

# LABEL SPECIFICATION COVER SHEET

**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                                                                     | Manufacturing Logistics                                                                                       |
|-------------------------------------------------------------------------------------|---------------------------------------------------------------------------------------------------------------|
| <b>Description:</b> Single Panel Carton Label                                       | <b>Design Program:</b> CLPS                                                                                   |
| <b>Drug Name/Strength:</b> Budesonide (400mcg, Pulmicort turbobaler®)               | <b>TCN#:</b> TCN05895                                                                                         |
| <b>Container Type:</b> Carton Label                                                 | <b>Template ID #:</b> 1.3500.1500.3500.1750.SC1                                                               |
| <b>Languages:</b> 1                                                                 | <b>Label Type:</b> Single                                                                                     |
| <b>Blinded Label:</b> No                                                            | <b>Open Direction:</b> N/A                                                                                    |
| <b>Last Coding Job:</b> N/A                                                         | <b>Overall Size:</b> 3 1/2" x 1 1/2"                                                                          |
| <b>Variable Field Associations:</b> F2, F3, F4                                      | <b>Repeat:</b> 1 3/4"                                                                                         |
| <b>Manufacture Quantity:</b> 1                                                      | <b>Gen Strip:</b> N/A                                                                                         |
| <b>Internal PFI Quantity:</b> 0                                                     | <b>Backtape:</b> N/A                                                                                          |
| <b>Colors</b>                                                                       | <b>Base Label Stock:</b> LAM2739 - Semi-Gloss Elite / Non-Opaque / S246 / 50# SCK / Component Part # RLP00009 |
| <b>Content Color 1:</b> Black                                                       | <b>Booklet Stock:</b> N/A                                                                                     |
| <b>Content Color 2:</b> N/A                                                         | <b>Over Laminate:</b> N/A                                                                                     |
| <b>Content Color 3:</b> N/A                                                         | <b>Under Laminate:</b> N/A                                                                                    |
| <b>Label Color:</b> White - (Material)                                              | <b>OSW Stock:</b> N/A                                                                                         |
| <b>Special Instructions:</b> N/A                                                    | <b>Mfg Type:</b> Manufacture New                                                                              |
| <b>Change Notices</b>                                                               | <b>Blank Stock:</b> No                                                                                        |
| N/A                                                                                 | <b>New Dies Req'd:</b> Flexo: No    Digital BK: No    Digicon: No    Onsert: No                               |
| <b>Deviation Reports</b>                                                            | <b>Base Panel Inks/Varnishes</b>                                                                              |
| N/A                                                                                 | <b>Print Station 1:</b> N/A                                                                                   |
| <b>Special Instructions</b>                                                         | <b>Print Station 2:</b> N/A                                                                                   |
| new client update requested:                                                        | <b>Print Station 3:</b> N/A                                                                                   |
| add a line as follows, this is a space to be filled in at site:                     | <b>Print Station 4:</b> N/A                                                                                   |
| Patient ID: _____                                                                   | <b>Print Station 5:</b> N/A                                                                                   |
| -----                                                                               | <b>Finishing Operations</b>                                                                                   |
| client update requested:                                                            | <b>Process Type:</b> In-Process                                                                               |
| add a line as follows, this is a space to be filled in by the investigator at site: | <b>Blinding Laminate:</b> N/A                                                                                 |
| Medication ID: _____                                                                | <b>Apply Laminates To:</b> N/A                                                                                |
| remove the second duplicate phrase Take 2 puffs twice a day, for 14 days.           | <b>Reorient:</b> No                                                                                           |
|                                                                                     | <b>Press Roll:</b> Yes <b>Core:</b> 4" <b>Max. Diam:</b> 11" <b>Unwind:</b> 4                                 |



| 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

.. /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.

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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**