

LABEL SPECIFICATION COVER SHEET

Label ID #: ASZ6535
 Current Job #: 1203-002-18 RL #5
 Original Job #: 1203-002-18 RL #4

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 9:03:15 AM CET
 Updated By: Schubert, Aline 1/14/2019 12:07:59 PM CET
 Project Manager Sign/Date: Schubert, Aline

Study Logistics

Description: Single Panel Carton Label - Tremelimumab
 Drug Name/Strength: Tremelimumab (400 mgvial).
 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

Text position 4

Manufacturing Logistics

Design Program: CLPS
 TCN#: TCN04730
 Template ID #: 1.2000.6000.2000.6250
 Label Type: Single
 Open Direction: N/A
 Overall Size: 2" x 6"
 Repeat: 6 1/4"
 Gen Strip: Clintrak Std.
 Backtape: N/A
 Base Label Stock: LAM2577 - 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 Laminates: N/A
 Apply Laminates To: N/A
 Reorient: No
 Press Roll: Yes Core: 4" Max. Diam: 11" Unwind: NA

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
- Revise Proof

Proceed with Order
Return for Review

B. Smith _____
 AUTHORIZED SIGNATURE DATE 16/01/19

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

E2

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 Tremelimumab 400mg (20mg/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

F3



ASZ6535

F4

[Handwritten Signature]

Client Approval: _____

IPI: _____ SIGNATURE ON FILE