

Production Order
Signature Page

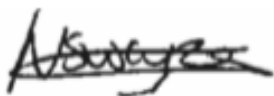
Customer: University of Oxford
Protocol: PRINCIPLE
Job Step/Version: 27547.9 v1
Site: Horsham
Step Description: Carton labelling of BUDESONIDE (Pulmicort Turbohaler) 400mcg

☒ **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.



Customer Representative Signature

Hannah Swayze

Customer Representative Name (print)

University of Oxford

Customer/Entity Name

21/01/2021

Date

Dr

Title

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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

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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

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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

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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

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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

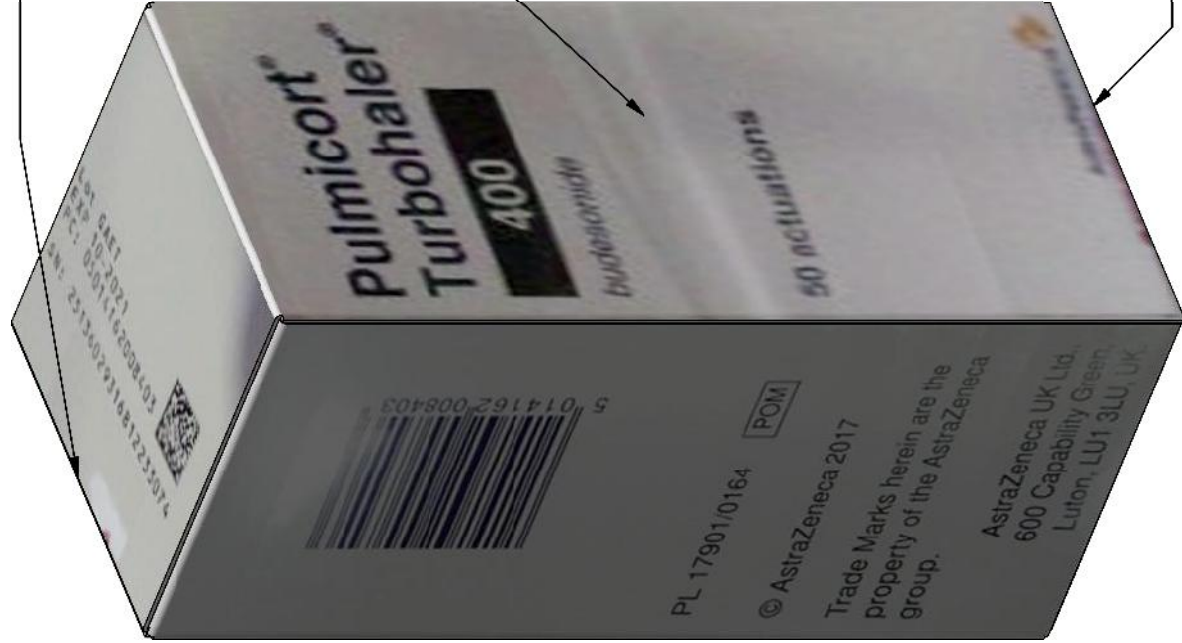
WORKSTATION 1
Apply carton label as per CADTD08916
Transfer carton to workstation 2

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.

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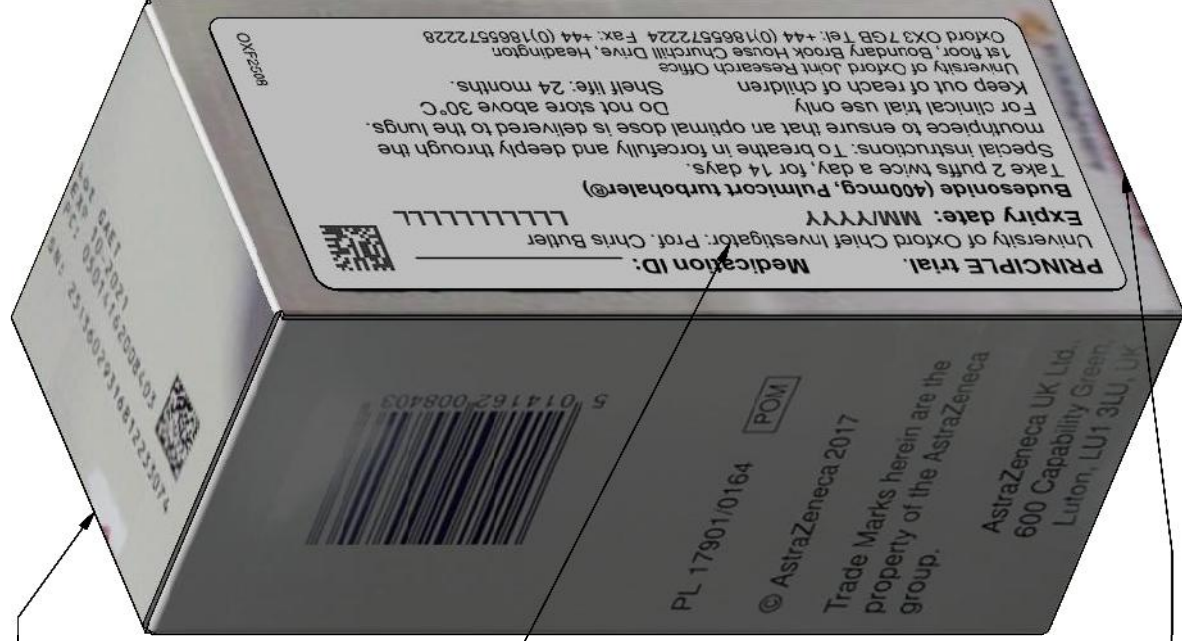
Assigned Author:	Pre-Review Approved By:
<i>Walby, James</i> 19/JAN/21 14:16 By signing, I release this EPO for approval.	<i>przybyszewska, Iwona</i> 19/JAN/21 14:19 By signing, I confirm that I have reviewed this EPO and that all the information is complete and correct.



Carton lid opening

Align and apply label
centrally to carton as shown

Carton base opening



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
REVISED BY: N/A	SCALE: NTS	REVISION: 1	ThermoFisher S C I E N T I F I C
DRAWING NO.: CADTD08916.dwg			

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

JOB NO: 27547	CLIENT: University of Oxford
STEP: 9	PROTOCOL: PRINCIPLE