

Assessment Type: **Final Assessment**

**Trial & Product Details:**

Sponsor Protocol Number:	STRESS-L
EudraCT Number:	2017-001785-14
Mawdsleys Trial Identifier:	STR
Product:	Landiolol hydrochloride
Strength:	300mg
Pharmaceutical Form:	Lyophilised powder for solution for intravenous injection and infusion for injection
Package Size:	20 X 50ml glass vials
Package Type:	Glass vials
Batch Number:	0079 (Packaging number)*
Patient Number:	N/A
Kit/Pack/Bottle Number(s):	N/A
Expiry Date:	11/2021
Quantity:	130 cartons x 20 vials per carton = 2600 vials
Goods Inwards Ref No.:	GIOR1051/STR/6
Date product received:	30/04/2019
Country to be supplied:	UK

**Manufacturer's Details**

Manufacturing Authorisation No.:	MIA IMP 741
Name of Authorisation Holder:	Mawdsley-Brooks & Co Ltd
Site Name and Address:	Mawdsleys Clinical Services, Quest 22, Silk Road, Off Wheatley Hall Road, Doncaster, DN2 4LT

I can confirm that the product described above has been assessed for quality and deemed acceptable.

Signed: David Clark

Date: 09 MAY 2019

Name: DAVID CLARK

Role: Q.P.

**Comments/remarks**

\*Bulk batch number 1805.

**Is temperature monitoring required during transit from Mawdsleys: Yes**

Mawdsleys order reference number(s): \_\_\_\_\_

I can confirm that where required temperature data during transit has been reviewed against guidance provided and the product is suitable for use.

Signed: \_\_\_\_\_

Date: \_\_\_\_\_

Name: \_\_\_\_\_

Role: \_\_\_\_\_