



LABEL SPECIFICATION COVER SHEET

Label ID #: ASZ6536
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 9:13:34 AM CET
Updated By: Schubert, Aline 1/8/2019 9:38:04 AM CET
Project Manager Sign/Date: Schubert, Aline

Study Logistics

Description: Single Panel Carton Label - MEDI4736
Drug Name/Strength: MEDI4736 (500mg/vial)
Container Type: Carton 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 - (Material)
Special Instructions: N/A

Change Notices

N/A

Deviation Reports

N/A

Special Instructions

N/A

Manufacturing Logistics

Design Program: CLPS
TCN#: TCN05478
Template ID #: 1.5000.2500.5000.3000.SC1
Label Type: Single
Open Direction: N/A
Overall Size: 5" x 2 1/2"
Repeat: 3"
Gen Strip: Clintrak Std.
Backtape: N/A
Base Label Stock: LAM2561 - Semi-Gloss Elite / Non-Opaque / S246 / 50# SCK / Clintrak 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

Variable Field Requirements

F #	Placeholder	Placeholder Description	Placements
F1	N/A	N/A	F1: PN1 (11pt)
F2	PPPPPPPPPP	Batch No	F2: PN1 (10pt)
F3	MM/YYYY	Expiry Date	F3: PN1 (10pt)
F4	XXXXXXXXXX- XXXXXXXXXX	(Barcode DataMatrix)	F4: PN1 (20pt)

CUSTOMER AUTHORIZATION

- Proof Approved Proceed with Order
 Revise Proof Return for Review

[Handwritten Signature]

16/01/19


AUTHORIZED SIGNATURE

DATE

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

F4

F3

Protocol : RAMPART (RE06)	EudraCT No: 2017-002929-39
Batch Number : PPPPPPPPPPP	Expiry date: MM/YYYY
Site: _____	
Principal Investigator: _____	
Carton containing 3 vials of MEDI4736 500mg (50mg/ml) Solution for infusion	
Directions for Use: To be administered in accordance with protocol instructions	
Store between 2-8°C DO NOT SHAKE	
Keep out of reach and sight of children	
For Clinical Trial Use only	
Sponsor: University College London, Gower Street, London, WC1E 6BT, Tel: 020 7679 2000	
Chief Investigator: Dr James Larkin	

ASZ6536

F2




Label ID#: ASZ6536

Label Designed By: Romaric Lidy

Label Revised By: Romaric Lidy

Template ID#: 1.5000.2500.5000.3000.SC1

Client Approval: _____


IPI: _____ **SIGNATURE ON FILE**