

## **Certificate Of Analysis**

CLIENT:

#:

142460-01

LOT #:

AW6022

**DESCRIPTION:** 

Thiopental Injection BP (Each vial contains Thiopental Sodium BP 500 mg)

DATE RECEIVED:

01/11/2011

STORAGE:

20°C to 25°C (68°F to 77°F)

CONTAINER:

(13) clear vials w/powder in a clear bag

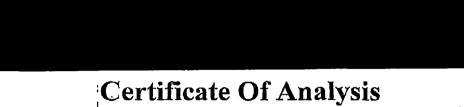
Test	Test Method	Limits .	Results	Date Tested
Identification A (IR)	USP 33	To Pass Test	Pass .	01/19/2011
Identification B (Sodium) <191>	USP 33	To Pass Test ."	Pass	01/19/2011
Identification C (Color)	USP 33	To Pass Test	Pass	01/20/2011
Loss on Drying <731>	USP 33	NMT 2.0%	0.56%	01/19/2011
Fleavy Metals (Method II) <231>	USP 33	NMT 0.002%	NMT 0.002%; Pass	01/19/2011
Ordinary Impurities (TLC) <466>	USP 33	NMT 2.0%	<2.0%; Pass	01/21/2011
Assay (UV)	USP 33	93.0-107.0%	93%	01/20/2011
Residual Solvents "A" (GC) <467>	USP 33	To Pass Test	Pass	01/27/2011
Completeness of Solution	USP 33	To Pass Test	Pass	01/31/2011

02/02/2011

Wet Chemistry Supervisor

Date Reported

Results reparted above relate only to the sample that was tested.



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DATE RECEIVED:

01/11/2011

STORAGE:

20°C to 25°C (68°F to 77°F)

CONTAINER:

(13):clear vials w/powder in a clear bag

Test	Test Method	Limits	Results	Date Tested
Constituted solution	USP 33	To Pass Test "	Pass	01/31/2011
pH<791>	USP 33	10.2 - 11.2	10.79	01/31/2011

This product was manufactured by Link Pharmaceuticals, Ltd. Horsham, West Sussex, RH12 1AH, UK / Lot: AW6022 / Exp: 05 2014.

02/02/2011

Date Reported

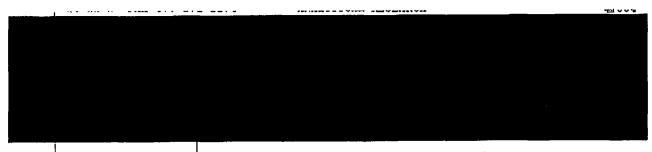
Wet Chemistry Supervisor

Results reported above relate only to the sample that was tested.

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## Certificate Of Analysis

CLIENT:

#: 14

142460-01

LOT #:

AW6022

DESCRIPTION:

Thiopental Injection BP (Each vial contains Thiopental Sodium BP 500 mg)

DATE RECEIVED:

01/11/2011

STORAGE:

20°C to 25°C (68°F to 77°F)

CONTAINER:

(13) clear vials w/powder in a clear bag

Analyte / Specifications	Expected Amount	Units	Results	% Of EXP.	Test Method	Date Tested
Thiopental Sodium	100	%/vial	93,728	93.7%	HPLC	1/14/2011
Specifications = 90% - 110%					1	

This product was manufactured by Link Pharmaceuticals, Ltd. Horsham, West Sussex, RH12 1AH, UK / Lot: AW 5022 / Exp: 05 2014.

01/14/2011

- Laboratory Director

Date Reported

Results reported above relate only to the sumple that was tested.

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## Microbiology Report

CLIENT:

**#:** 142460-01

LOT #: AW6022

DESCRIPTION: Thiopental Injection BP (Each vial contains Thiopental Sodium BP 500 mg)

**DATE RECEIVED: 01/11/2011** 

STORAGE:

20°¢ to 25°C (68°F to 77°F)

CONTAINER:

(13) clear vials w/powder in a clear bag

ANALYSIS	Limits	Results	Te'st Method	Date Tested
Stexility (* Preliminary *)	Sterile / Not Sterile	Sterile	USP 71	01/14/2011
Endotoxin	NMT 1.0 EU/mg	n<0.04 EU/mg	USP 85	01/17/2011
Fungal	Sterile / Not Sterile	Sterile	M8(-114	01/14/2011

This product was manufactured by Link Pharmaceuticals, Ltd. Horsham, West Sussex, RH12 1AH, UK / Lot: AW6022 / Exp. 05 2014.

01/18/2011

Microbiologist

Date Reported

Sterlity - An Initial report will be issued after approximately 72 hours of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days: If there is any change in the sample a supplemental report will be issued.

Fungal - An Initial report will be issued after 4-5 days of incubation. In accordance with the USP guidelines, the samples will be incubated for 14 days; if there is any change in the sample a supplemental report will be issued.

Endproxin - To calculate the endotoxin limit use the following formulao: El. = K/M where K = tolorance [lmit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg

Paranteral: K is 5 EU/kg for any route of administration /Intrathecal; K is 0.2 EU/kg body weight)

Radiopharmaccutical paranterol: K is 175/V or Intrathecal radiopharmaceuticuls: K is 14/V, where V is the maximum recommended dose in mL. Derival Application: K/M, where K = 5 EU/kg and M is the (maximum dose/m2/hour × 1.80 m2)/70 Kg.

Results reported above relate only to the sample that was tested

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## **Certificate Of Analysis**

CLIENT: LINK PHARMACEUTICALS LIMITED

**BISHOPS WEALD HOUE** 

**ALBION WAY** 

HORSHAM, WEST SUSSEX, RH12 1AH,

ЦK

#:

145680-01

LOT #:

AW6022

DESCRIPTION:

Thiopental Sodium 500 mg/vial

DATE RECEIVED:

03/02/2011

STORAGE:

20°C to 25°C (68°F to 77°F)

CONTAINER:

Ten clear vials w/powder in a clear bag

Test	Test Method	Limits	Results	Date Tested
Uniformity of Dosage Units <905>	USP 33	NMT 15	5.8	03/31/2011
Assay (HPLC)	HPLC	93% - 107%	93.0%	03/31/2011

03/31/2011

- Wet Chemistry Supervisor

Date Reported

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