[redacted]

Certificate Of Analysis

CLIENT:

[redacted] #: 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
Heavy 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

[redacted]

02/02/2011

[redacted] Wet Chemistry Supervisor — Date Reported

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

[redacted]

Certificate Of Analysis

CLIENT:

[redacted] #: 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
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.

[redacted]

02/02/2011

[redacted] - Wet Chemistry Supervisor — Date Reported

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

[redacted]

Certificate Of Analysis

CLIENT:

[redacted] #: 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 Specifications = 90% - 110%	100	%/vial	93.728	93.7%	HPLC	1/14/2011

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

[redacted]

[redacted] - Laboratory Director

01/14/2011

Date Reported

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

[redacted] *Form QUF-078-V4 03/05/2010*

[redacted]

Microbiology Report

CLIENT:

[redacted] #: 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

ANALYSIS	Limits	Results	Test Method	Date Tested
Sterility (* Preliminary *)	Sterile / Not Sterile	Sterile	USP 71	01/14/2011
Endotoxin	NMT 1.0 EU/mg	<0.04 EU/mg	USP 85	01/17/2011
Fungal	Sterile / Not Sterile	Sterile	MBI-114	01/14/2011

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

[redacted]

[redacted] - Microbiologist

01/18/2011
Date Reported

Sterility - 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.

Endotoxin - To calculate the endotoxin limit use the following formulae: EL = K/M where K = tolerance limit (EU/kg) and M = Maximum dose/kg/hour or Maximum dose/kg
Parenteral: K is 5 EU/kg for any route of administration /Intrathecal: K is 0.2 EU/kg body weight)
Radiopharmaceutical parenteral: K is 175/V or Intrathecal radiopharmaceuticals: K is 14/V, where V is the maximum recommended dose in mL.
Dermal 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.

[redacted] *Form QUF-078-V4 03/05/2010*

[redacted]

Certificate Of Analysis

CLIENT: LINK PHARMACEUTICALS LIMITED
BISHOPS WEALD HOUE
ALBION WAY
HORSHAM, WEST SUSSEX, RH12 1AH,
UK

[redacted] #: 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

[redacted]

[redacted] - Wet Chemistry Supervisor

03/31/2011
Date Reported

[redacted] *Form QUF-078-V4 03/05/2010*

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