

Certificate of QA Approval

Client	University of Oxford
Job Step Number	27547.9
Protocol	PRINCIPLE
Bulk Lot Numbers	GAET

Products of Step

Qty. Produced	Part Number	Description
99.000000	HF75173	BUDESONIDE (Pulmicort Turbohaler) 400mcg 50 doses Inhalation Powder Inhaler in Labeled Carton Prt: PRINCIPLE Manufacturing Lot: 27547.9 Customer Lot: 27547.9
1.000000	HF75176	RETAIN SAMPLE: BUDESONIDE (Pulmicort Turbohaler) 400mcg 50 doses Inhalation Powder Inhaler in Labeled Carton Prt: PRINCIPLE Manufacturing Lot: 27547.9 Customer Lot: 27547.9

Included Documents

Certificate of Approval

Attachment : Form - Certificate of QA Review

Production Order

Line Clearance Log

Personnel Log

In-Process Inspection Summary

Quality Audit Log

Material Accountability

Sample Labels

PASS Verification Report

Destruction of Material

Attachment : Image - The first labelled carton.

Required Attachment : Form - Label Proof

Attachment : Form - Supporting Documents

Instruction Comments

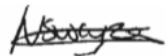
Certificate of QA Approval

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>Vizor, David</i>	27/JAN/21 10:23	<i>Nichols, Jean</i>	28/JAN/21 17:15

☒ 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.



29/01/2021

Customer Representative Signature

Date

Hannah Swayze

Dr

Customer Representative Name (print)

Title

University of Oxford

Customer/Entity Name

Certificate of QA Review

Product	BUDESONIDE (Pulmicort Turbohaler) 400mcg 50 doses Inhalation Powder Inhaler in Labeled Carton Prt: PRINCIPLE
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Fisher references

Part number:	HF75173
Receive lot number:	FH214403
Job number:	27547.9
Quantity	99

Client references

Customer lot number:	27547.9
Expiration Date:	10/2021

References for any relevant deviations

PR# Not Applicable

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).

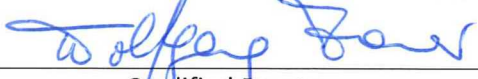
Any deviations have been investigated.

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

Reviewer:  Date: 28 Jan 2021
Jean Nichols

Quality Assurance

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

Approver:  Date: 28-Jan-2021
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	

Production Order

Customer: University of Oxford
Protocol: PRINCIPLE
Job/Version: 27547.9 v1
Site: Horsham
Step Description: Carton labelling of BUDESONIDE (Pulmicort Turbohaler) 400mcg

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



Production Order

SubStep 1 - Labeling Service

Service Output

Quantity	Part #	Description
99	HF75173	BUDESONIDE (Pulmicort Turbohaler) 400mcg 50 doses Inhalation Powder Inhaler in Labeled Carton Prt: PRINCIPLE
		Manufacturers Lot
		27547.9
1	HF75176	RETAIN SAMPLE: BUDESONIDE (Pulmicort Turbohaler) 400mcg 50 doses Inhalation Powder Inhaler in Labeled Carton Prt: PRINCIPLE
		Manufacturers Lot
		27547.9

Service Input

Quantity	Part #	Description
100	BB23813	Pulmicort Turbohaler 400mcg per actuation inhaler Labeled Pack (comm. pack of 1 inhaler of 50 actuations, Astra Zeneca, UK) Marketed Product
		Manufacturers Lot
		GAET
100	HL73830	LABEL White Printed 3 1/2 x 1 1/2 inch Placed On Carton TG Budesonide(400mcg,Pulmicort turbohaler) English OXF2508.2 (HL73829) Prt: PRINCIPLE

Station Assignments

Station	Part #	Description
1	BB23813	Pulmicort Turbohaler 400mcg per actuation inhaler Labeled Pack (comm. pack of 1 inhaler of 50 actuations, Astra Zeneca, UK) Marketed Product
1	HL73830	LABEL White Printed 3 1/2 x 1 1/2 inch Placed On Carton TG Budesonide(400mcg,Pulmicort turbohaler) English OXF2508.2 (HL73829) Prt: PRINCIPLE

Image Plan

Quantity	Part #	Description	Instruction
1	HF75173	BUDESONIDE (Pulmicort Turbohaler) 400mcg 50 doses Inhalation Powder Inhaler in Labeled Carton 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 carton

Startup Inspection Procedure

Perform Startup Inspections After
5 Minutes

**Production Order****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
- 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

Production Order**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 1166
Controlled drug: No
Storage: 15-25°C
Packaging: 15-25°C
Amber lighting required: No
Humidity: Not Controlled

Attachments:
CADTD08916 revision 1
Label proofs

Label variable information:
P Lot ID: 27547.9
Expiry Date: 10/2021

Sequence/material numbers:
Retain Sample (sequence number: 1001) material number: OL1001
Study stock (sequence number range: 1002 to 1100) material number range: OL1002 to OL1100
Material numbers are provided in the label barcodes for PASS scanning purposes only.

Consistency Instructions:
Use the photo(s) from Job 27547.9, Sub-step [1] as a reference to ensure consistency in Sub-step [1]

INSTRUCTIONS

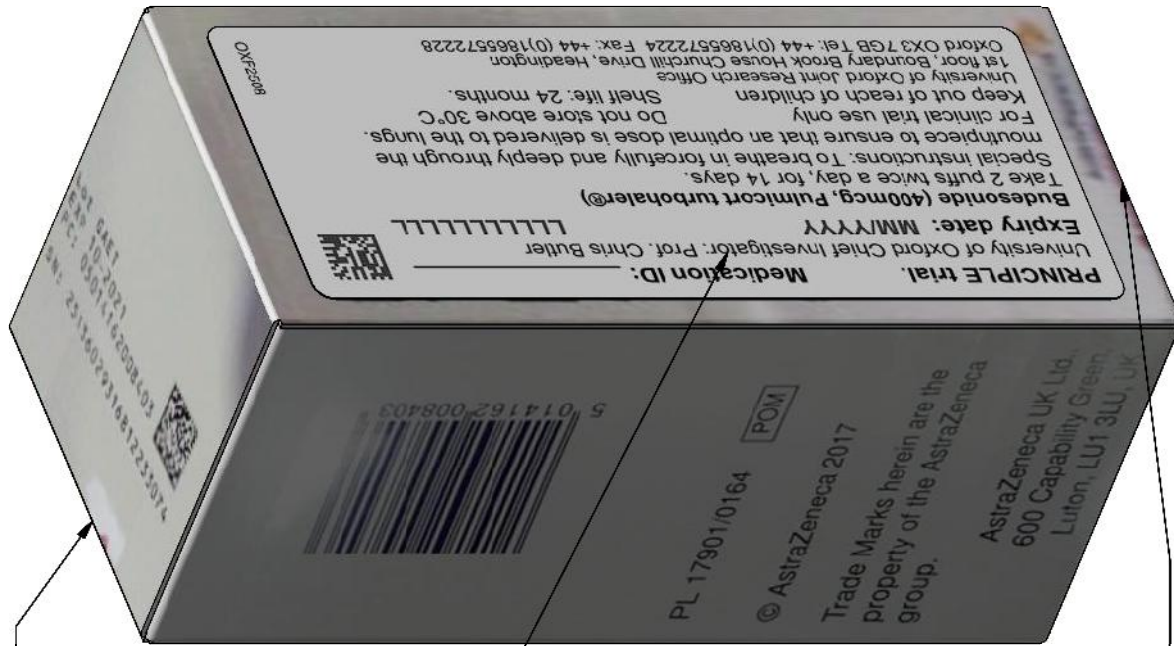
WORKSTATION 1
Apply carton label as per CADTD08916
Transfer carton to workstation 2

WORKSTATION 2
Verify carton label application as per CADTD08916
Note: Scan using PASS
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

Assigned Author:	Pre-Review Approved By:
<i>Walby, James</i> 19/JAN/21 14:16 By signing, I release this EPO for approval.	<i>przybyszewska, Iwona</i> 19/JAN/21 14:19 By signing, I confirm that I have reviewed this EPO and that all the information is complete and correct.

Production Batch Record



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

TITLE: Labelling Diagram		LABEL SIZE: 3 1/2" x 1 1/2"	
DRAWN BY: kscarsbrook	DATE: 08/Jan/21	COMP NO.: N/A	TOOL NO.: N/A
REVISOR BY: N/A	SCALE: NTS	ThermoFisher SCIENTIFIC	
DRAWING NO.: CADT08916.dwg	REVISION: 1		
JOB NO: 27547		CLIENT: University of Oxford	
STEP: 9		PROTOCOL: PRINCIPLE	



Fisher Clinical Services

Production Order

Signature Page

Customer: University of Oxford
Protocol: PRINCIPLE
Job Step/Version: 27547.9 v1
Site: Horsham
Step Description: Carton labelling of BUDESONIDE (Pulmicort Turbohaler) 400mcg

☒ 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.

21/01/2021

Customer Representative Signature

Date

Hannah Swayze

Dr

Customer Representative Name (print)

Title

University of Oxford

Customer/Entity Name

Line Clearance Log

Room	Date/Time	Previous Job Step	Clearance type
ROOM10	27/JAN/21 06:46	28822.6	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>Vizor, David</i> 27/JAN/21 06:46 By signing, I confirm that I have performed the Line Clearance and that all the information is complete and correct.	<i>Hawkes, Garry</i> 27/JAN/21 07:03 I verify that the Line Clearance has been correctly performed.

Personnel Log**Room** ROOM10**Task Assignment**

Personnel Name	SubStep	Task	Component	Time In	Time Out
Vizor , David	1	Line Leader	N/A	27/JAN/21 07:17	27/JAN/21 10:01
Vizor , David	1	Labeling - Verify Label (Part #)	HL73830	27/JAN/21 08:10	27/JAN/21 10:01
Schmidt , Judit	1	Labeling - Apply Label (Part #)	HL73830	27/JAN/21 08:10	27/JAN/21 10:01
Schmidt , Judit	1	Utility	BB23813	27/JAN/21 08:10	27/JAN/21 10:01

In Process Inspection Summary**SubStep 1 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: 2

Total units inspected: 2

In Process Inspection Summary

Service Run Summary

Start Date / Time	Started By	Stop Date / Time	Stop By	Reason
27/JAN/21 08:48	Vizor, David	27/JAN/21 09:56	Vizor, David	End of Sub Step

Inspection Details

Date / Time	Container	Units	Level Defects			Inspector	Is Complete	Status	Failure Level	Inspection Type
			I	II	III					
27/JAN/21 08:50	1	1	0	N/A	N/A	Vizor, David	Y	Pass	No Defects	Startup

Defect Test Results

Defect Level	Description	Quantity
1	Torn label	0
1	Incorrect label placement	0
1	Damaged product or component	0
1	Label print excessive fading or smears	0
1	Tamper evident seal missing	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					
27/JAN/21 09:46	1	1	0	N/A	N/A	Vizor, David	Y	Pass	No Defects	InProcess

Defect Test Results

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

End Check

Quality Audit Log

Date/Time	SubStep	Auditor	Comments
27/JAN/21 08:57	1	Matthews, Clair	Start Up, All Applicable Tests MT, No Observations
27/JAN/21 09:45	1	Matthews, Clair	Retain Sample, All Applicable Tests MT, No Observations
27/JAN/21 09:46	1	Matthews, Clair	End Check, All Applicable Tests MT, No Observations

Accountability

SubStep	Type	Room	Result
1	Closed Step	ROOM10	Passed

Products

Component	UOM	Rejects	Samples	Produced
HF75176	carton	0	0	1
HF75173	carton	0	0	99

Product ID Labels

Component	Used	Destroyed	Printed
HF75173	1	0	1
HF75176	2	0	2

Components

Component	Receiving #	Cust. Lot	Mfg. Lot	UOM	Samples	Rejected	BOH	Used in Job	Issued	% Accountability	Limits
BB23813	DH165268	N/A	GAET	pack	0	0	0	100	100	100%	98.00% - 102.00%
HL73830	LH131068	N/A	PDR343831	label	0	1	0	100	101	100%	100.00% - 100.00%

Accountability Comments

1 x HL73830 was used on sample label page and rejected in GPM for accountability purposes.

Reject Summary

Component	Receiving #	Reason	UOM	Quantity
HL73830	LH131068.2	N/A	label	1.0000

Performed By	Verification By
<i>Vizor, David</i> 27/JAN/21 09:57 I confirm that I have entered the Accountability data and that the data is correct.	<i>Schmidt, Judit</i> 27/JAN/21 09:59 I confirm the Accountability data is correct.

FIN

27/Jan/21
07:43:52 AM



HF75173 (FH214403.1)

Ambient 15°C to 25°C

Customer: University of Oxford

Manuf. Lot: 27547.9

Expiration Date: Oct 31, 2021

Description:

BUDESONIDE (Pulmicort Turbohaler) 400mcg 50 doses Inhalation
Powder Inhaler in Labeled Carton Prt: PRINCIPLE

Customer Lot: 27547.9

FIN

27/Jan/21
07:44:39 AM



HF75176 (FH214404.1)

Ambient 15°C to 25°C

Customer: University of Oxford

Manuf. Lot: 27547.9

Expiration Date: Oct 31, 2021

Description:

RETAIN SAMPLE: BUDESONIDE (Pulmicort Turbohaler) 400mcg 50
doses Inhalation Powder Inhaler in Labeled Carton Prt: PRINCIPLE

Customer Lot: 27547.9

PASS Verification Report**Service Output****SubStep:** 1

HF75173 - BUDESONIDE (Pulmicort Turbohaler) 400mcg 50 doses Inhalation Powder Inhaler in Labeled Carton Prt: PRINCIPLE

Scan Summary

Personnel	Treatment Group	Completed Scans	Not Produced	Sequence Range	Material Range
Vizor, David	OL	99	0	1002 - 1100	OL1002 - OL1100

PASS Verification Report**Service Output****SubStep:** 1

HF75176 - RETAIN SAMPLE: BUDESONIDE (Pulmicort Turbohaler) 400mcg 50 doses Inhalation Powder Inhaler in Labeled Carton Prt: PRINCIPLE

Scan Summary

Personnel	Treatment Group	Completed Scans	Not Produced	Sequence Range	Material Range
Vizor, David	OL	1	0	1001	OL1001

Destruction of Material**Substep: 1**

Component	Description	Receiving #	Customer Lot	Mfg. Lot	Destroyed
HL73830	LABEL White Printed 3 1/2 x 1 1/2 inch Placed On Carton TG Budesonide(400mcg,Pulmicort turbohaler) English OXF2508.2 (HL73829) Prt: PRINCIPLE	LH131068.2	N/A	PDR343831	1

Material Destruction Comments

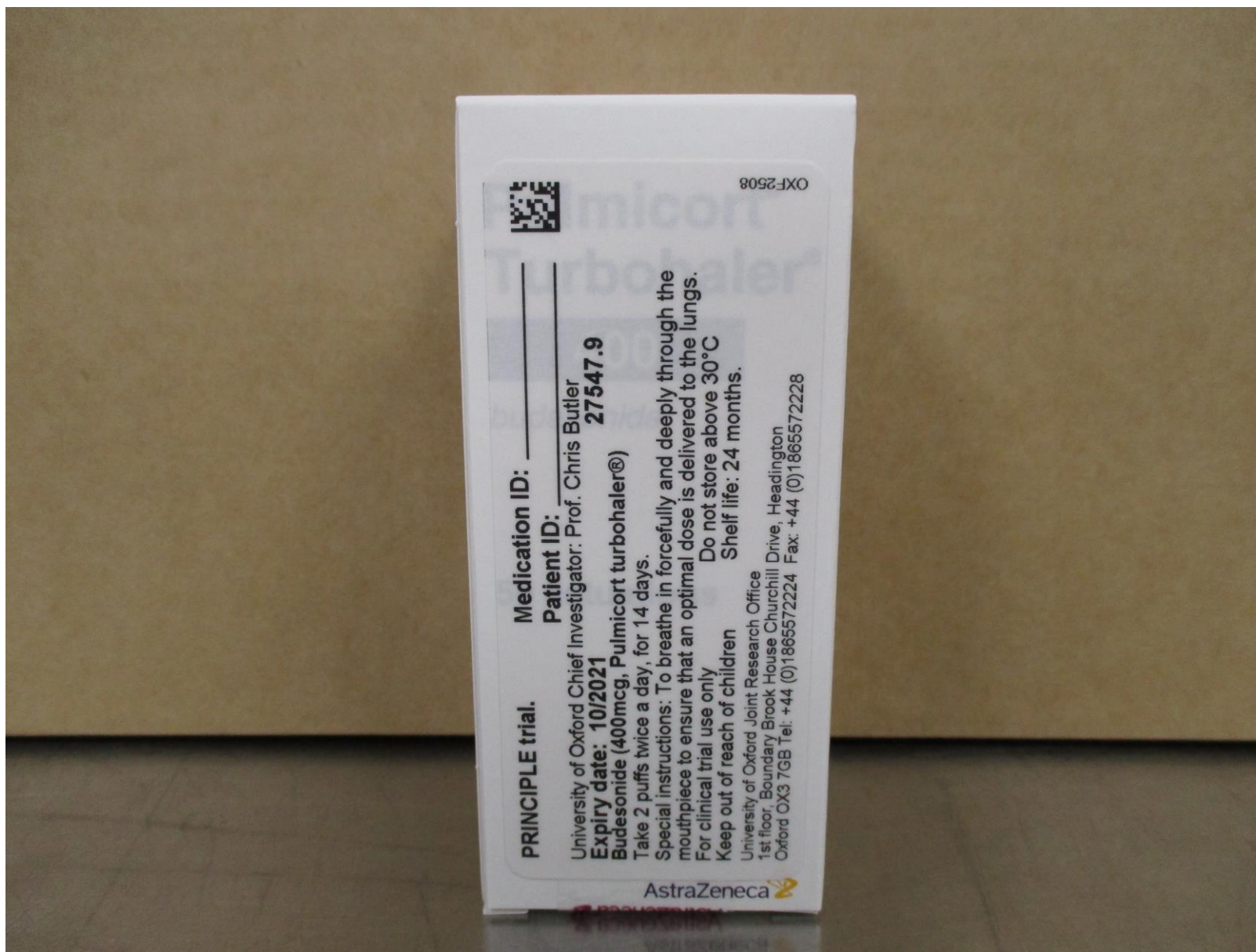
I confirm that Items have been destroyed in compliance with local site SOPs.

Destroyed By		Verified By	
<i>Schmidt, Judit</i>	27/JAN/21 09:59	<i>Vizor, David</i>	27/JAN/21 09:59

Job#: 27547.9

Step: 1

Title: The first labelled carton.



27/01/2021 08:53



Label ID #: OXF2508.2
Current Job #: 2467-001-20 RL #5
Original Job #: 2467-001-20 RL #5

Client Part #: N/A
Protocol: PRINCIPLE (FCS #217819) (47547)
Blinded Study: No
Label Package Integration: No

Client Name: University of Oxford
Created By: Kandri, Amina 11/17/2020 11:09:41 AM CET
Updated By: Kandri, Amina 1/13/2021 10:29:44 AM CET
Project Manager Sign/Date: Kandri, Amina

Study Logistics

Description: Single Panel Carton Label
Drug Name/Strength: Budesonide (400mcg, Pulmicort turbobaler®)
Container Type: Carton Label
Languages: 1
Blinded Label: No
Last Coding Job: N/A
Variable Field Associations: F2, F3, 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

new client update requested:

add a line as follows, this is a space to be filled in at site:

Patient ID: _____

client update requested:

add a line as follows, this is a space to be filled in by the investigator at site:

Medication ID: _____

remove the second duplicate phrase Take 2 puffs twice a day, for 14 days.

Manufacturing Logistics

Design Program: CLPS
TCN#: TCN05895
Template ID #: 1.3500.1500.3500.1750.SC1
Label Type: Single
Open Direction: N/A
Overall Size: 3 1/2" x 1 1/2"
Repeat: 1 3/4"
Gen Strip: N/A
Backtape: N/A
Base Label Stock: LAM2739 - Semi-Gloss Elite / Non-Opaque / S246 / 50# SCK / Component Part # RLP00009
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

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



Fisher Clinical Services			Production Batch Record		Job Step: 27547.9	
Variable Field Requirements						
F #	Placeholder	Placeholder Description	Placements			
F1	N/A	N/A	F1: PN1	(6pt)		
F2	LLLLLLLLLLLL	Lot:	F2: PN1	(8pt)		
F3	MM/YYYY	Expiry date:	F3: PN1	(8pt)		
F4	XXXXXXXXXX	(Barcode\DataMatrix)	F4: PN1	(18pt)		

CUSTOMER AUTHORIZATION

☒ **Proof Approved**

Proceed with Order

☐ **Revise Proof**

Return for Review



AUTHORIZED SIGNATURE

14/01/2021

DATE

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



F3

F2

F4

PRINCIPLE trial.

Medication ID: _____

Patient ID: _____

University of Oxford Chief Investigator: Prof. Chris Butler

Expiry date: MM/YYYY

Budesonide (400mcg, Pulmicort turbohaler®)

Take 2 puffs twice a day, for 14 days.

Special instructions: To breathe in forcefully and deeply through the mouthpiece to ensure that an optimal dose is delivered to the lungs.

For clinical trial use only

Keep out of reach of children

Do not store above 30°C

Shelf life: 24 months.

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

OXF2508

Label ID#: OXF2508.2

Label Designed By: Kübra Nur Cakmak

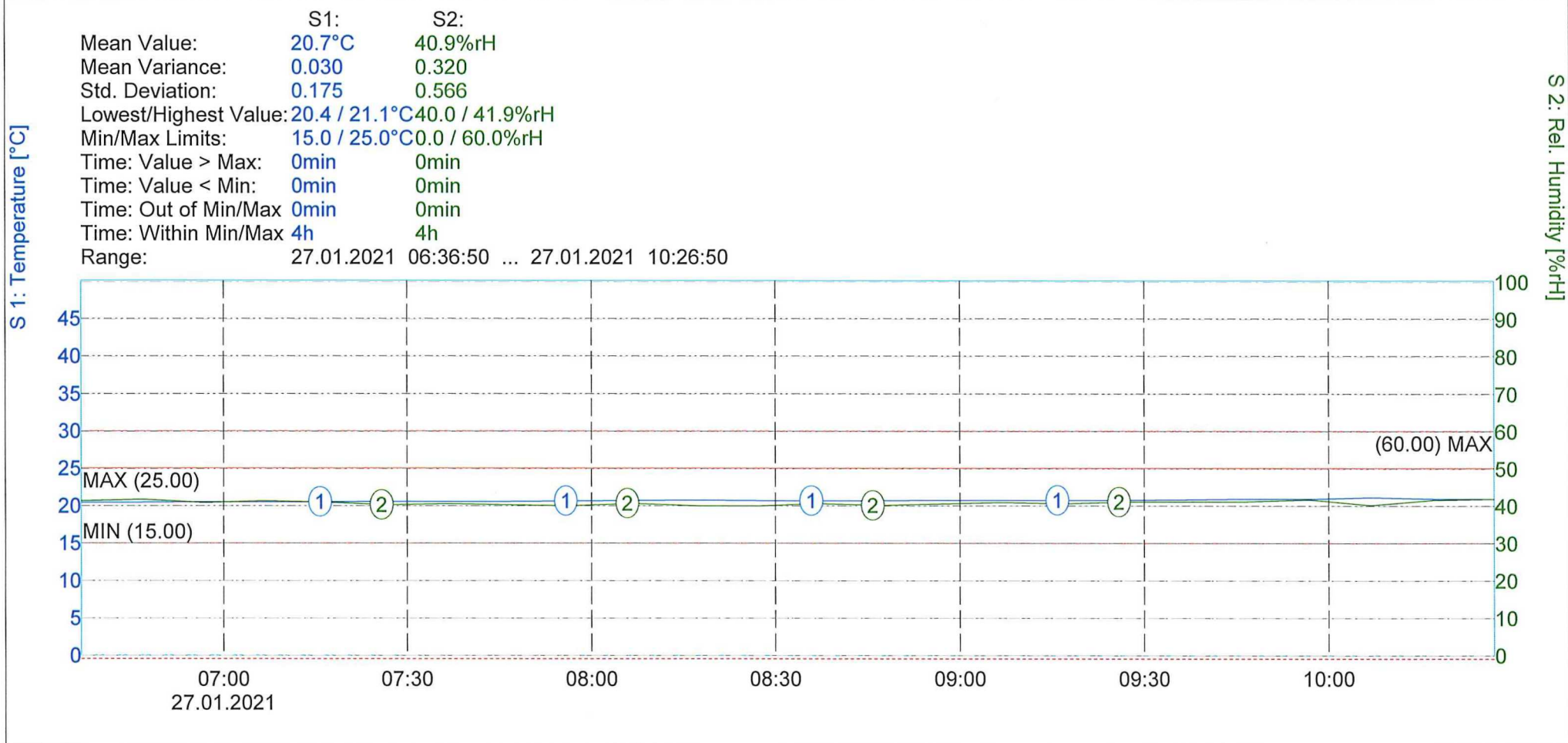
Label Revised By: Kübra Nur Cakmak

Template ID#: 1.3500.1500.3500.1750.SC1

Client Approval: 

IPI: **SIGNATURE ON FILE**

ECOLOG-NET LH2 ID:10454 ID-S2:201328499 - elproLOG ANALYZE QLS 3.64.01
 Date of Reading: 27.01.2021 10:36:21
 Log Interval: 10 min
 Module Tag: Primary Packaging Room 10
 Data Description: Job # 27547.9



Room/Cabin # 10

Job # 27547.9

General Room / Cabin Area Clearance Record

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>Q</u> Date <u>27 JAN 2021</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
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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 27 JAN 2021	N/A	N/A	N/A	N/A
Ensure that ANY Equipment NOT being used is covered to reduce the possibility of contamination		Q	QH	JS	Q
If applicable, remove any equipment dust covers and check for any contaminants. Clean if required		Q	QH	JS	Q
Clean/check floors, walls, windows, all vents and all high-level areas including tops of door ledges		Q	QH	JS	Q
Clean/check around PC and underneath the station, shelves, racking & cable trunking		Q	QH	JS	Q
Clean/check underneath static equipment, tables (release wheel brakes and clean/check), chairs, balances		Q	QH	JS	Q
All waste bags are removed. Reject tote and Quarantine containers are empty, cleaned and stored upside down		Q	QH	JS	Q
Check and complete logbooks as applicable		Q	QH	JS	Q

Operations – Start Clearance	Quality Check – Start Clearance
Initial, Date & Time <u>Q 27 JAN 2021 06:46</u>	Initial, Date & Time <u>QH 27 JAN 2021 07:03</u>

Primary Only - END AREA CLEARANCE Has room and equipment been cleaned within 3 days of completion of job	Yes/No/N/A (delete as appropriate) If NO, refer to SOP2006-f Initial <u>JS</u> and Date <u>27 JAN 2021</u>
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Operations – End Clearance	
Initial, Date & Time <u>JS 27 JAN 2021 10:10</u>	Initial, Date & Time <u>Q 27 JAN 2021 10:19</u>

① ⑤ crossed ^② in error JS 27 JAN 2021
 THROUGH
 ② ⑤ JS 27 JAN 2021

Packaging Sample Label Page

Job # 27547.9

Component # HL73830

Receive # LH131068

Initial&Date: Q/27 JAN 2021

PRINCIPLE trial. Medication ID: _____
Patient ID: _____
University of Oxford Chief Investigator: Prof. Chris Butler
Expiry date: 10/2021 27547.9
Budesonide (400mcg, Pulmicort turbohaler®)
Take 2 puffs twice a day, for 14 days.
Special instructions: To breathe in forcefully and deeply through the
mouthpiece to ensure that an optimal dose is delivered to the lungs.
For clinical trial use only Do not store above 30°C
Keep out of reach of children Shelf life: 24 months.
University of Oxford Joint Research Office
1st floor, Boundary Brook House Churchill Drive, Headington
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