTOCOL: PRINCIPLE		
DRAWING NO.: CADTD07844.dwg							

CAD-1547/04

Production Batch Record



Production Order Signature Page

Customer: University of Oxford
Protocol: PRINCIPLE
Job Step/Version: 27547.4 v2
Site: Horsham
Step Description: Compilation of non-drug kit and Hydroxychloroquine Kits

☒ **Approved**

Your signature below indicates your approval of the above referenced Electronic Production Order.

☐ **Rejected**

Your signature below indicates your rejection of the above referenced Electronic Production Order.



Customer Representative Signature	29.04.2020	Date
Hannah Swayze	Dr	Title
Customer Representative Name (print)		
University of Oxford		
Customer/Entity Name		

Instruction Comments
SubStep: 1

Service	Created By	Created On	Comments
Recovery	Cross, David	30/APR/20 09:22	The photo instructions state meditation, this is a typographical error and should say medication. No quality impact
	Jeffs, Caroline	30/APR/20 09:24	Component HJ10684 receive CH175115 removed from cabin for printing of Medication Cards.
	Jeffs, Caroline	30/APR/20 09:34	Follow You Printer being used to print medication cards and contact cards is G716M580230.
	Jeffs, Caroline	30/APR/20 14:38	Component HJ10684 receive CH175115 returned to cabin following completion of printed medication cards.

(9.4)

SubStep: 2

Service	Created By	Created On	Comments
	Jeffs, Caroline	30/APR/20 16:02	Follow You Printer being used to print medication cards and contact cards is G716M580230.
	Jeffs, Caroline	30/APR/20 16:02	Component HJ10684 receive CH175115 removed from cabin for printing of Contact Cards.
	Adshead, Stephen	30/APR/20 20:45	Component HJ10684 receive CH175115 returned to cabin following completion of printed contact cards.
	Eldridge, Ken	30/APR/20 21:44	Please ignore this comment as it is a duplicate of instruction comment made on 30 Apr 2020 @ 20:45. - Component HJ10684 receive CH175115 returned to cabin following completion of printed contact cards.
	Jeffs, Caroline	01/MAY/20 10:01	Component HJ10684 receive CH175115 removed from cabin to enable printing of patient contact cards.
	Jeffs, Caroline	01/MAY/20 10:03	Follow You Printer being used to print medication cards and contact cards is G716M580230.
	Jeffs, Caroline	01/MAY/20 16:10	Component HJ10684 receive CH175115 returned to cabin following completion of printed contact cards.

(9.3)

(9.5)

SubStep: 3

Service	Created By	Created On	Comments
Labeling	Draper, Graham	01/MAY/20 19:34	The description on the ID label of the bulk component of HL69222/LH122237 differs from the description in GPM. This is acceptable as the description was updated in GPM and not updated physically on the box. No impact to quality.

Instruction Comments
SubStep: 4

Service	Created By	Created On	Comments	
	Cross, David	04/MAY/20 10:14	The coshh for this job is 562, this matches the line card and is present in the cabin but is typographically incorrect in the PO were it states 526. No quality impact	(9.1)
	Cross, David	04/MAY/20 10:16	On workstation 2 it states CADTD0782 but it should be CADTD07821. This is a typographical error no quality impact	
	Cross, David	04/MAY/20 11:49	During start-up, it was identified that the numbers within PASS set up did not match the numbers in label barcodes, and therefore labels could not be scanned in PASS. The Pass in this case serves only for reconciliation and accountability purposes and therefore the issue can be resolved online using an existing approved process where the labels predisposed prior to labelling. Slight modification to EPO did not represent quality risk to the existing job.	(9.2)
	Nayee, Ushir	05/MAY/20 15:31	QA Review performed	

Line Clearance Log

Room	Date/Time	Previous Job Step	Clearance type
CABIN17	30/APR/20 08:19	21783.43	Secondary Line Clear

Line Clearance Detail

SubStep: 1

Instruction	Performed	Comments
Materials from the previous job have been removed from the room.	☒ Yes ☐ No	N/A
Room has been inspected and appears clean with no visible product residue.	☒ Yes ☐ No	N/A
Auxilliary equipment including floor mats, racks and bins have been inspected and appear clean with no visible product residue.	☒ Yes ☐ No	N/A
Verify that special humidity/temp. alarm set-points and room lighting are set to conditions indicated on the Production Order.	☒ Yes ☐ No	N/A

Task Approved By:	Quality Inspected By:
<i>Kaine, Marites</i> 30/APR/20 08:19 By signing, I confirm that I have performed the Line Clearance and that all the information is complete and correct.	<i>Cross, David</i> 30/APR/20 08:23 I verify that the Line Clearance has been correctly performed.

Line Clearance Log

Room	Date/Time	Previous Job Step	Clearance type
CABIN17	30/APR/20 15:51	21783.43	Secondary Line Clear

Line Clearance Detail

SubStep:

2

Instruction	Performed	Comments
Materials from the previous job have been removed from the room.	☐ Yes ☒ No	The yellow waste bag has been left online for the oncoming sub-step.
Room has been inspected and appears clean with no visible product residue.	☒ Yes ☐ No	N/A
Auxilliary equipment including floor mats, racks and bins have been inspected and appear clean with no visible product residue.	☒ Yes ☐ No	N/A
Verify that special humidity/temp. alarm set-points and room lighting are set to conditions indicated on the Production Order.	☒ Yes ☐ No	N/A

Task Approved By:	Quality Inspected By:
<i>Adshead, Stephen</i> 30/APR/20 15:51 By signing, I confirm that I have performed the Line Clearance and that all the information is complete and correct.	<i>Draper, Graham</i> 30/APR/20 15:52 I verify that the Line Clearance has been correctly performed.

Line Clearance Log

Room	Date/Time	Previous Job Step	Clearance type
CABIN17	01/MAY/20 17:20	21783.43	Secondary Line Clear

Line Clearance Detail

SubStep: 3

Instruction	Performed	Comments
Materials from the previous job have been removed from the room.	☐ Yes ☒ No	The yellow waste bag and the component required for the oncoming sub-step have been left on-line.
Room has been inspected and appears clean with no visible product residue.	☒ Yes ☐ No	N/A
Auxilliary equipment including floor mats, racks and bins have been inspected and appear clean with no visible product residue.	☒ Yes ☐ No	N/A
Verify that special humidity/temp. alarm set-points and room lighting are set to conditions indicated on the Production Order.	☒ Yes ☐ No	N/A

Task Approved By:	Quality Inspected By:
<i>Adshead, Stephen</i> 01/MAY/20 17:20 By signing, I confirm that I have performed the Line Clearance and that all the information is complete and correct.	<i>Mbemba, Hyacinthe</i> 01/MAY/20 17:38 I verify that the Line Clearance has been correctly performed.

Line Clearance Log

Room	Date/Time	Previous Job Step	Clearance type
CABIN17	04/MAY/20 08:23	21783.43	Secondary Line Clear

Line Clearance Detail

SubStep:

4

Instruction	Performed	Comments
Materials from the previous job have been removed from the room.	☐ Yes ☒ No	The yellow bin bag plus all the components required for this oncoming sub-step have been left on line.
Room has been inspected and appears clean with no visible product residue.	☒ Yes ☐ No	N/A
Auxilliary equipment including floor mats, racks and bins have been inspected and appear clean with no visible product residue.	☒ Yes ☐ No	N/A
Verify that special humidity/temp. alarm set-points and room lighting are set to conditions indicated on the Production Order.	☒ Yes ☐ No	N/A

Task Approved By:	Quality Inspected By:
<i>Rezmoves, zsanett</i> 04/MAY/20 08:23 By signing, I confirm that I have performed the Line Clearance and that all the information is complete and correct.	<i>Cross, David</i> 04/MAY/20 08:29 I verify that the Line Clearance has been correctly performed.

Personnel Log

Room CABIN17

Task Assignment

Personnel Name	SubStep	Task	Component	Time In	Time Out
Kaine , Marites	1	Line Leader	N/A	30/APR/20 09:08	30/APR/20 13:58
Niedzieska , Alicja	1	Utility	HJ10684	30/APR/20 09:15	30/APR/20 13:59
Kaine , Marites	1	Recovery - Inspector	HJ10684	30/APR/20 09:15	30/APR/20 13:58
Niedzieska , Alicja	1	Recovery - Packer	HJ10684	30/APR/20 09:16	30/APR/20 13:59
Niedzieska , Alicja	1	Utility	N/A	30/APR/20 15:08	30/APR/20 15:45
Adshead , Stephen	1	Line Leader	N/A	30/APR/20 15:08	30/APR/20 15:45
Niedzieska , Alicja	1	Recovery - Packer	HJ10684	30/APR/20 15:10	30/APR/20 15:45
Adshead , Stephen	1	Recovery - Inspector	HJ10684	30/APR/20 15:10	30/APR/20 15:45
Niedzieska , Alicja	2	Recovery - Packer	HJ10684	30/APR/20 15:54	30/APR/20 18:56
Adshead , Stephen	2	Line Leader	N/A	30/APR/20 15:54	30/APR/20 21:45
Adshead , Stephen	2	Recovery - Inspector	HJ10684	30/APR/20 15:54	30/APR/20 21:45
Adshead , Stephen	2	Utility	N/A	30/APR/20 15:54	30/APR/20 21:45
Denizer , Osman	2	Recovery - Packer	N/A	30/APR/20 20:33	30/APR/20 21:45
Jeffer , Caroline	2	Recovery - Inspector	N/A	01/MAY/20 09:56	01/MAY/20 17:17
Mohamad , Amir	2	Line Leader	N/A	01/MAY/20 09:56	01/MAY/20 14:37
Jeffer , Caroline	2	Recovery - Packer	N/A	01/MAY/20 09:56	01/MAY/20 17:17
Jeffer , Caroline	2	Utility	N/A	01/MAY/20 09:57	01/MAY/20 17:17
Adshead , Stephen	2	Line Leader	N/A	01/MAY/20 14:37	01/MAY/20 17:17
Adshead , Stephen	2	Recovery - Inspector	N/A	01/MAY/20 14:37	01/MAY/20 17:17
Adshead , Stephen	3	Line Leader	N/A	01/MAY/20 17:41	01/MAY/20 21:53
Denizer , Osman	3	Utility	HL69222	01/MAY/20 19:18	01/MAY/20 21:52
Adshead , Stephen	3	Utility	HL69222	01/MAY/20 19:18	01/MAY/20 21:53
Denizer , Osman	3	Utility	HJ10688	01/MAY/20 19:18	01/MAY/20 21:52

Personnel Log

Adshead , Stephen	3	Utility	S27547.4.2A	01/MAY/20 19:18	01/MAY/20 21:53
Adshead , Stephen	3	Utility	HJ10688	01/MAY/20 19:18	01/MAY/20 21:53
Adshead , Stephen	3	Utility	N/A	01/MAY/20 19:18	01/MAY/20 21:53
Denizer , Osman	3	Utility	S27547.4.2A	01/MAY/20 19:18	01/MAY/20 21:52
Kurtulus , Recep	3	Utility	HL69222	01/MAY/20 19:18	01/MAY/20 21:51
Kurtulus , Recep	3	Utility	S27547.4.2A	01/MAY/20 19:18	01/MAY/20 21:51
Levin , Lorraine	3	Utility	N/A	01/MAY/20 20:32	01/MAY/20 21:51
Dessena , Vincenzo	3	Utility	N/A	01/MAY/20 20:47	01/MAY/20 21:51
Voice , Peter	3	Utility	S27547.4.2A	04/MAY/20 06:19	04/MAY/20 07:57
Rezmuves , zsanett	3	Utility	HJ10688	04/MAY/20 06:19	04/MAY/20 07:57
Rezmuves , zsanett	3	Utility	N/A	04/MAY/20 06:19	04/MAY/20 07:57
Gordon , Catherine	3	Utility	S27547.4.2A	04/MAY/20 06:19	04/MAY/20 07:57
Rezmuves , zsanett	3	Utility	S27547.4.2A	04/MAY/20 06:19	04/MAY/20 07:57
Gordon , Catherine	3	Utility	HJ10688	04/MAY/20 06:19	04/MAY/20 07:57
Gordon , Catherine	3	Utility	HL69222	04/MAY/20 06:19	04/MAY/20 07:57
Rezmuves , zsanett	3	Utility	HL69222	04/MAY/20 06:19	04/MAY/20 07:57
Voice , Peter	3	Utility	HL69222	04/MAY/20 06:19	04/MAY/20 07:57
Rezmuves , zsanett	3	Line Leader	N/A	04/MAY/20 06:19	04/MAY/20 07:57
Gordon , Catherine	4	Utility	HJ10672	04/MAY/20 09:14	04/MAY/20 10:53
Rezmuves , zsanett	4	Utility	S27547.4.2A	04/MAY/20 09:14	04/MAY/20 13:49
Csokmei , Daniel	4	Utility	HL69222	04/MAY/20 09:14	04/MAY/20 13:51
Csokmei , Daniel	4	Utility	N/A	04/MAY/20 09:14	04/MAY/20 13:51
Rezmuves , zsanett	4	Utility	N/A	04/MAY/20 09:14	04/MAY/20 13:49
Rezmuves , zsanett	4	Utility	S27547.4.1A	04/MAY/20 09:14	04/MAY/20 13:49
Gordon , Catherine	4	Utility	HL69222	04/MAY/20 09:14	04/MAY/20 10:53
Gordon , Catherine	4	Labeling - Verify Label (Part #)	HL69219	04/MAY/20 09:14	04/MAY/20 10:53

Personnel Log

Csokmei , Daniel	4	Utility	HJ10672	04/MAY/20 09:14	04/MAY/20 13:51
Csokmei , Daniel	4	Utility	S27547.4.2A	04/MAY/20 09:14	04/MAY/20 13:51
Rezmuves , zsanett	4	Utility	HL69222	04/MAY/20 09:14	04/MAY/20 13:49
Voice , Peter	4	Utility	HB34790	04/MAY/20 09:14	04/MAY/20 10:53
Gordon , Catherine	4	Utility	S27547.4.1A	04/MAY/20 09:14	04/MAY/20 10:53
Voice , Peter	4	Labeling - Apply Label (Part #)	HL69219	04/MAY/20 09:14	04/MAY/20 10:53
Rezmuves , zsanett	4	Utility	HJ10672	04/MAY/20 09:14	04/MAY/20 13:49
Rezmuves , zsanett	4	Line Leader	N/A	04/MAY/20 09:14	04/MAY/20 13:49
Gordon , Catherine	4	Utility	S27547.4.2A	04/MAY/20 09:14	04/MAY/20 10:53
Csokmei , Daniel	4	Utility	S27547.4.1A	04/MAY/20 09:14	04/MAY/20 13:51
Hawkins , Chris	4	Utility	S27547.4.1A	04/MAY/20 10:53	04/MAY/20 13:52
Hawkins , Chris	4	Labeling - Verify Label (Part #)	HL69219	04/MAY/20 10:53	04/MAY/20 13:52
Gordon , Catherine	4	Utility	HB34790	04/MAY/20 10:53	04/MAY/20 13:51
Hawkins , Chris	4	Utility	HL69222	04/MAY/20 10:53	04/MAY/20 13:52
Hawkins , Chris	4	Utility	HJ10672	04/MAY/20 10:53	04/MAY/20 10:55
Gordon , Catherine	4	Labeling - Apply Label (Part #)	HL69219	04/MAY/20 10:53	04/MAY/20 13:51
Hawkins , Chris	4	Utility	S27547.4.2A	04/MAY/20 10:53	04/MAY/20 13:52
Kurtulus , Recep	4	Utility	HJ10672	04/MAY/20 15:02	04/MAY/20 20:22
Denizer , Osman	4	Utility	S27547.4.2A	04/MAY/20 15:02	04/MAY/20 20:22
Denizer , Osman	4	Utility	HL69222	04/MAY/20 15:02	04/MAY/20 20:22
Denizer , Osman	4	Utility	HJ10672	04/MAY/20 15:02	04/MAY/20 20:22
Adshead , Stephen	4	Utility	HJ10672	04/MAY/20 15:02	04/MAY/20 20:22
Denizer , Osman	4	Utility	S27547.4.1A	04/MAY/20 15:02	04/MAY/20 20:22
Adshead , Stephen	4	Line Leader	N/A	04/MAY/20 15:02	04/MAY/20 20:22
Adshead , Stephen	4	Utility	S27547.4.1A	04/MAY/20 15:02	04/MAY/20 20:22
Adshead , Stephen	4	Utility	S27547.4.2A	04/MAY/20 15:02	04/MAY/20 20:22

Personnel Log

Kurtulus , Recep	4	Utility	HL69222	04/MAY/20 15:02	04/MAY/20 20:22
Kurtulus , Recep	4	Utility	S27547.4.2A	04/MAY/20 15:02	04/MAY/20 20:22
Kurtulus , Recep	4	Utility	S27547.4.1A	04/MAY/20 15:02	04/MAY/20 20:22
Dessena , Vincenzo	4	Labeling - Apply Label (Part #)	HL69219	04/MAY/20 15:02	04/MAY/20 20:22
Adshead , Stephen	4	Utility	HL69222	04/MAY/20 15:02	04/MAY/20 20:22
Denizer , Osman	4	Labeling - Verify Label (Part #)	HL69219	04/MAY/20 15:02	04/MAY/20 20:22
Dessena , Vincenzo	4	Utility	HB34790	04/MAY/20 15:02	04/MAY/20 20:22
Adshead , Stephen	4	Utility	N/A	04/MAY/20 15:02	04/MAY/20 20:22

Room CABIN17**Force Logoff**

Personnel Name	Time In	Time Out	Logged Out By	Comments
Niedzieska , Alicja	30/APR/20 09:16	30/APR/20 13:59	Kaine, Marites	Personnel forced log off as operations did not log off on the time of action.

In Process Inspection Summary

SubStep 1 Recovery

Inspection Procedure

Timing: 999

Startup Instructions: Due to the nature of inspection which requires 100% check of all stock, no start-up inspection is required.

Please enter Not Required for the Inspect Test "Surface blemishes such as dirt"

Inprocess Instructions: Note: Please ensure required number of In-Process Inspections are completed before job close out for GPM purposes.
Due to the nature of inspection which requires 100% check of all stock, no start-up inspection is required.

Inspection Summary

Number of inspections: 2

Total units inspected: 2

Service Run Summary

Start Date / Time	Started By	Stop Date / Time	Stop By	Reason
30/APR/20 09:17	Kaine, Marites	30/APR/20 09:20	Kaine, Marites	Service Stopped
30/APR/20 15:11	Adshead, Stephen	30/APR/20 15:31	Adshead, Stephen	End of Sub Step

Inspection Details

Date / Time	Container	Units	Level Defects			Inspector	Is Complete	Status	Failure Level	Inspection Type
			I	II	III					
30/APR/20 09:18	1	1	0	N/A	N/A	Kaine, Marites	Y	Pass	No Defects	Startup

Defect Test Results

Defect Level	Description	Quantity
1	Surface blemishes such as dirt	N/A

N/A not required

In Process Inspection Summary**Inspection Details**

Date / Time	Container	Units	Level Defects			Inspector	Is Complete	Status	Failure Level	Inspection Type
			I	II	III					
30/APR/20 15:13	1	1	0	N/A	N/A	Adshead, Stephen	Y	Pass	No Defects	InProcess

Defect Test Results

Defect Level	Description	Quantity
1	Surface blemishes such as dirt	N/A

N/A not required

In Process Inspection Summary

SubStep 2 Recovery

Inspection Procedure

Timing: 999

Startup Instructions: Due to the nature of inspection which requires 100% check of all stock, no start-up inspection is required.

Please enter Not Required for the Inspect Test "Surface blemishes such as dirt"

Inprocess Instructions: Note: Please ensure required number of In-Process Inspections are completed before job close out for GPM purposes.
Due to the nature of inspection which requires 100% check of all stock, no start-up inspection is required.

Inspection Summary

Number of inspections: 3

Total units inspected: 3

Service Run Summary

Start Date / Time	Started By	Stop Date / Time	Stop By	Reason
30/APR/20 15:59	Adshead, Stephen	30/APR/20 16:13	Adshead, Stephen	Service Stopped
01/MAY/20 09:58	Mohamad, Amir	01/MAY/20 10:05	Mohamad, Amir	Service Stopped
01/MAY/20 16:23	Adshead, Stephen	01/MAY/20 17:01	Adshead, Stephen	End of Sub Step

Inspection Details

Date / Time	Container	Units	Level Defects			Inspector	Is Complete	Status	Failure Level	Inspection Type
			I	II	III					
30/APR/20 16:00	1	1	0	N/A	N/A	Adshead, Stephen	Y	Pass	No Defects	Startup

Defect Test Results

Defect Level	Description	Quantity
1	Surface blemishes such as dirt	N/A

N/A not required

In Process Inspection Summary

Inspection Details

Date / Time	Container	Units	Level Defects			Inspector	Is Complete	Status	Failure Level	Inspection Type
			I	II	III					
01/MAY/20 10:00	1	1	0	N/A	N/A	Mohamad, Amir	Y	Pass	No Defects	InProcess

Defect Test Results

Defect Level	Description	Quantity
1	Surface blemishes such as dirt	N/A

N/A - Not required.

Inspection Details

Date / Time	Container	Units	Level Defects			Inspector	Is Complete	Status	Failure Level	Inspection Type
			I	II	III					
01/MAY/20 16:26	1	1	0	N/A	N/A	Adshead, Stephen	Y	Pass	No Defects	InProcess

Defect Test Results

Defect Level	Description	Quantity
1	Surface blemishes such as dirt	N/A

N/A not required.

In Process Inspection Summary**SubStep 3 Labeling****Inspection Procedure****Timing:** 240**Startup Instructions:** Verify accuracy of the door sign and Inspect 1 unit at start of sub step (up to + 15 minutes) versus the Production Order, blinding/consistency Images, CADTD, sample label page and CSD (if applicable)**Damaged Product or Component**

- Ensure Stock is issued to correct workstation
- Ensure the correct CADTD and blinding/consistency images are at the correct workstation
- Verify accuracy of label text versus the Service Input
- Verify accuracy of label text versus Assembly Instruction notes section
- Verify accuracy of label text versus the sample label page
- Verify any applicable ancillary components are present
- Verify all components are free from damage
- Verify the drug, if visible, is not damaged
- Confirm presence of patient information leaflet (if applicable)
- Inspect the inside of kit prior to closure (if applicable)

Incorrect Label Placement

- Verify the proper adherence of label(s)
- Confirm correct label placement
- Confirm correct commercial label placement/coverage(if applicable)
- Confirm correct tamper evident seal placement(if applicable)
- For applicable automated labelling ensure the alignment of the label placement on the unit is correct to the specification

In Process Inspection Summary**Tamper Evident Seal Missing**

- Ensure tamper evident seal is present (if applicable)

Foreign Material

- Verify all components are free from contamination
- Verify the drug, if visible, is free from contamination

Label Print Excessive Fading and/or Smears

- Inspect labels to ensure all text is legible
- Verify text appearance is consistent
- Ensure no text defects are present

Torn Label

- Verify the label is not damaged

Inprocess Instructions: Verify accuracy of the door sign and Inspect 1 unit every 240 minutes (+/- 10 minutes) during production, after any machine adjustment/repair and at resume service versus the Production Order, blinding/consistency Images, CADTD, sample label page and CSD (if applicable).

For ALL In Process and End Production IPC follow the inspection criteria as detailed in the Start Up Inspection

Inspection Summary

Number of inspections: 3

Total units inspected: 3

In Process Inspection Summary

Service Run Summary

Start Date / Time	Started By	Stop Date / Time	Stop By	Reason
01/MAY/20 19:38	Adshead, Stephen	01/MAY/20 21:50	Adshead, Stephen	End of Shift
04/MAY/20 06:26	Rezmuves, zsanett	04/MAY/20 07:44	Rezmuves, zsanett	End of Sub Step

Inspection Details

Date / Time	Container	Units	Level Defects			Inspector	Is Complete	Status	Failure Level	Inspection Type
			I	II	III					
01/MAY/20 19:38	1	1	0	N/A	N/A	Adshead, Stephen	Y	Pass	No Defects	Startup

Defect Test Results

Defect Level	Description	Quantity
1	Foreign material on label	0
1	Incorrect label placement	0
1	Tamper evident seal missing	0
1	Label print excessive fading or smears	0
1	Torn label	0
1	Damaged product or component	0

N/A

In Process Inspection Summary**Inspection Details**

Date / Time	Container	Units	Level Defects			Inspector	Is Complete	Status	Failure Level	Inspection Type
			I	II	III					
04/MAY/20 06:27	2	1	0	N/A	N/A	Rezmuves, zsanett	Y	Pass	No Defects	InProcess

Defect Test Results

Defect Level	Description	Quantity
1	Torn label	0
1	Damaged product or component	0
1	Label print excessive fading or smears	0
1	Tamper evident seal missing	0
1	Incorrect label placement	0
1	Foreign material on label	0

N/A

In Process Inspection Summary**Inspection Details**

Date / Time	Container	Units	Level Defects			Inspector	Is Complete	Status	Failure Level	Inspection Type
			I	II	III					
04/MAY/20 07:32	2	1	0	N/A	N/A	Rezmuves, zsanett	Y	Pass	No Defects	InProcess

Defect Test Results

Defect Level	Description	Quantity
1	Foreign material on label	0
1	Incorrect label placement	0
1	Tamper evident seal missing	0
1	Label print excessive fading or smears	0
1	Damaged product or component	0
1	Torn label	0

End check

In Process Inspection Summary**SubStep 4 Labeling****Inspection Procedure****Timing:** 240**Startup Instructions:** Verify accuracy of the door sign and Inspect 1 unit at start of sub step (up to + 15 minutes) versus the Production Order, blinding/consistency Images, CADTD, sample label page and CSD (if applicable)**Damaged Product or Component**

- Ensure Stock is issued to correct workstation
- Ensure the correct CADTD and blinding/consistency images are at the correct workstation
- Verify accuracy of label text versus the Service Input
- Verify accuracy of label text versus Assembly Instruction notes section
- Verify accuracy of label text versus the sample label page
- Verify any applicable ancillary components are present
- Verify all components are free from damage
- Verify the drug, if visible, is not damaged
- Confirm presence of patient information leaflet (if applicable)
- Inspect the inside of kit prior to closure (if applicable)

Incorrect Label Placement

- Verify the proper adherence of label(s)
- Confirm correct label placement
- Confirm correct commercial label placement/coverage(if applicable)
- Confirm correct tamper evident seal placement(if applicable)
- For applicable automated labelling ensure the alignment of the label placement on the unit is correct to the specification

In Process Inspection Summary**Tamper Evident Seal Missing**

- Ensure tamper evident seal is present (if applicable)

Foreign Material

- Verify all components are free from contamination
- Verify the drug, if visible, is free from contamination

Label Print Excessive Fading and/or Smears

- Inspect labels to ensure all text is legible
- Verify text appearance is consistent
- Ensure no text defects are present

Torn Label

- Verify the label is not damaged

Inprocess Instructions:

Verify accuracy of the door sign and Inspect 1 unit every 240 minutes (+/- 10 minutes) during production, after any machine adjustment/repair and at resume service versus the Production Order, blinding/consistency Images, CADTD, sample label page and CSD (if applicable).

For ALL In Process and End Production IPC follow the inspection criteria as detailed in the Start Up Inspection

Inspection Summary

Number of inspections: 5

Total units inspected: 5

In Process Inspection Summary

Service Run Summary

Start Date / Time	Started By	Stop Date / Time	Stop By	Reason
04/MAY/20 11:51	Rezmoves, zsanett	04/MAY/20 13:48	Rezmoves, zsanett	End of Shift
04/MAY/20 15:11	Adshead, Stephen	04/MAY/20 16:18	Adshead, Stephen	Break
04/MAY/20 17:00	Adshead, Stephen	04/MAY/20 18:18	Adshead, Stephen	Break
04/MAY/20 18:57	Adshead, Stephen	04/MAY/20 20:07	Adshead, Stephen	End of Sub Step

Inspection Details

Date / Time	Container	Units	Level Defects			Inspector	Is Complete	Status	Failure Level	Inspection Type
			I	II	III					
04/MAY/20 11:51	1	1	0	N/A	N/A	Rezmoves, zsanett	Y	Pass	No Defects	Startup

Defect Test Results

Defect Level	Description	Quantity
1	Foreign material on label	0
1	Incorrect label placement	0
1	Tamper evident seal missing	0
1	Label print excessive fading or smears	0
1	Damaged product or component	0
1	Torn label	0

N/A

In Process Inspection Summary**Inspection Details**

Date / Time	Container	Units	Level Defects			Inspector	Is Complete	Status	Failure Level	Inspection Type
			I	II	III					
04/MAY/20 15:13	1	1	0	N/A	N/A	Adshead, Stephen	Y	Pass	No Defects	InProcess

Defect Test Results

Defect Level	Description	Quantity
1	Torn label	0
1	Damaged product or component	0
1	Label print excessive fading or smears	0
1	Tamper evident seal missing	0
1	Incorrect label placement	0
1	Foreign material on label	0

N/A

In Process Inspection Summary**Inspection Details**

Date / Time	Container	Units	Level Defects			Inspector	Is Complete	Status	Failure Level	Inspection Type
			I	II	III					
04/MAY/20 17:01	2	1	0	N/A	N/A	Adshead, Stephen	Y	Pass	No Defects	InProcess

Defect Test Results

Defect Level	Description	Quantity
1	Foreign material on label	0
1	Incorrect label placement	0
1	Tamper evident seal missing	0
1	Label print excessive fading or smears	0
1	Damaged product or component	0
1	Torn label	0

N/A

In Process Inspection Summary**Inspection Details**

Date / Time	Container	Units	Level Defects			Inspector	Is Complete	Status	Failure Level	Inspection Type
			I	II	III					
04/MAY/20 18:59	2	1	0	N/A	N/A	Adshead, Stephen	Y	Pass	No Defects	InProcess

Defect Test Results

Defect Level	Description	Quantity
1	Torn label	0
1	Damaged product or component	0
1	Incorrect label placement	0
1	Tamper evident seal missing	0
1	Label print excessive fading or smears	0
1	Foreign material on label	0

N/A

In Process Inspection Summary**Inspection Details**

Date / Time	Container	Units	Level Defects			Inspector	Is Complete	Status	Failure Level	Inspection Type
			I	II	III					
04/MAY/20 19:50	2	1	0	N/A	N/A	Adshead, Stephen	Y	Pass	No Defects	InProcess

Defect Test Results

Defect Level	Description	Quantity
1	Foreign material on label	0
1	Label print excessive fading or smears	0
1	Tamper evident seal missing	0
1	Incorrect label placement	0
1	Damaged product or component	0
1	Torn label	0

End Check

Quality Audit Log

Date/Time	SubStep	Auditor	Comments
30/APR/20 09:19	1	Cross, David	Component check performed to enable printing. No observation
30/APR/20 15:15	1	Draper, Graham	End of printing - All applicable tests MT. 1 card taken randomly from each the start, middle and end of the print run and checked against supplied PDF. No observations.
30/APR/20 15:58	2	Draper, Graham	Component check performed to enable printing. No observations.
01/MAY/20 16:27	2	Draper, Graham	End of printing - All applicable tests MT. 1 card taken randomly from each the start, middle and end of the print run and checked against supplied PDF. No observations.
01/MAY/20 19:41	3	Draper, Graham	Start up check - All applicable tests MT. See instructions comment 19:33 01-May-2020. No observations.
01/MAY/20 19:59	3	Draper, Graham	Retain sample - All applicable tests MT. No observations.
04/MAY/20 07:33	3	Maftai, Marius	End check. All applicable tests MT. No observations
04/MAY/20 12:00	4	Cross, David	Start up performed. Please see all inspection comments. All applicable checks MT. No observation
04/MAY/20 12:05	4	Cross, David	Retain sample performed All applicable checks MT. No observation
04/MAY/20 17:10	4	Diestro, Kim	Shift check performed. All applicable tests MT. No Observations.
04/MAY/20 19:51	4	Diestro, Kim	End check performed. All applicable tests MT. No observations.

(5 . 1)

Accountability

SubStep	Type	Room	Result
1	Closed Step	CABIN17	Passed

Products

Component	UOM	Rejects	Samples	Produced
S27547.4.1A	N/A	0	0	525

Product ID Labels

Component	Used	Destroyed	Printed
S27547.4.1A	1	0	1

Components

Component	Receiving #	Cust. Lot	Mfg. Lot	UOM	Samples	Rejected	BOH	Used in Job	Issued	% Accountability	Limits
HJ10684	CH175115	N/A	1104943594	Ream	0	0.005	2.945	1.05	4	100%	0.00% - 999.00%

Accountability Comments

Accountability Accepted.

Reject Summary

Component	Receiving #	Reason	UOM	Quantity
HJ10684	CH175115.2	N/A	Ream	0.0100

Performed By	Verification By
<i>Adshead, Stephen</i> 30/APR/20 15:40 I confirm that I have entered the Accountability data and that the data is correct.	<i>Niedzieska, Alicja</i> 30/APR/20 15:44 I confirm the Accountability data is correct.

Accountability

SubStep	Type	Room	Result	(7.1)
2	Closed Step	CABIN17	Passed	

Products

Component	UOM	Rejects	Samples	Produced
S27547.4.2A	N/A	0	0	1,050

Product ID Labels

Component	Used	Destroyed	Printed
S27547.4.2A	1	0	1

Components

Component	Receiving #	Cust. Lot	Mfg. Lot	UOM	Samples	Rejected	BOH	Used in Job	Issued	% Accountability	Limits
HJ10684	CH175115	N/A	1104943594	Ream	0	1.4	1	0.528	2.945	99.4228%	0.00% - 999.00%

Accountability Comments

The rejected amount of HJ10684 includes cards S27547.4.2A originally printed single sided on 30 Apr 2020. The cards were then correctly printed double sided. Accountability accepted.

Reject Summary

Component	Receiving #	Reason	UOM	Quantity
HJ10684	CH175115.3	N/A	Ream	1.4000

Performed By	Verification By
<i>Adshead, Stephen</i> 01/MAY/20 17:06 I confirm that I have entered the Accountability data and that the data is correct.	<i>Askarova, Gula</i> 01/MAY/20 17:09 I confirm the Accountability data is correct.

Accountability

SubStep	Type	Room	Result
3	Closed Step	CABIN17	Passed

Products

Component	UOM	Rejects	Samples	Produced
HF70221	envelope	0	0	1
HF70216	envelope	0	0	499

Product ID Labels

Component	Used	Destroyed	Printed
HF70216	2	2	4
HF70221	2	0	2

Components

Component	Receiving #	Cust. Lot	Mfg. Lot	UOM	Samples	Rejected	BOH	Used in Job	Issued	% Accountability	Limits
HJ10688	CH175086	N/A	1104943590	box	0	0	0	10	10	100%	0.00% - 999.00%
HL69222	LH122237	N/A	OXF2501	label	0	1	500	500	1,001	100%	0.00% - 999.00%
S27547.4.2A	CH175273	N/A	27547.4	N/A	0	0	550	500	1,050	100%	98.00% - 102.00%

Accountability Comments

1 x HL69222 was used on sample label page and rejected in GPM for accountability purposes.
2 x ID label for HF70216 were rejected and destroyed as surplus to requirement.

Reject Summary

Component	Receiving #	Reason	UOM	Quantity
HL69222	LH122237.2	N/A	label	1.0000

Performed By	Verification By
Rezmuves, zsanett 04/MAY/20 07:48	Nayee, Daxa 04/MAY/20 07:56

Accountability

I confirm that I have entered the Accountability data and that the data is correct.

I confirm the Accountability data is correct.

Accountability

SubStep	Type	Room	Result
4	Closed Step	CABIN17	Passed

Products

Component	UOM	Rejects	Samples	Produced
HF70215	envelope	0	0	499
HF70220	envelope	0	0	1

Product ID Labels

Component	Used	Destroyed	Printed
HF70220	2	0	2
HF70215	2	0	2

Components

Component	Receiving #	Cust. Lot	Mfg. Lot	UOM	Samples	Rejected	BOH	Used in Job	Issued	% Accountability	Limits
HB34790	DH152481	N/A	9R1AR	carton	0	0	1	125	126	100%	98.00% - 102.00%
HJ10672	CH175118	N/A	1104937458	box	0	0	0	10	10	100%	0.00% - 999.00%
HL69219	LH122206	N/A	PDR325805	label	0	1	0	500	501	100%	100.00% - 100.00%
HL69222	LH122237	N/A	OXF2501	label	0	0	0	500	500	100%	0.00% - 999.00%
S27547.4.1A	CH175234	N/A	27547.4	N/A	0	25	0	500	525	100%	98.00% - 102.00%
S27547.4.2A	CH175273	N/A	27547.4	N/A	0	50	0	500	550	100%	98.00% - 102.00%

Accountability Comments

1 x HL69219 used on the sample label page has been reconciled as rejected for accountability purposes.
25 x S27547.4.1A and 50 x S27547.4.2A have been destroyed as they were surplus to requirement.

Reject Summary

Component	Receiving #	Reason	UOM	Quantity
S27547.4.1A	CH175234.2	N/A	N/A	25.0000

Accountability

S27547.4.2A	CH175273.2	N/A	N/A	50.0000
HL69219	LH122206.2	N/A	label	1.0000

Performed By	Verification By
<i>Adshead, Stephen</i> 04/MAY/20 20:09 I confirm that I have entered the Accountability data and that the data is correct.	<i>Villen, Leonora</i> 04/MAY/20 20:17 I confirm the Accountability data is correct.

30/Apr/20
09:18:28 AM



S27547.4.1A (CH175234.1)

Ambient 15°C to 25°C

Customer: University of Oxford

Manuf. Lot: 27547.4

Expiration Date: N/A

Description:

PRINTED MEDICATION CARD Prt: PRINCIPLE

Customer Lot:

30/Apr/20
03:55:39 PM



S27547.4.2A (CH175273.1)

Ambient 15°C to 25°C

Customer: University of Oxford

Manuf. Lot: 27547.4

Expiration Date: N/A

Description:

PRINTED PATIENT CONTACT CARD Prt: PRINCIPLE

Customer Lot:

FIN

01/May/20
06:09:01 PM



HF70216 (FH202663.1)

Ambient 15°C to 25°C

Customer: University of Oxford

Manuf. Lot: 27547.4

Expiration Date: N/A

Description:

PAPERWORK ONLY (No Drug) Information Booklet, Patient Contact Card
In Envelope Prt: PRINCIPLE

Customer Lot: 27547.4

FIN

01/May/20
06:09:47 PM



HF70221 (FH202664.1)

Ambient 15°C to 25°C

Customer: University of Oxford

Manuf. Lot: 27547.4

Expiration Date: N/A

Description:

RETAIN SAMPLE: PAPERWORK ONLY (No Drug) Information Booklet,
Patient Contact Card In Envelope Prt: PRINCIPLE

Customer Lot: 27547.4

FIN

04/May/20
09:11:16 AM



HF70215 (FH202688.1)

Ambient 15°C to 25°C

Customer: University of Oxford

Manuf. Lot: 27547.4

Expiration Date: Apr 30, 2022

Description:

HYDROXYCHLOROQUINE SULFATE (Plaquenil) 200mg 15 Fill Tablet
Labeled Blister, Information Booklet, Patient contact Card, Medication
Card Unlabeled Envelope Prt: PRINCIPLE

Customer Lot: 9R1AR

FIN

04/May/20
09:12:22 AM



HF70220 (FH202689.1)

Ambient 15°C to 25°C

Customer: University of Oxford

Manuf. Lot: 27547.4

Expiration Date: Apr 30, 2022

Description:

RETAIN SAMPLE: HYDROXYCHLOROQUINE SULFATE (Plaquenil)
200mg 15 Fill Tablet Labeled Blister, Information Booklet, Patient contact
Card, Medication Card in Unlabeled Envelope Prt: PRINCIPLE

Customer Lot: 9R1AR

Destruction of Material

Substep: 1

Component	Description	Receiving #	Customer Lot	Mfg. Lot	Destroyed
HJ10684	HP color choice, A4,250 gsm, laser paper, White (ream 250 sheets) Part No: 297832452 Prt: PRINCIPLE	CH175115.2	N/A	1104943594	0

Material Destruction Comments

I confirm that Items have been destroyed in compliance with local site SOPs.

Destroyed By		Verified By	
<i>Niedzieska, Alicja</i>	30/APR/20 15:44	<i>Adshead, Stephen</i>	30/APR/20 15:44

Substep: 2

Component	Description	Receiving #	Customer Lot	Mfg. Lot	Destroyed
HJ10684	HP color choice, A4,250 gsm, laser paper, White (ream 250 sheets) Part No: 297832452 Prt: PRINCIPLE	CH175115.3	N/A	1104943594	1

Material Destruction Comments

I confirm that Items have been destroyed in compliance with local site SOPs.

Destroyed By		Verified By	
<i>Askarova, Gula</i>	01/MAY/20 17:09	<i>Adshead, Stephen</i>	01/MAY/20 17:09

Destruction of Material

Substep: 3

Component	Description	Receiving #	Customer Lot	Mfg. Lot	Destroyed
HL69222	LABEL White 8 1/4 x 11 11/16 inch Placed On Leaflet/Booklet TG Instructions booklet for participants English OXF2501 (HL69221) Prt: PRINCIPLE	LH122237.2	N/A	OXF2501	1

Material Destruction Comments

I confirm that Items have been destroyed in compliance with local site SOPs.

Destroyed By		Verified By	
<i>Nayee, Daxa</i>	04/MAY/20 07:56	<i>Rezmuves, zsanett</i>	04/MAY/20 07:56

Substep: 4

Component	Description	Receiving #	Customer Lot	Mfg. Lot	Destroyed
HL69219	LABEL White Single Panel 2 x 6 inch Placed On Blister Card TG Blister of 15ct Hydroxychloroquine sulphate 200mg tablets English OXF2505 (HL69217) Prt: PRINCIPLE	LH122206.2	N/A	PDR325805	1
S27547.4.1A	PRINTED MEDICATION CARD Prt: PRINCIPLE	CH175234.2	N/A	27547.4	25
S27547.4.2A	PRINTED PATIENT CONTACT CARD Prt: PRINCIPLE	CH175273.2	N/A	27547.4	50

Material Destruction Comments

I confirm that Items have been destroyed in compliance with local site SOPs.

Destroyed By		Verified By	
<i>Villen, Leonora</i>	04/MAY/20 20:17	<i>Adshead, Stephen</i>	04/MAY/20 20:17

Quality Audit Data Revision History Report

Footnote	Original Author	Author	Updated Date/Time	Comments
5.1.1	Cross, David	Cross, David	30/APR/20 12:18	Changed to reflect actual process at start of job
Comment Changed From			Comment Changed To	
Start up performed All applicable checks MT. No observation			Component check performed to enable printing. No observation	

Accountability Data Revision History Report

Footnote	Original Author	Author	Updated Date/Time	Comments
7.1.1	Adshead, Stephen	Adshead, Stephen	05/MAY/20 17:14	Clarifying comment.
Comment Changed From			Comment Changed To	
Accountability accepted.			The rejected amount of HJ10684 includes cards S27547.4.2A originally printed single sided on 30 Apr 2020. The cards were then correctly printed double sided. Accountability accepted.	

Instructions Data Revision History Report

Footnote	Original Author	Author	Updated Date/Time	Comments
9.1.1	Cross, David	Cross, David	05/MAY/20 06:46	Typo

Comment Changed From	Comment Changed To
The cosh for this job is 562, this matches the line card and is present in the cabin but is typographically incorrect in the PO were it states 526. No quality impact	The coshh for this job is 562, this matches the line card and is present in the cabin but is typographically incorrect in the PO were it states 526. No quality impact

Footnote	Original Author	Author	Updated Date/Time	Comments
9.2.1	Cross, David	Sevcovs, Dmitrijs	05/MAY/20 14:49	clarification

Comment Changed From	Comment Changed To
Workstation 3 states to pass scan, this is not possible due to scan set up but our procedures allow us to pre dispense as pass is for scanning purposes only	During start-up, it was identified that the numbers within PASS set up did not match the numbers in label barcodes, and therefore labels could not be scanned in PASS. The Pass in this case serves only for reconciliation and accountability purposes and therefore the issue can be resolved online using an existing approved process where the labels predisposed prior to labelling. Slight modification to EPO did not represent quality risk to the existing job.

Footnote	Original Author	Author	Updated Date/Time	Comments
9.3.1	Jeffs, Caroline	Adshead, Stephen	30/APR/20 20:48	Text correction.

Comment Changed From	Comment Changed To
Component HJ10684 receive CH-175115 removed from cabin for printing of Medication Cards.	Component HJ10684 receive CH175115 removed from cabin for printing of Contact Cards.

Footnote	Original Author	Author	Updated Date/Time	Comments
9.4.1	Jeffs, Caroline	Eldridge, Ken	05/MAY/20 14:51	Typo corrected.

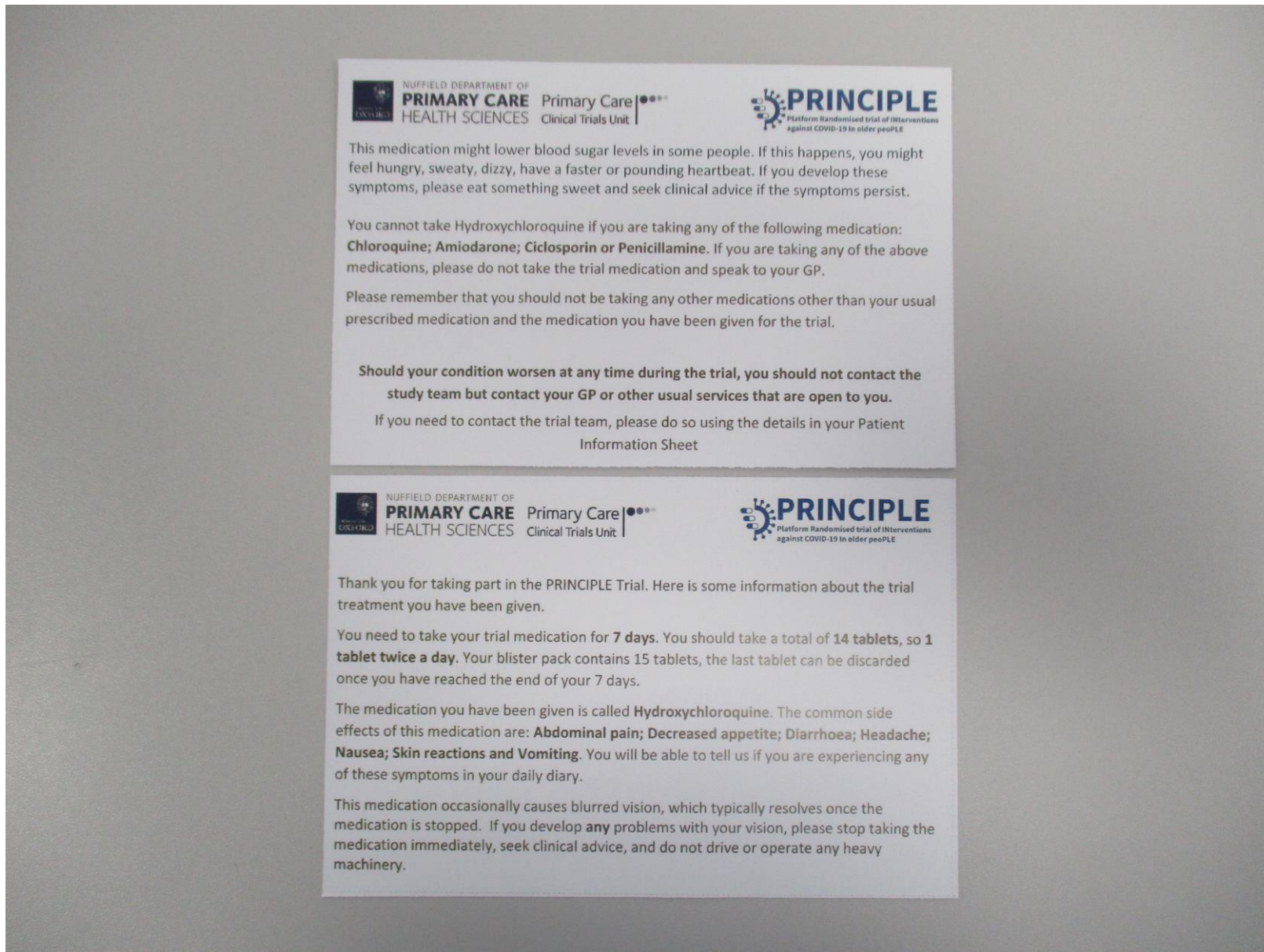
Comment Changed From	Comment Changed To
Component HJ10684 receive CH-175115 removed from cabin for printing of Medication Cards.	Component HJ10684 receive CH175115 removed from cabin for printing of Medication Cards.

Footnote	Original Author	Author	Updated Date/Time	Comments
9.5.1	Eldridge, Ken	Eldridge, Ken	30/APR/20 21:47	Comment written in error as already added.

Comment Changed From	Comment Changed To
Component HJ10684 receive CH175115 returned to cabin following completion of printed contact cards.	Please ignore this comment as it has already been added. - Component HJ10684 receive CH175115 returned to cabin following completion of printed contact cards.

Instructions Data Revision History Report

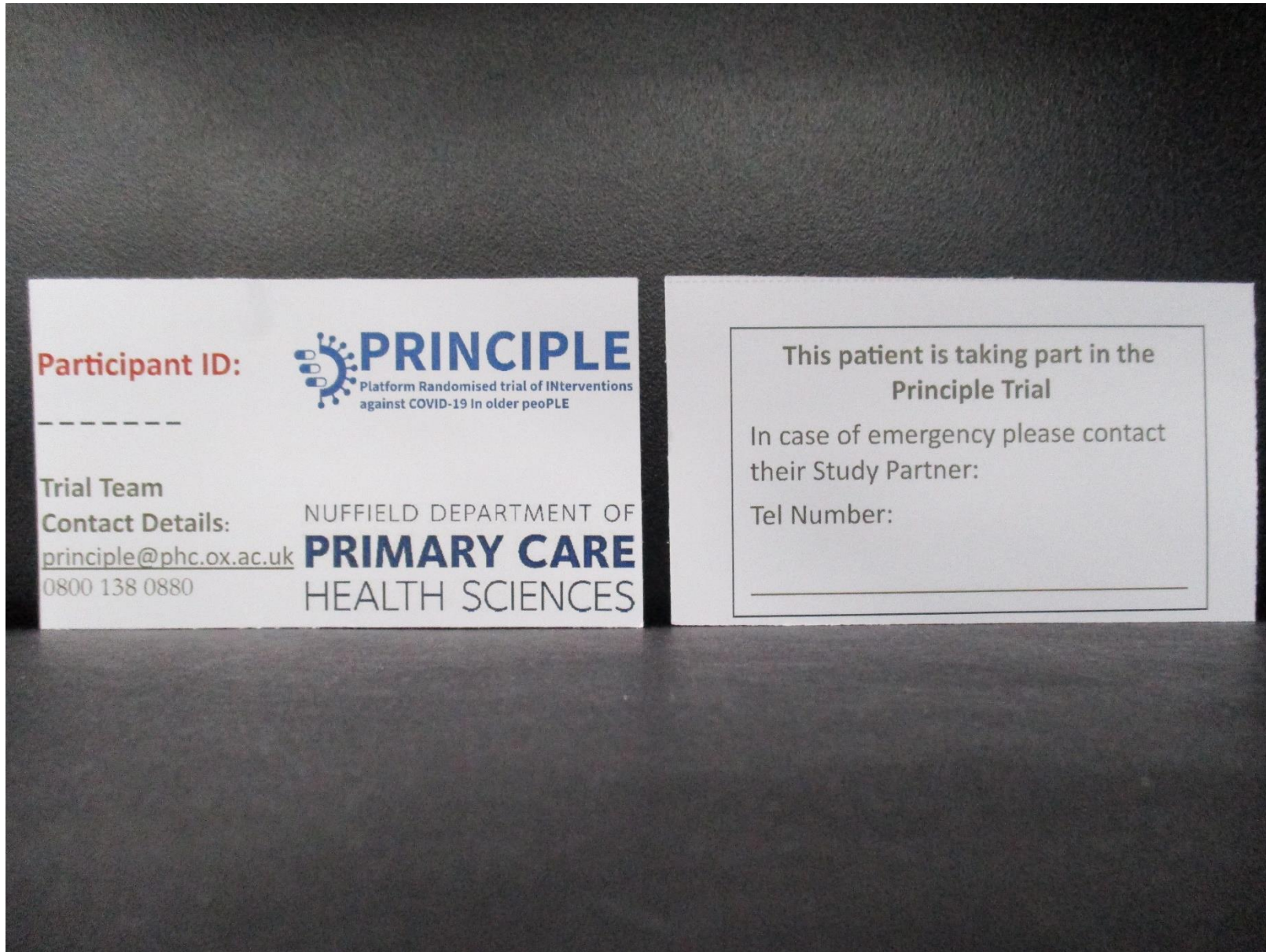
Footnote	Original Author	Author	Updated Date/Time	Comments
9.5.2	Eldridge, Ken	Eldridge, Ken	05/MAY/20 14:55	Comment clarified.
Comment Changed From			Comment Changed To	
Please ignore this comment as it has already been added. - Component HJ10684 receive CH175115 returned to cabin following completion of printed contact cards.			Please ignore this comment as it is a duplicate of instruction comment made on 30 Apr 2020 @ 20:45. - Component HJ10684 receive CH175115 returned to cabin following completion of printed contact cards.	



30/04/2020 14:49

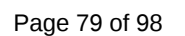
Printed:05/MAY/20 17:32

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01/05/2020 16:27

Printed:05/MAY/20 17:32





01/05/2020 19:50

Printed:05/MAY/20 17:32

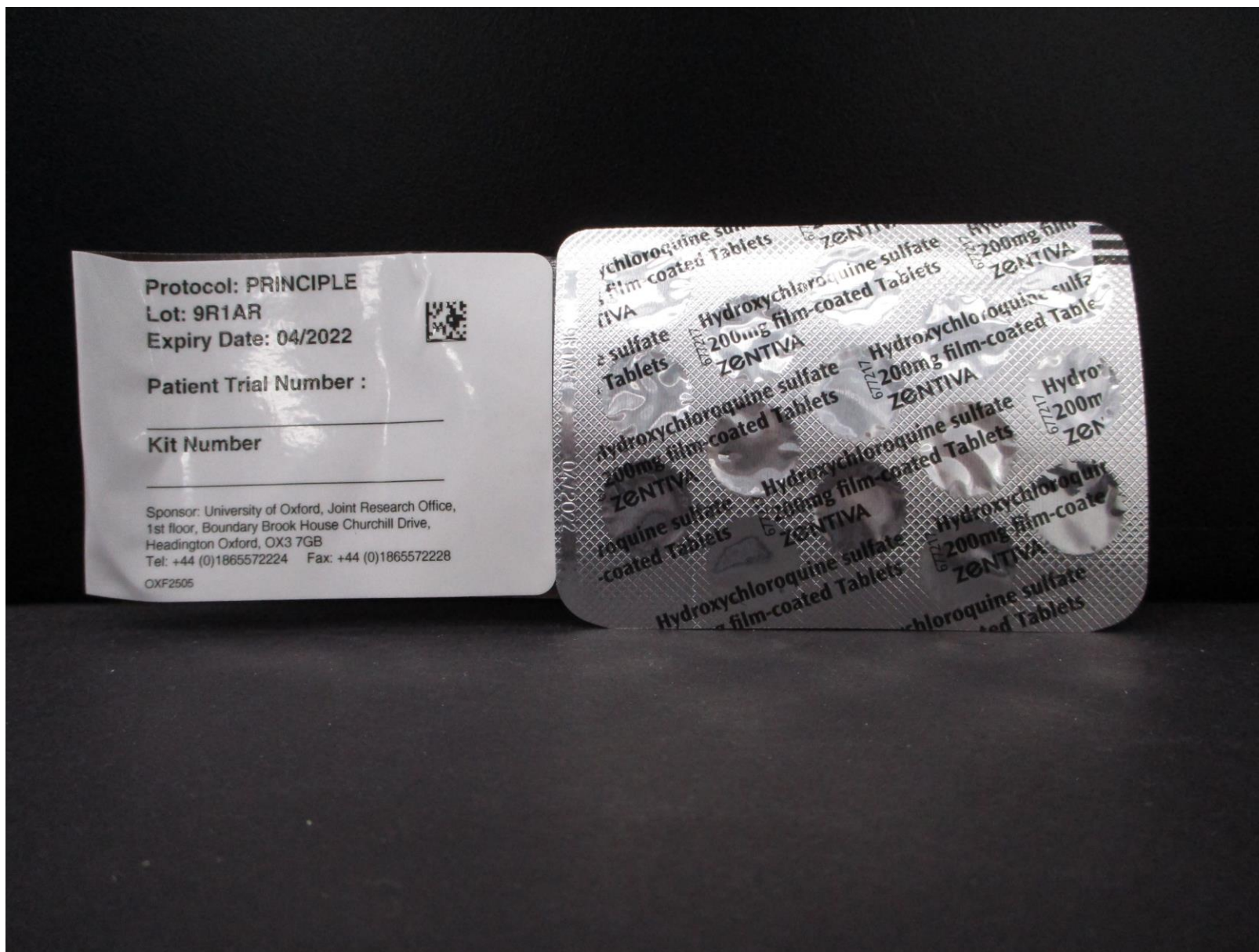
Page 80 of 98



Job#: 27547.4

Step: 4

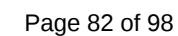
Title: The first labelled blister



04/05/2020 11:52

Printed:05/MAY/20 17:32

Page 81 of 98





04/05/2020 11:56

Printed:05/MAY/20 17:32

Page 83 of 98



Label ID #: OXF2505

Current Job #: 2467-001-20 RL #1

Original Job #: 2467-001-20 RL #1

Client Part #: N/A

Protocol: PRINCIPLE (FCS #217819) (427547)

Blinded Study: No

Label Package Integration: No

Client Name: University of Oxford

Created By: Meier, Lars 4/21/2020 10:32:08 AM CET

Updated By: Meier, Lars 4/21/2020 10:32:07 AM CET

Project Manager Sign/Date: Meier, Lars

Study Logistics

Description:	Single Panel Blister Card Flag Label (with patient number)
Drug Name/Strength:	Blister of 15ct Hydroxychloroquine sulphate 200mg tablets
Container Type:	Blister Card Label
Languages:	1
Blinded Label:	No
Last Coding Job:	N/A
Variable Field Associations:	F4
Manufacture Quantity:	1
Internal PFI Quantity:	0

Colors

Content Color 1:	Black
Content Color 2:	N/A
Content Color 3:	N/A
Label Color:	White - (Material)
Special Instructions:	N/A

Change Notices

N/A

Deviation Reports

N/A

Special Instructions

Flag Label construction:

Leave 1/2" inch on the left hand free and the remaining part will be folded back onto itself.

Manufacturing Logistics

Design Program:	CLPS
TCN#:	TCN04730
Template ID #:	1.2000.6000.2000.6250
Label Type:	Single
Open Direction:	N/A
Overall Size:	2" x 6"
Repeat:	6 1/4"
Gen Strip:	Standard
Backtape:	N/A
Base Label Stock:	LAM2518 - Semi-Gloss Elite Fascover ES / Opaque / S246 / 50# SCK / Component Part # RLP00013
Booklet Stock:	N/A
Over Laminate:	2 Mil Clear BOPP TC / Non-Opaque / E898 / 1.5 Mil PET / Component Part # RLT00012
Under Laminate:	N/A
OSW Stock:	N/A
Mfg Type:	Manufacture New
Blank Stock:	No
New Dies Req'd:	Flexo: No Digital BK: No Digicon: No Onsert: No

Base Panel Inks/Varnishes

Print Station 1:	N/A
Print Station 2:	N/A
Print Station 3:	N/A
Print Station 4:	N/A
Print Station 5:	N/A

Finishing Operations

Process Type:	In-Process
Blinding Laminate:	N/A
Apply Laminates To:	N/A
Reorient:	No
Press Roll: Yes Core: 4" Max. Diam: 11" Unwind: 4	



Variable Field Requirements

F #	Placeholder	Placeholder Description	Placements
F1	N/A	N/A	F1: PN1 (6pt)
F2	N/A	N/A	F2: PN1 (6pt)
F3	N/A	N/A	F3: PN1 (6pt)
F4	XXXXXXXXX	(Barcode\DataMatrix)	F4: PN1 (20pt)

CUSTOMER AUTHORIZATION

☐

Proof Approved

Proceed with Order

☐

Revise Proof

Return for Review

21.04.2020

AUTHORIZED SIGNATURE

DATE

Customer approval applies to all sections of this
label specification cover sheet.

Blister of 15ct Hydroxychloroquine sulphate
 200mg tablets.
 PRINCIPLE trial.
 University of Oxford
 Chief Investigator: Prof. Chris Butler
FOR ORAL USE ONLY
 Take one tablet (200mg) hydroxychloroquine twice
 daily for 7 days by mouth (14 tablets in Total)

Special instructions:
 Each dose should be taken with a meal or glass of milk.
 Antacids may reduce absorption of hydroxychloroquine
 so it is advised that a 4-hour interval be observed
 between taking hydroxychloroquine and an antacid.
 For Clinical Trial Use only Store Below 25°C
KEEP OUT OF REACH AND SIGHT OF CHILDREN

Protocol: PRINCIPLE
Lot: 9R1AR
Expiry Date: 04/2022

Patient Trial Number :

Kit Number

Sponsor: University of Oxford, Joint Research Office,
 1st floor, Boundary Brook House Churchill Drive,
 Headington Oxford, OX3 7GB
 Tel: +44 (0)186572224 Fax: +44 (0)186572228
 OXF2505

F4

Label ID#: OXF2505

Label Designed By: Romaric Lidy

Label Revised By: Romaric Lidy

Template ID#: 1.2000.6000.2000.6250

Client Approval: _____

IPI: _____ **SIGNATURE ON FILE**



Label ID #: OXF2501

Current Job #: 2467-001-20 RL #1

Original Job #: 2467-001-20 RL #1

Client Part #: N/A

Protocol: PRINCIPLE (FCS #217819) (427547)

Blinded Study: No

Label Package Integration: No

Client Name: University of Oxford

Created By: Meier, Lars 4/20/2020 8:52:47 AM CET

Updated By: Meier, Lars 4/22/2020 3:43:21 PM CET

Project Manager Sign/Date: Meier, Lars

Study Logistics

Description: External 4 Page Leaflet/Booklet for PRINCIPLE Information for participants_v1.2

Drug Name/Strength: PHE_11571_Throat and Nose self sampling swab

Container Type: See Spec. Instr.

Languages: 1

Blinded Label: No

Last Coding Job: N/A

Variable Field Associations: (No F-Values Assigned)

Manufacture Quantity: 1

Internal PFI Quantity: 0

Change Notices

N/A

Deviation Reports

N/A

Special Instructions

Container type = PIL - patient information leaflet.
4 page leaflet - 2 double sided printed and staple.
Size = A4 (210mm by 297mm)

Manufacturing Logistics

Design Program: In-Design

TCN#: N/A

Template ID #: N/A

Label Type: External Booklet

Open Direction: Right to Left

Overall Size: 8 1/4" x 11 11/16"

Repeat: 12"

Gen Strip: N/A

Backtape: N/A

Base Label Stock: External Stock / Non-Opaque / External Stock / External Stock / Component Part # RLP00028

Booklet Stock: N/A

Over Laminate: N/A

Under Laminate: N/A

OSW Stock: N/A

Mfg Type: Manufacture New

Blank Stock: No

New Dies Req'd: Flexo: No Digital BK: No Digicon: No Onsert: No

Base Panel Inks/Varnishes

Print Station 1: N/A

Print Station 2: N/A

Print Station 3: N/A

Print Station 4: N/A

Print Station 5: N/A

Special Instructions: N/A**Finishing Operations**

Process Type: In-Process

Blinding Laminate: N/A

Apply Laminates To: N/A

Reorient: No

Press Roll: No **Core:** N/A **Max. Diam:** N/A **Unwind:** N/A



Booklet Language Placement						
Page Number	Description	Content Color 1	Content Color 2	Content Color 3	Page Color	Special Instructions
1	External 4 Page Leaflet/Booklet for PRINCIPLE Information for participants_v1.2	Black	N/A	N/A	White	N/A

CUSTOMER AUTHORIZATION

☒

Proof Approved

Proceed with Order

☐

Revise Proof

Return for Review

APPROVED
COPY

4/22/2020
9:27:00 AM CET

AUTHORIZED SIGNATURE

DATE

Customer approval applies to all sections of this label specification cover sheet.

Horizontal perforations 12TPI.



Welcome to the PRINCIPLE Trial!
Thank you so much for agreeing to take part.

Instructions for participants

Thank you for taking part in the PRINCIPLE trial.
This information booklet will help guide you through what will happen during your time in the trial.
Please read on for more details about the trial medication and other key details.

Contact us

If you have any questions, please contact us on:

E-mail: principle@phc.ox.ac.uk

Telephone: 0800 138 0880

PRINCIPLE Information for Participants_v1.2_16 Apr 2020
IRAS ID: 281958 REC: 20/SC/0158
1 of 4

Label ID #: OXF2501

Label Designed By: Romaric Lidy

Label Updated By: N/A

Template ID#: 1.8250.11687.8250.12000
Printed:05/MAY/20 17:32

Client Approval: _____

IPI: _____ SIGNATURE ON FILE



LABEL PROOF

Horizontal perforations 12TPI.

Summary

Please take your trial medication (unless in Usual Care Group) for the *required number* of days. More detail is provided in the study medication card about how and when to take your medication

During the trial period, we ask you to answer a few short questions each day in an online daily diary about your symptoms. If we do not receive your diary answers, we will call you and/or your trial partner to ask a few short questions.

Your participation will last for a total of 28 days. We will ask for your consent to contact you if we are able to offer a blood test for COVID-19, in the recovery phase of your illness.

PRINCIPLE Information for Participants_v1.2_16 Apr 2020
IRAS ID: 281958 REC: 20/SC/0158
2 of 4

Label ID #: OXF2501

Label Designed By: Romaric Lidy

Label Updated By: N/A

Template ID#: 1.8250.11687.8250.12000
Printed:05/MAY/20 17:32

Client Approval: _____

IPI: _____ **SIGNATURE ON FILE**

LABEL PROOF

Horizontal perforations 12TPI.

3 of 4

Page 91 of 981



Horizontal perforations 12TPI.

**Your participation in this trial will
help us identify which treatments
are beneficial for COVID.**

**We are very grateful for your
contribution.**

PRINCIPLE Information for Participants_v1.2_16 Apr 2020
IRAS ID: 281958 REC: 20/SC/0158
4 of 4

Label ID #: OXF2501

Label Designed By: Romaric Lidy

Label Updated By: N/A

Template ID#: 1.8250.11687.8250.12000
Printed:05/MAY/20 17:32

Client Approval: _____

IPI: _____ **SIGNATURE ON FILE**

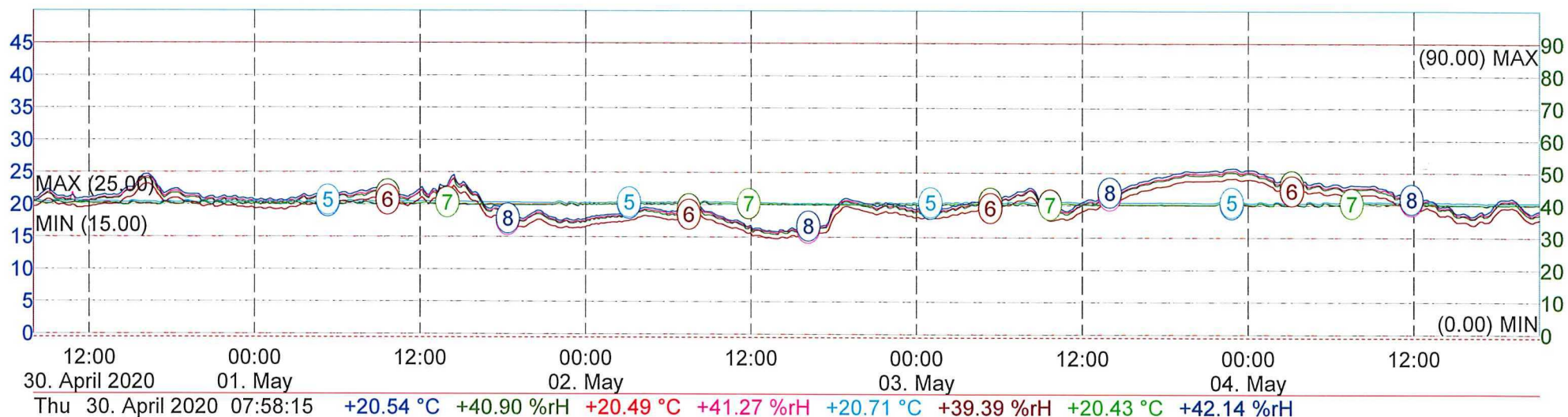
ECOLOG-NET LA8 ID:10521 - elproLOG ANALYZE QLS 3.64.01
 Date of Reading: 04. May 2020 21:41:37
 Log Interval: 10 min
 Module Tag: Secondary Packaging
 Data Description: Job# 27547.4



S 1+3+5+7: Loc 1 Temp + Loc 2 Temp + Loc 3 Temp + Loc 4 Temp [°C]

S 2+4+6+8: Loc 1 Humidity + Loc 2 Humidity + Loc 3 Humidity + Loc 4 Humidity [%rH]

	Loc 1 Temp:		Loc 1 Humidity:		Loc 2 Temp:		Loc 2 Humidity:		Loc 3 Temp:		Loc 3 Humidity:		Loc 4 Temp:		Loc 4 Humidity:	
Mean Value:	20.1°C		40.7%rH		20.1°C		41.1%rH		20.4°C		39.1%rH		20.1°C		41.8%rH	
Mean Variance:	0.017		19.076		0.013		19.361		0.013		18.673		0.013		20.003	
Std. Deviation:	0.130		4.368		0.116		4.400		0.115		4.321		0.113		4.472	
Lowest/Highest Value:	19.8 / 20.5°C		30.8 / 50.2%rH		19.9 / 20.5°C		31.1 / 50.8%rH		20.1 / 20.7°C		29.4 / 48.3%rH		19.8 / 20.4°C		31.6 / 51.5%rH	
Min/Max Limits:	15.0 / 25.0°C		0.0 / 90.0%rH		15.0 / 25.0°C		0.0 / 90.0%rH		15.0 / 25.0°C		0.0 / 90.0%rH		15.0 / 25.0°C		0.0 / 90.0%rH	
Time: Value > Max:	0min		0min		0min		0min		0min		0min		0min		0min	
Time: Value < Min:	0min		0min		0min		0min		0min		0min		0min		0min	
Time: Out of Min/Max	0min		0min		0min		0min		0min		0min		0min		0min	
Time: Within Min/Max	4d 13h		4d 13h		4d 13h		4d 13h		4d 13h		4d 13h		4d 13h		4d 13h	
Range:	30. April 2020 07:58:15 ... 04. May 2020 21:08:15															



General Room / Cabin Area Clearance Record

Room/Cabin # 17

Job # 27547.4

START CLEAN Has Room/Cabin & equipment been cleaned in last 28 days? YES / NO (delete as applicable) If NO, refer to SOP2006-g. Initial <u>MK</u> Date <u>30 APR 2020</u>	- If YES, cross through and N/A column A. - If NO, clean Room/Cabin and initial column A.	Perform Start Clearance and initial column B
		Perform Start Clearance and initial column B

Item / Area (N/A all Clearance columns not required)	Start Clean Ops (A) (initial)	Start Clearance Ops (B) (initial)	Start Clearance Quality (Initial)	End Clean Ops (Initial)	End Clearance Ops (Initial)
Primary Only - Clean the outside of the storage cupboard. Remove all items from the cupboard. Using alcohol wipes and starting from the top shelf going down, clean/check inside of storage cupboard. Using alcohol wipes, clean any unopened bags containing trays, sieves, scoops, tweezers' and counting plates. Items removed must be restocked. ONLY items listed on the cupboard inventory are to be put inside	N/A MK 30 APR 2020	N/A	N/A	N/A	N/A
Ensure that ANY Equipment NOT being used is covered to reduce the possibility of contamination		N/A	N/A	N/A	N/A
If applicable, remove any equipment dust covers and check for any contaminants. Clean if required		N/A	N/A	N/A	N/A
Clean/check floors, walls, windows, all vents and all high-level areas including tops of door ledges		MK	DC	PM	L
Clean/check around PC and underneath the station, shelves, racking & cable trunking		MK	DC	PM	L
Clean/check underneath static equipment, tables (release wheel brakes and clean/check), chairs, balances		MK	DC	PM	L
All waste bags are removed. Reject tote and Quarantine containers are empty, cleaned and stored upside down		MK	DC	PM	L
Check and complete logbooks as applicable		MK	DC	PM	L

Operations – Start Clearance	Quality Check – Start Clearance
Initial, Date & Time <u>MK 30 APR 2020 08:19</u>	Initial, Date & Time <u>DC 30 APR 2020 08:22</u>

Primary Only - END AREA CLEARANCE Has room and equipment been cleaned within 3 days of completion of job	Yes/No/NA (delete as appropriate) If NO, refer to SOP2006-f Initial <u>A</u> and Date <u>04 MAY 2020</u>
--	--

Operations – End Clearance
Initial, Date & Time <u>PM 04 MAY 2020 20:34</u>

Job # 27547.4

Component # HL69219

Receive # LH122206

Initial&Date: *BR 04 MAY 2020*

Blister of 15ct Hydroxychloroquine sulphate
200mg tablets.

PRINCIPLE trial.

University of Oxford

Chief Investigator: Prof. Chris Butler

FOR ORAL USE ONLY

Take one tablet (200mg) hydroxychloroquine twice
daily for 7 days by mouth (14 tablets in Total)

Special instructions:

Each dose should be taken with a meal or glass of milk.

Antacids may reduce absorption of hydroxychloroquine
so it is advised that a 4-hour interval be observed
between taking hydroxychloroquine and an antacid.

For Clinical Trial Use only Store Below 25°C

KEEP OUT OF REACH AND SIGHT OF CHILDREN

Protocol: PRINCIPLE

Lot: 9R1AR

Expiry Date: 04/2022



Patient Trial Number :

Kit Number

Sponsor: University of Oxford, Joint Research Office,
1st floor, Boundary Brook House Churchill Drive,
Headington Oxford, OX3 7GB
Tel: +44 (0)1865572224 Fax: +44 (0)1865572228
OXF2505

Production Batch Record Replacement Label Tracker

Job #	27547.4	Cabin/Room #	17
Section 1 – Label Details (to be completed by Packaging)			
Component #	S27547.4-1A HJ106840	Receive #	CH175234 CH175115(2)
Patient #(s)	N/A		
Blank Label Component #	HJ10684	Blank Label Receive #	CH175115
Blank Label Description	HP colour choice, A4, 250gsm, laser paper, white (from 250 sheets) Part No. 297832452 P.T: Principle		
Section 2 - Label Details Check (to be completed by Packaging) Place this document on top of the sealed tote			
Delete as appropriate • Emailed to Basel: <u>Basel reprints Horsham</u> (Between 21:00 – 13:00) • Emailed to Bohemia: <u>Bohemia reprints Horsham</u> (Between 13:00 – 21:00) • Sent to PM for External replacement printing		First Check (Initial & date) J 30 Apr 2020 Second Check (Initial & date) Ar 30 APR 2020	
For External reprints, N/A Section 3 and file completed form in non-GMP batch record supporting documentation			
For Horsham replacement, complete Section 3 and file completed form in GMP batch documentation			
Section 3 – Printing (to be completed by Packaging)			
Purchase Order Number	N/A		
Area Clearance (prior to printing)	Which booth is in use: 1 / - * Is the booth clean and clear from previous print run: Yes / No * Is the printer clean and clear from previous print run: Yes / No * Has the log book been completed from the previous job: Yes / No * *Delete as appropriate If NO to the above do not proceed and refer to Team Leader		
Checked By	(initial & date) J 30 Apr 2020	Verified By	(initial & date) Ar 30 APR 2020
Blank Label Stock Checked by:	(initial & date) J 30 Apr 2020		
# Blank Labels Issued from Inventory CH-1555 (a)	# Labels Used (including samples) (b)	# Labels Rejected (c)	# Labels Returned to Inventory/enter on CH-1555 (d)
525 1000 525 263	4500 263 523 268	40 5	732
# Labels Printed (excluding samples)	500		
Printed by:	(initial & date) J 30 Apr 2020	Verified by:	(initial & date) Ar 30 APR 2020
Area Clearance (after printing)	Has the printed label waste been placed in Yellow bag? Yes / No * Is the booth clean and clear from the print run? Yes / No * Is the printer clean and clear from print run: Yes / No * Is the blank label stock removed from the booth? Yes / No * Is the printed label stock reconciled at 100% and removed from booth? Yes / No * Has the printer memory been cleared? Yes / No * Complete the log book *Delete as appropriate If NO to the above do not proceed and refer to Team Leader		
Approved By	(initial & date) J 30 Apr 2020	Verified By	(initial & date) Ar 30 APR 2020

(1)(2)(E)(C) Entered incorrectly as the finished component will be a sub-assembly component.
 Due to the form being used to track printing of medication cards. J 30 Apr 2020
 (3)(C) This job is not a reprint, form is being used to track the printing of the
 medication cards for Oxford University Job. J 30 Apr 2020
 (4)(5)(6)(7)(8)(E)(C) J 30 Apr 2020

Production Batch Record Replacement Label Tracker

Job #	27547.4	Cabin/Room #	17	
Section 1 – Label Details (to be completed by Packaging)				
Component #	S27547.4.2A	Receive #	CH175273	
Patient #(s)	N/A	PDR #	N/A	
Blank Label Component #	HJ10684	Blank Label Receive #	CH175115	
Blank Label Description	HP Colour choice, A4, 250gsm, Laser paper, white (cream 250 sheets) Part NO. 297832452 Fit: PRINCIPLE			
Section 2 - Label Details Check (to be completed by Packaging) Place this document on top of the sealed tote				
Delete as appropriate N/A of 30 APR 2020 • Emailed to Basel: <u>Basel reprints Horsham</u> (Between 21:00 – 13:00) • Emailed to Bohemia: <u>Bohemia reprints Horsham</u> (Between 13:00 – 21:00) • Sent to PM for External replacement printing		First Check (Initial & date) of 30 Apr 2020 Second Check (Initial & date) of 30 APR 2020		
For External reprints, N/A Section 3 and file completed form in non-GMP batch record supporting documentation				
For Horsham replacement, complete Section 3 and file completed form in GMP batch documentation				
Section 3 – Printing (to be completed by Packaging)				
Purchase Order Number				
Area Clearance (prior to printing)	Which booth is in use: 1 / 2 * Is the booth clean and clear from previous print run: Yes / No * Is the printer clean and clear from previous print run: Yes / No * Has the log book been completed from the previous job: Yes / No * *Delete as appropriate If NO to the above do not proceed and refer to Team Leader			
Checked By	(initial & date) of 30 Apr 2020	Verified By	(initial & date) of 30 APR 2020	
Blank Label Stock Checked by:	(initial & date) of 30 Apr 2020			
# Blank Labels Issued from Inventory CH-1555 (a)	# Labels Used (including samples) (b)	# Labels Rejected (c)	# Labels Returned to Inventory/enter on CH-1555 (d)	Reconciliation % 100 x (b+c+d)/a
732	③ ① ② ⑤ 263	34	435	100.0
# Labels Printed (excluding samples)	1050			
Printed by:	(initial & date) of 30 Apr 2020	Verified by:	(initial & date) A 30 APR 2020	
Area Clearance (after printing)	Has the printed label waste been placed in Yellow bag? Yes / No * Is the booth clean and clear from the print run? Yes / No * Is the printer clean and clear from print run: Yes / No * Is the blank label stock removed from the booth? Yes / No * Is the printed label stock reconciled at 100% and removed from booth? Yes / No * Has the printer memory been cleared? Yes / No * Complete the log book *Delete as appropriate If NO to the above do not proceed and refer to Team Leader			
Approved By	(initial & date) of 30 Apr 2020	Verified By	(initial & date) A 30 APR 2020	

① (CL) Not required as form being used for printing of contact cards for University of Oxford Job. of 30 Apr 2020
 ② (CL) A 30 APR 2020
 ③ (CL) THIS PRODUCED 1050 CONTACT CARDS. A 30 APR 2020

Production Batch Record

Replacement Label Tracker

①

Job #	27547.4	Cabin/Room #	17		
Section 1 – Label Details (to be completed by Packaging)					
Component #	S27547.4.2A	Receive #	CH175273	PDR #	N/A
Patient #(s)	N/A				
Blank Label Component #	HJ10684	Blank Label Receive #	CH175115		
Blank Label Description	HP color choice, A4,250 gsm, laser paper, White (ream 250 sheets) Part No: 297832452 Prt: PRINCIPLE				
Section 2 - Label Details Check (to be completed by Packaging) Place this document on top of the sealed tote					
Delete as appropriate • Emailed to Basel: <u>Basel reprints Horsham</u> (Between 21:00 – 13:00) • Emailed to Bohemia: <u>Bohemia reprints Horsham</u> (Between 13:00 – 21:00) • Sent to PM for External replacement printing			First Check (Initial & date) J 01 May 2020 Second Check (Initial & date) TSI 01 May 2020		
For External reprints, N/A Section 3 and file completed form in non-GMP batch record supporting documentation					
For Horsham replacement, complete Section 3 and file completed form in GMP batch documentation					
Section 3 – Printing (to be completed by Packaging)					
Purchase Order Number					
Area Clearance (prior to printing)	Which booth is in use: 1 / 2 * Is the booth clean and clear from previous print run: Yes / No * Is the printer clean and clear from previous print run: Yes / No * Has the log book been completed from the previous job: Yes / No * *Delete as appropriate If NO to the above do not proceed and refer to Team Leader				
Checked By	(initial & date) J 01 May 2020	Verified By	(initial & date) TSI 01 May 2020		
Blank Label Stock Checked by:	(initial & date) J 01 May 2020				
# Blank Labels Issued from Inventory CH-1555 (a)	# Labels Used (including samples) (b)	# Labels Rejected (c)	# Labels Returned to Inventory/enter on CH-1555 (d)	Reconciliation % 100 x (b+c+d)/a	
435	132	5+53	250	100%	
# Labels Printed (excluding samples)	1050				
Printed by:	(initial & date) J 01 May 2020	Verified by:	(initial & date) A 01 MAY 2020		
Area Clearance (after printing)	Has the printed label waste been placed in Yellow bag? Yes / No * Is the booth clean and clear from the print run? Yes / No * Is the printer clean and clear from print run: Yes / No * Is the blank label stock removed from the booth? Yes / No * Is the printed label stock reconciled at 100% and removed from booth? Yes / No * Has the printer memory been cleared? Yes / No * Complete the log book *Delete as appropriate If NO to the above do not proceed and refer to Team Leader				
Approved By	(initial & date) J 01 May 2020	Verified By	(initial & date) A 01 MAY 2020		

① (E) FORM COMPLETED RETROSPECTIVELY AS MISSED AT POINT OF ACTION. J 01 May 2020
 ② (E) NOT REQUIRED AS FORM USED FOR PRINTING OF CONTACT CARDS. J 01 May 2020
 ③ (E) A 01 MAY 2020

④ (E) Signed retrospectively as missed at point of action. TSI 04 May 2020

⑤ (E) Signed retrospectively as missed at point of action. TSI 05 May 2020

⑥ (E) Missed at time of action

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