



LABEL SPECIFICATION COVER SHEET

Label ID #: ASZ6074.1
Current Job #: 1203-002-18 RL #1
Original Job #: 1203-002-18 RL #1

Client Part #: N/A
Protocol: RAMPART (FCS#211915) (419705)
Blinded Study: **No**
Label Package Integration: **No**

Client Name: AstraZeneca
Created By: Schubert, Aline 1/16/2018 11:22:18 AM CET
Updated By: Meier, Lars 2/1/2018 3:11:22 PM CET
Project Manager Sign/Date: Schubert, Aline

Study Logistics	Manufacturing Logistics
Description: Single Panel Carton Label - Tremelimumab	Design Program: CLPS
Drug Name/Strength: Tremelimumab (400 mgvial).	TCN#: TCN04730
Container Type: Carton Label	Template ID #: 1.2000.6000.2000.6250
Languages: 1	Label Type: Single
Blinded Label: No	Open Direction: N/A
Last Coding Job: N/A	Overall Size: 2" x 6"
Variable Field Associations: F2, F3, F4	Repeat: 6 1/4"
Manufacture Quantity: 1	Gen Strip: Clintrak Std.
Clintrak PFI Quantity: 0	Backtape: N/A
Special Instructions	Base Label Stock: LAM2577 - Semi-Gloss Elite / Non-Opaque / S246 / 50# SCK / Clintrak Part # RLP00009
Text position 4	Booklet Stock: N/A
Change Notices	Laminate: N/A
N/A	OSW Stock: N/A
Deviation Reports	Mfg Type: Manufacture New
N/A	Blank Stock: No
	New Dies Req'd: Flexo: 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: NA

Colors**Content Color 1:** Black**Content Color 2:** N/A**Content Color 3:** N/A**Label Color:** White - (Material)**Special Instructions:** N/A

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

AUTHORIZED SIGNATURE

DATE

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



clinical labeling services

CLPS LABEL PROOF

F2

Protocol : RAMPART (RE06) EudraCT No: 2017-002329-39

Batch Number : P P P P P P P P P P Expiry date: MM.YYYY

Site: _____ Principal Investigator: _____

Carton containing 2 vials containing Tremellinmab 400mg
For Intravenous Infusion only

Directions for Use: To be administered in accordance with protocol instructions
Store between 2-8°C 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

ASZ6074

F3

F4

Label ID#: ASZ6074.1

Label Designed By: Romaric Lidy

Label Revised By: Valerie Zimmermann

Template ID#: 1.2000.6000.2000.6250

Client Approval: _____

IPI: _____ **SIGNATURE ON FILE**