

Subject ID 044 - 1 ☐ ☐

Subject Initials ☐ ☐ ☐

Eligibility

Inclusion Criteria (all answers must be YES to be included in the trial)		Yes	No
1	Age 18-45 years, inclusive.....	<input type="checkbox"/> 1	<input type="checkbox"/> 0
2	Willingness to submit to diagnostic machine testing .....	<input type="checkbox"/> 1	<input type="checkbox"/> 0
3	Male or non-pregnant, non-lactating female. Women of reproductive potential must be practicing adequate contraception (e.g., intrauterine device or double barrier device such as a diaphragm or condom plus spermicide). Abstinence is not considered to be an acceptable method of contraception. Additionally, women of reproductive potential must have a negative urine pregnancy at screening and prior to enrollment.....	<input type="checkbox"/> 1	<input type="checkbox"/> 0
4	In good health as determined by medical history and physical examinations.....	<input type="checkbox"/> 1	<input type="checkbox"/> 0
5	Capable of understanding and complying with the protocol and has signed the informed consent document.....	<input type="checkbox"/> 1	<input type="checkbox"/> 0
Exclusion Criteria (all answers must be NO to be included in the trial)		Yes	No
1	Pregnant or lactating females.....	<input type="checkbox"/> 1	<input type="checkbox"/> 0
2	History of anaphylaxis.....	<input type="checkbox"/> 1	<input type="checkbox"/> 0
3	History or presence of hepatitis.....	<input type="checkbox"/> 1	<input type="checkbox"/> 0

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Demographics/Medical History

Demographics	
Sex:	Race:
<input type="checkbox"/> 1 Male	<input type="checkbox"/> 1 Caucasian
<input type="checkbox"/> 2 Female	<input type="checkbox"/> 2 Black
	<input type="checkbox"/> 3 Hispanic
	<input type="checkbox"/> 4 Asian
	<input type="checkbox"/> 5 Other (specify):
Date of Birth:	Date Informed Consent Signed :
mm / dd / yy	mm / dd / yy

Pregnancy test	
Result:	<input type="checkbox"/> 0 Negative
	<input type="checkbox"/> 2 Not applicable

Medical History		
Body System	Normal	Abnormal (describe)
Neuro	<input type="checkbox"/> 0	
HEENT	<input type="checkbox"/> 0	
Heart	<input type="checkbox"/> 0	
Lungs	<input type="checkbox"/> 0	
Abdomen	<input type="checkbox"/> 0	
Musculoskeletal	<input type="checkbox"/> 0	
Peripheral Vascular	<input type="checkbox"/> 0	
Skin	<input type="checkbox"/> 0	
Additional Findings:		

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Physical Examination

	Study Day 1		Study Day 2	
Body System	Normal	Abnormal (describe)	Normal	Abnormal (describe)
Neurological	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
HEENT	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
Heart	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
Lungs	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
Abdomen	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
Musculoskeletal	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
Peripheral Vascular	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
Skin	<input type="checkbox"/> 0		<input type="checkbox"/> 0	<input type="checkbox"/> 1 Unchanged from Study Day 1
Additional Findings:			<input type="checkbox"/> 1 Unchanged from Study Day 1	

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Laboratory

	Study Day 1	Study Day 2
Name of Lab		
Lab test	Result	Result
	<input type="checkbox"/> , Not Done	<input type="checkbox"/> , Not Done
Sodium		
Potassium		
Chloride		
BUN		
Creatinine		
Total Protein		
Albumin		
Direct bilirubin		
Total bilirubin		
ALT/SGPT		
AST/SGOT		
LDH		
WBC		
Neutrophils		
Eosinophils		
Basophils		
Lymphocytes		
Monocytes		
Hct%		
Hgb		
Platelets		
INR		
PT		
PTT		

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                                 mm    dd    yy

Evaluations and Dosing

## Baseline Vital Signs

Time (24 Hour)	Temp (°F)	HR (per minute)	RR (per minute)	BP (syst/dia)	O <sub>2</sub> Sat (%)
:				/	

Weight	Height	Health Questionnaire Score	
_____ . _____ Kg	_____ . _____ inches	Pre	Post

Cohort	Infusion Period # 1	Infusion Period # 2
1 <input type="checkbox"/>	<input type="checkbox"/> <sub>1</sub> Bottle      1.25 mg/kg	<input type="checkbox"/> <sub>1</sub> Bottle      1.25 mg/kg
2 <input type="checkbox"/>	<input type="checkbox"/> <sub>2</sub> Bag      0.65 mg/kg	<input type="checkbox"/> <sub>2</sub> Bag      0.65 mg/kg
	<input type="checkbox"/> <sub>3</sub> Bag, other <u>  0  </u> . _____	<input type="checkbox"/> <sub>3</sub> Bag, other <u>  0  </u> . _____
	Amount PROD infused	Amount PROD infused
<input type="checkbox"/> Other _____	_____ . _____ mg	_____ . _____ mg

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## Study Day 1

## Vital Signs

Timepoint	Time (24 Hour)	HR (per min)	BP (syst/dia)	O <sub>2</sub> Sat (%)
- 5 minutes	:		/	
0 minutes	:		/	
5 minutes	:		/	
10 minutes	:		/	
15 minutes	:		/	
20 minutes	:		/	
25 minutes	:		/	
30 minutes	:		/	
35 minutes	:		/	
40 minutes	:		/	
45 minutes	:		/	
50 minutes	:		/	
55 minutes	:		/	
60 minutes	:		/	
65 minutes	:		/	
70 minutes	:		/	
End of Infusion Period #2	:			
1 hour after Infusion Period #2	:		/	

Concomitant Medications

☐ None

Medication	Dose	Unit	Route	Date (mm / dd / yy)	Time (24 Hour)
1				___/___/___	:
2				___/___/___	:
3				___/___/___	:
4				___/___/___	:
5				___/___/___	:
6				___/___/___	:
7				___/___/___	:
8				___/___/___	:
9				___/___/___	:
10				___/___/___	:
11				___/___/___	:
12				___/___/___	:

☐ Check if subsequent pages

**Report all Serious Adverse Events  
IMMEDIATELY**

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Event Description		Onset	Resolution	Severity	Relationship to PROD	Actions taken (✓ all applicable)
1	Date (mm/dd/yy)	___/___/___	___/___/___	<input type="checkbox"/> <sub>1</sub> Mild <input type="checkbox"/> <sub>2</sub> Moderate <input type="checkbox"/> <sub>3</sub> Severe <input type="checkbox"/> <sub>4</sub> Life-threatening	<input type="checkbox"/> <sub>1</sub> Unrelated <input type="checkbox"/> <sub>2</sub> Possibly <input type="checkbox"/> <sub>3</sub> Probably <input type="checkbox"/> <sub>4</sub> Definitely	<input type="checkbox"/> <sub>0</sub> None <input type="checkbox"/> <sub>1</sub> Treatment <input type="checkbox"/> <sub>2</sub> PROD stopped <input type="checkbox"/> <sub>3</sub> Discontinued trial <input type="checkbox"/> <sub>4</sub> SAE Reported
	Time (24 hour)	:	: <input type="checkbox"/> <sub>1</sub> Continuing			
2	Date (mm/dd/yy)	___/___/___	___/___/___	<input type="checkbox"/> <sub>1</sub> Mild <input type="checkbox"/> <sub>2</sub> Moderate <input type="checkbox"/> <sub>3</sub> Severe <input type="checkbox"/> <sub>4</sub> Life-threatening	<input type="checkbox"/> <sub>1</sub> Unrelated <input type="checkbox"/> <sub>2</sub> Possibly <input type="checkbox"/> <sub>3</sub> Probably <input type="checkbox"/> <sub>4</sub> Definitely	<input type="checkbox"/> <sub>0</sub> None <input type="checkbox"/> <sub>1</sub> Treatment <input type="checkbox"/> <sub>2</sub> PROD stopped <input type="checkbox"/> <sub>3</sub> Discontinued trial <input type="checkbox"/> <sub>4</sub> SAE Reported
	Time (24 hour)	:	: <input type="checkbox"/> <sub>1</sub> Continuing			
3	Date (mm/dd/yy)	___/___/___	___/___/___	<input type="checkbox"/> <sub>1</sub> Mild <input type="checkbox"/> <sub>2</sub> Moderate <input type="checkbox"/> <sub>3</sub> Severe <input type="checkbox"/> <sub>4</sub> Life-threatening	<input type="checkbox"/> <sub>1</sub> Unrelated <input type="checkbox"/> <sub>2</sub> Possibly <input type="checkbox"/> <sub>3</sub> Probably <input type="checkbox"/> <sub>4</sub> Definitely	<input type="checkbox"/> <sub>0</sub> None <input type="checkbox"/> <sub>1</sub> Treatment <input type="checkbox"/> <sub>2</sub> PROD stopped <input type="checkbox"/> <sub>3</sub> Discontinued trial <input type="checkbox"/> <sub>4</sub> SAE Reported
	Time (24 hour)	:	: <input type="checkbox"/> <sub>1</sub> Continuing			
4	Date (mm/dd/yy)	___/___/___	___/___/___	<input type="checkbox"/> <sub>1</sub> Mild <input type="checkbox"/> <sub>2</sub> Moderate <input type="checkbox"/> <sub>3</sub> Severe <input type="checkbox"/> <sub>4</sub> Life-threatening	<input type="checkbox"/> <sub>1</sub> Unrelated <input type="checkbox"/> <sub>2</sub> Possibly <input type="checkbox"/> <sub>3</sub> Probably <input type="checkbox"/> <sub>4</sub> Definitely	<input type="checkbox"/> <sub>0</sub> None <input type="checkbox"/> <sub>1</sub> Treatment <input type="checkbox"/> <sub>2</sub> PROD stopped <input type="checkbox"/> <sub>3</sub> Discontinued trial <input type="checkbox"/> <sub>4</sub> SAE Reported
	Time (24 hour)	:	: <input type="checkbox"/> <sub>1</sub> Continuing			

Investigator's Signature \_\_\_\_\_

Date \_\_\_\_\_

☐ <sub>1</sub> Check if subsequent pages



Subject ID 044 - 1 ☐ ☐Subject Initials ☐ ☐ ☐Study Day 2          /     /      
mm    dd    yy

Study Completion

## Study Completion/Termination

Vital Signs					
Time (24 Hour)	Temp (°F)	HR (per minute)	RR (per minute)	BP (syst/dia)	O <sub>2</sub> Sat (%)
:				/	

Did the subject complete the trial ?      ☐ <sub>1</sub> Yes      ☐ <sub>0</sub> No

If No, please complete the following (✓ all applicable)

Reason for discontinuation		Date mm / dd / yy	
<input type="checkbox"/> <sub>1</sub>	Adverse Event	<u>   </u> / <u>   </u> / <u>   </u>	event:
<input type="checkbox"/> <sub>2</sub>	Withdrew consent	<u>   </u> / <u>   </u> / <u>   </u>	reason:
<input type="checkbox"/> <sub>3</sub>	Lost to follow up	<u>   </u> / <u>   </u> / <u>   </u>	reason:
<input type="checkbox"/> <sub>4</sub>	Right-to-left cardiac shunt	<u>   </u> / <u>   </u> / <u>   </u>	
<input type="checkbox"/> <sub>5</sub>	Other	<u>   </u> / <u>   </u> / <u>   </u>	specify:

## Summary of Protocol Compliance

Was the protocol followed without deviations?      ☐ <sub>1</sub> Yes      ☐ <sub>0</sub> No

If No, please complete the following (✓ all applicable)

Departures		
<input type="checkbox"/> <sub>1</sub>	Entrance Criteria not met	specify:
<input type="checkbox"/> <sub>2</sub>	PROD not administered fully	reason:
<input type="checkbox"/> <sub>3</sub>	Images not obtained	explain:
<input type="checkbox"/> <sub>4</sub>	Safety data not obtained or not collected at scheduled time point	explain:
<input type="checkbox"/> <sub>5</sub>	Other	specify: