



LABEL SPECIFICATION COVER SHEET

Label ID #: ASZ6537
Current Job #: 1203-002-18 RL #5
Original Job #: 1203-002-18 RL #5

Client Part #: N/A
Protocol: RAMPART (FCS#211915)
Blinded Study: **No**
Label Package Integration: **No**

Client Name: AstraZeneca
Created By: Schubert, Aline 1/8/2019 9:39:27 AM CET
Updated By: Schubert, Aline 1/8/2019 9:39:28 AM CET
Project Manager Sign/Date: Schubert, Aline

Study Logistics

Description: Single Panel Vial Label
Drug Name/Strength: MEDI4736 injection 500 mg NSC 778709 50 mg/mL, 10 mL solution for infusion
Container Type: Vial Label
Languages: 1
Blinded Label: No
Last Coding Job: N/A
Variable Field Associations: F2, F3, F4
Manufacture Quantity: 1
Clintrak PFI Quantity: 0

Colors

Content Color 1: Black
Content Color 2: N/A
Content Color 3: N/A
Label Color: White
Special Instructions: N/A

Change Notices

N/A

Deviation Reports

N/A

Special Instructions

N/A

Manufacturing Logistics

Design Program: CLPS
TCN#: TCN03422
Template ID #: 1.1000.2625.1000.2750.SC1
Label Type: Single
Open Direction: N/A
Overall Size: 1" x 2 5/8"
Repeat: 2 3/4"
Gen Strip: N/A
Backtape: N/A
Base Label Stock: STK1998 - Semi-Gloss Elite Fascover ES / Opaque / S246 / 50# SCK / Clintrak Part # RLP00013
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: 6" Max. Diam: 12.75" Unwind: 4

Variable Field Requirements

F #	Placeholder	Placeholder Description	Placements
F1	N/A	N/A	F1: PN1 (6pt)
F2	BBBBBBBBBB	Batch No.	F2: PN1 (6pt)
F3	MM/YYYY	Expiry Date	F3: PN1 (6pt)
F4	XXXXXXXXXX	(Barcode\DataMatrix)	F4: PN1 (16pt)

CUSTOMER AUTHORIZATION

- Proof Approved** Proceed with Order
 Revise Proof Return for Review

[Handwritten Signature]

AUTHORIZED SIGNATURE

16/01/19

DATE

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

F2

Protocol : RAMPART (RE06) EudraCT No: 2017-002329-39
 Batch Number : BBBBBBBBBB Expiry date: MM/YYYY
 Patient Trial Number : _____ Site: _____
 Principal Investigator : _____
 Vial containing MEDI4736 500mg (50mg/ml) Solution for infusion
 Directions for Use: To be administered in accordance with
 protocol instructions For Clinical Trial Use only
 Store between 2-8°C Protect from light DO NOT SHAKE
 Keep out of reach and sight of children
 Sponsor: University College London, Gower Street, London, WC1E 6BT,
 Tel: 020 7679 2000 Chief Investigator: Dr James Larkin ASZ6537

F3



F4

Client Approval: _____

IPI: _____ SIGNATURE ON FILE

Label ID#: ASZ6537

Label Designed By: Romaric Lidy

Label Revised By: Romaric Lidy

Template ID#: 1.1000.2625.1000.2750.SC1