



The REDOX[®] Study
REDucing DEaths due to OXidative STress

Pharmacy Logs and Worksheets



Monthly Site Inventory Log

Month _____ Year _____

To be filled out by Site Pharmacy monthly and faxed to Clinical Evaluation Research Unit (CERU).

Name of Site: _____

Pharmacist: _____

Phone: _____

Product	Supplier	Minimum Supply needed	Actual supplies	Amount needed	Checked by CERU Project Leader/delegate
Dipeptiven (100 ml bottles) (10 bottles per carton)	Calea	80 bottles*	____ bottles	____ bottles	
EN REDOXS formula (500 mls bottles) (12 bottles per carton)					
AOX + GLN	Calea	36 bottles ^α	____ bottles	____ bottles	
AOX	Calea	36 bottles ^α	____ bottles	____ bottles	
GLN	Calea	36 bottles ^α	____ bottles	____ bottles	
Placebo	Calea	36 bottles ^α	____ bottles	____ bottles	
Selenium (10 ml vials)	Baxter	50 vials ^β	____ vials	____ vials	

* based on 4 patients, each needing 2 bottles per day for 10 days

^α based on 4 patients, each needing 1 bottle per day for 9 days

^β based on 4 patients, each needing approximately 1.5 vials/day per day for 8 days

Signature of person completing log: _____

Date _____

Fax completed form to: CERU (613) 548-2428

Attention: REDOX[®] Study (613) 549-6666 ext 3830



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Monthly Site Temperature Log

Month _____ Year _____

To be filled out by Site Pharmacy daily and faxed to Clinical Evaluation Research Unit (CERU) monthly.

Name of Site: _____ Pharmacist: _____ Phone: _____

Date	Temperature Low Température Bas	Temperature Current Température Présent	Temperature High Température Haut	Date	Temperature Low Température Bas	Temperature Current Température Présent	Temperature High Température Haut
01				16			
02				17			
03				18			
04				19			
05				20			
06				21			
07				22			
08				23			
09				24			
10				25			
11				26			
12				27			
13				28			
14				29			
15				30			
				31			

Signature of person submitting log: _____

Fax completed form to: CERU (613) 548-2428
Attention: Rupinder Dhaliwal (613) 549-6666 ext 3830



Enteral Product Label Log

Page ___ of ___

Pharmacist to place removable labels here daily (use one page is for 3 days)

Patient CR #: _____ Patient Initials: _____ Enrollment#: _____

Treatment Group (circle one): AOX GLN AOX+ GLN Placebo

Date dd/mm/yyyy

Date dd/mm/yyyy

Date dd/mm/yyyy



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Appendices

Appendix A: Pharmacy Web Access Signature Log

Appendix B: Randomization Process on Web

Appendix C: Enteral Study Supplement Label Template

Appendix D: Parenteral Study Supplement Worksheets

Appendix E: Parenteral Study Supplement Label Template

Appendix F: Height and Dose of Dipeptiven



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Pharmacy Web access Signature Log

INSTITUTION:
INVESTIGATOR:

SITE NUMBER:

Please complete the Electronic Data Capture (EDC) System Access Signature Sheet for each Pharmacist/technician at your site who will be checking the randomization or dispensing/checking study supplements. A signature and email address is required to create user accounts for the web based system for the REDOXS[®] Study.

NAME	TITLE	SIGNATURE	EMAIL	DATE

NOTE:

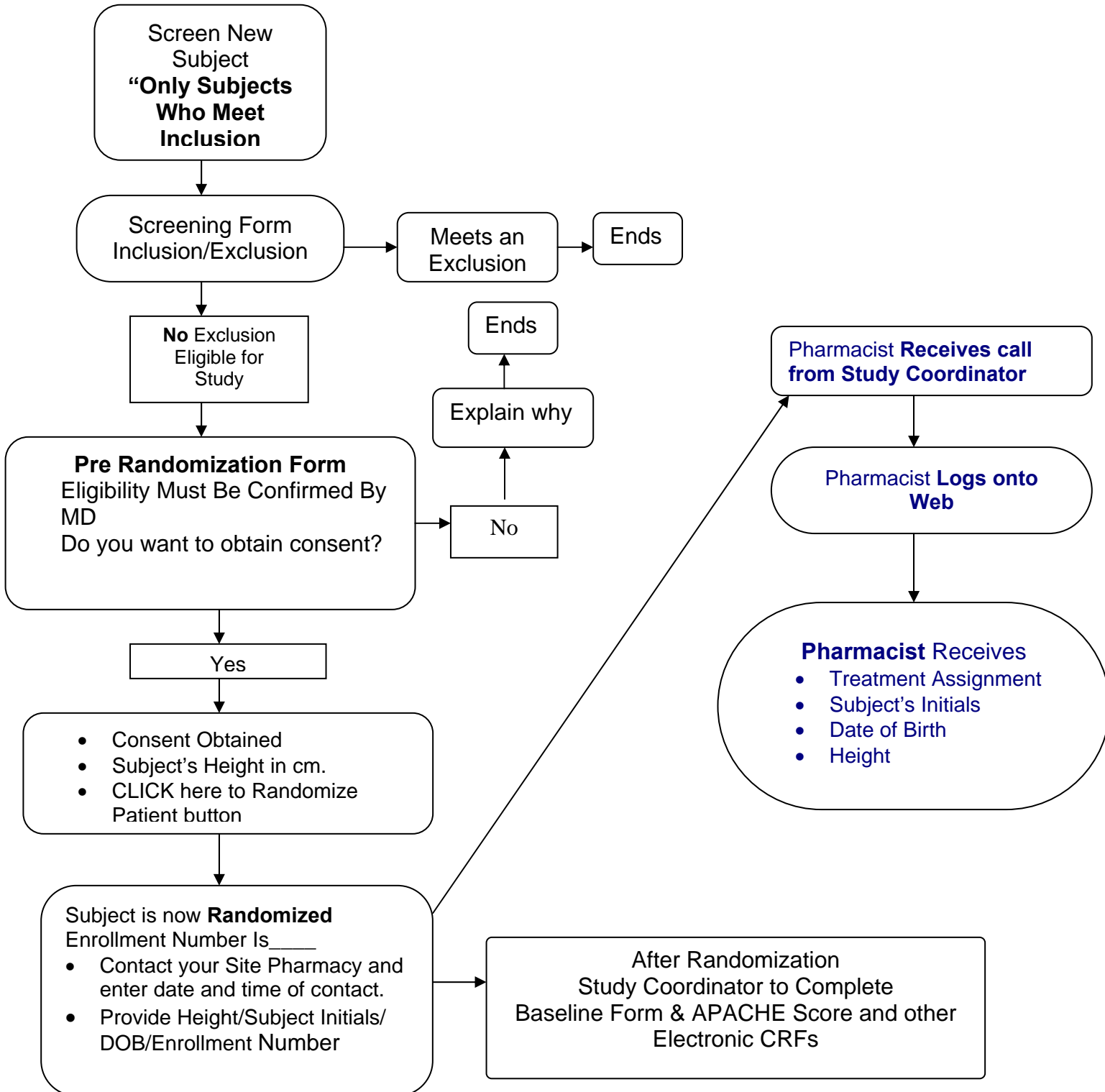
By completing the information in the table above, the individual confirms they have been delegated the responsibility of checking the randomization and dispensing/verifying study supplements for the REDOXS[®] Study.

The individual agrees to keep their password confidential to prevent unauthorized access to the data.

Reference: ICH GCP 5.5.3



Appendix B Randomization Process on Web





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Appendix C

Enteral Study Supplement
Study: REDOX[®]
Enteral Component

For Clinical trial Use Only

Enrollment #:
Patient ID/CR#:
Patient Name:
Physician:

Directions: Infuse at 20 mL/hr
Storage: keep between 15-25 C
Expiry: use within 24 hours

Date:



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Appendix D

Parenteral Study Supplement Worksheets

Use the appropriate worksheet according to the group the patient has been randomized to.

These worksheets will assist in calculating the volumes of the parenteral study supplements and normal saline needed.

Worksheet for Antioxidants (AOX)

Worksheet for Glutamine (GLN)

Worksheet for (Antioxidant + Glutamine) AOX + GLN

Worksheet for Placebo



Parenteral Supplements Worksheet Antioxidants (AOX)

Patient will receive Selenium (Antioxidants) and normal saline

Patient CR #: _____ Patient Initials: _____ Enrollment #: _____

1. Patient's height = **Not needed for calculating AOX dose** _____ cms
2. Normal Body Weight = (#1) minus 100 cms = **Not needed** _____ kgms
3. Dose of Dipeptiven* to be added = 0 mL
4. Dose of Selenium to be added = 12.5 mL
5. Total Volume to be removed from 250 ml normal saline bag before adding study supplements = 12.5 mL (add #3 and #4)
6. Add (#3) + (#4) + normal saline = 250 mL
7. Record the volumes of Selenium and Normal Saline on the Parenteral Study Supplement Log for this patient daily.
8. Generate a label and attach to bag.



Parenteral Supplements Worksheet for patients ≥ 196 cm tall Antioxidants (AOX)

Patient CR #: _____ Patient Initials: _____ Enrollment #: _____

Dosing:

1. **Dosage of Selenium = 500mcg/day = 12.5mL/day regardless of height**
2. **Rate of infusion determined from chart below.** (rate may be increased up to 2x the amount on day 1 for hours missed to conform to standard dosing times)
3. Dose will be diluted in a NS bag to a final volume indicated in chart below. Inherent overfill of bag to be ignored.

Go to Height Chart (see below). Record:

1. Patient Height _____ cm
2. Final Total Volume of bag (from chart below) _____ ml
3. Rate to be infused (from chart below) _____ ml/hr
4. Volume of Selenium to be added _____ 12.5 mL
5. Amount of NS to be removed _____ mL OR added _____ mL
(circle one)

Height	Final Total Volume of Bag	Rate to be Infused	Volume of Selenium to be added	Amount of NS to be removed	Amount of NS to be added
196 cm	253 mL	10.5 mL/hr	12.5mL	9.5 mL	
198 cm	258 mL	10.8 mL/hr	12.5mL	4.5 mL	
201 cm	266 mL	11.1 mL/hr	12.5mL		3.5 mL
203 cm	271 mL	11.3 mL/hr	12.5mL		8.5 mL
206 cm	278 mL	11.6 mL/hr	12.5mL		15.5 mL
208 cm	283 mL	11.8 mL/hr	12.5mL		20.5 mL
211 cm	291 mL	12.1mL/hr	12.5mL		28.5 mL
213 cm	296 mL	12.3mL/hr	12.5mL		33.5 mL



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6. Retrieve 250mL bag of NS and appropriate amount of selenium required.
7. Remove or add appropriate amount of normal saline from 250mL NS bag.
8. Draw up 12.5mL Selenium and add to above NS bag. Mix.
9. Final total volume= _____ mL (As per chart -Ignore overflow)
10. Infusion rate _____ mL/hr.(As per chart)
11. Expiry Dating= 96 hrs at room temperature.
12. Generate a label and attach to bag.
13. Record the volumes of Selenium and Normal Saline on the Parenteral Study Supplement Log for this patient daily.



Parenteral Supplements Worksheet Glutamine (GLN)

Patient will receive Dipeptiven (Glutamine) and normal saline

Patient CR #: _____ Patient Initials: _____ Enrollment #: _____

1. Patient's height = _____ cms
2. Normal Body Weight = (#1) minus 100 cms = _____ kgms
3. Dose of Dipeptiven* to be added = (#2) x 2.5 mL _____ mL
4. Dose of Selenium to be added = 0 mL
5. Total Volume to be removed from 250 ml normal saline bag before adding study supplements = _____ mL (add #3 and #4)
6. Add (#3) + (#4) + normal saline = 250 mL
7. Record the volumes of Dipeptiven and Normal Saline on the Parenteral Study Supplement Log for this patient daily.
8. Generate a label and attach to bag.

***Dipeptiven 2.5 ml/kg/day = Glutamine 0.35 g/kg/day = L-alanyl-L-glutamine 0.5 g/kg/day**



Parenteral Supplements Worksheet for patients ≥ 196 cm tall Glutamine (GLN)

Patient CR #: _____ Patient Initials: _____ Enrollment #: _____

Dosing:

- **Dosage of Glutamine** 0.35g/kg/day = L-alanyl-L-glutamine 0.5g/kg/day=
Dipeptivan®2.5mL/kg/day
- **Dosing will be based on patient's Normal Body Weight using Broca Formula as follows:**
 - Normal Weight (kg)= Patient's Height(cm) - 100
- Dose will be diluted in a NS bag to a final volume indicated in chart below. (Volume of NS to be removed from 250mL NS bag = 237mL). Inherent overfill of bag to be ignored.
- **Rate of infusion determined from chart below.** (rate may be increased up to 2x the amount on day 1 for hours missed to conform to standard dosing times)

Go to Height Chart (see below). Record:

1. Patient Height _____ cm
2. Final Total Volume of bag (from chart below) _____ ml
3. Rate to be infused (from chart below) _____ ml/hr
4. Volume of Glutamine (Dipeptiven®) to be added _____ mL
(from chart below)

Height	Final total volume of bag	Rate to be infused	Volume of Glutamine to be added	Amount of normal saline to be removed
196 cm	253 mL	10.5 mL/hr	240 mL	237 mL
198 cm	258 mL	10.8 mL/hr	245 mL	237 mL
201 cm	266 mL	11.1 mL/hr	253 mL	237 mL
203 cm	271 mL	11.3 mL/hr	258 mL	237 mL
206 cm	278 mL	11.6 mL/hr	265 mL	237 mL
208 cm	283 mL	11.8 mL/hr	270 mL	237 mL
211 cm	291 mL	12.1mL/hr	278 mL	237 mL
213 cm	296 mL	12.3mL/hr	283 mL	237 mL



5. Retrieve 250mL bag of NS and appropriate amount of Dipeptiven®
NOTE: Dipeptiven® bottles can be shared between multiple patients if needed. Eg. If one patient needs 150ml Dipeptiven and the next patient needs 130ml please use 3 bottles(100ml each) for both instead of using 4 bottles (100mL each)for both patients. Once opened, the Dipeptiven is to be mixed into the other parenteral components immediately.
6. Remove 237 mL of NS from 250mL NS bag.
7. Draw up _____mL of Dipeptiven®(as per chart) and add to above normal saline bag. Mix.
8. Total final volume = _____ mL(as per chart -ignore overflow)
9. Infusion rate = _____mL/hr (as per chart)
10. Expiry dating = 96 hours at room temperature.
11. Generate a label and attach to bag.
12. Record the volumes of Dipeptiven and Normal Saline on the Parenteral Study Supplement Log for this patient daily.



Parenteral Supplements Worksheet **Antioxidants + Glutamine (AOX+GLN)**

Patient will receive Selenium (Antioxidants), Dipeptiven (Glutamine) and normal saline

Patient CR #: _____ Patient Initials: _____ Enrollment #: _____

1. Patient's height = _____ cms
2. Normal Body Weight = (#1) minus 100 cms = _____ kgms
3. Dose of Dipeptiven* to be added = (#2) x 2.5 mL _____ mL
4. Dose of Selenium to be added = 12.5 mL mL
5. Total Volume to be removed from 250 ml normal saline bag before adding study supplements = _____ mL (add #3 and #4)
6. Add (#3) + (#4) + normal saline = 250 mL
7. Record the volumes of Dipeptiven, Selenium and Normal Saline on the Parenteral Study Supplement Log for this patient daily.
8. Generate a label and attach to bag.

***Dipeptiven 2.5 ml/kg/day = Glutamine 0.35 g/kg/day = L-alanyl-L-glutamine 0.5 g/kg/day**



Parenteral Supplements Worksheet for patients \geq 196 cm tall **Antioxidants + Glutamine (AOX+GLN)**

Patient CR #: _____ Patient Initials: _____ Enrollment #: _____

Dosing:

1. **Dosage of Selenium = 500mcg/day = 12.5mL/day regardless of height;**
2. **Dosage of Glutamine** 0.35g/kg/day = L-alanyl-L-glutamine 0.5g/kg/day=
Dipeptivan®2.5mL/kg/day
3. **Dosing will be based on patient's Normal Body Weight using Broca Formula as follows:**

$$\text{Normal Weight (kg)} = \text{Patient's Height(cm)} - 100$$

4. Dose will be diluted in a NS bag to a final volume indicated in chart below. Inherent overfill of bag to be ignored.
5. **Rate of infusion determined from chart below.** (rate may be increased up to 2x the amount on day 1 for hours missed to conform to standard dosing times)

Go to Height Chart (see below). Record:

1. Patient Height _____ cm
2. Final Total Volume of bag (from chart below) _____ mL
3. Rate to be infused (from chart below) _____ ml/hr
4. Volume of Selenium to be added _____ 12.5 mL
5. Volume of Glutamine (Dipeptiven®) to be added _____ mL
(from chart below)



Height	Final total volume of bag	Rate to be infused	Volume of Selenium to be added	Volume of Glutamine to be added	Amount of normal saline to be removed
196 cm	253 ml	10.5 ml/hr	12.5ml	240 ml	250 ml
198 cm	258 ml	10.8 ml/hr	12.5ml	245 ml	250 ml
201 cm	266 ml	11.1 ml/hr	12.5ml	253 ml	250 ml
203 cm	271 ml	11.3 ml/hr	12.5ml	258 ml	250 ml
206 cm	278 ml	11.6 ml/hr	12.5ml	265 ml	250 ml
208 cm	283 ml	11.8 ml/hr	12.5ml	270 ml	250 ml
211 cm	291 ml	12.1ml/hr	12.5ml	278 ml	250 ml
213 cm	296 ml	12.3ml/hr	12.5ml	283 ml	250 ml

- Retrieve 250mL bag of NS and appropriate amount of selenium and Dipeptiven®

NOTE: Dipeptiven® bottles can be shared between multiple patients if needed. Eg. If one patient needs 150ml Dipeptiven® and the next patient needs 130ml please use 3 bottles(100ml each) for both instead of using 4 bottles (100mL each)for both patients. Once opened, the Dipeptiven® is to be mixed into the other parenteral components immediately.

- Remove 250mL of NS from a 250mL NS bag.
- Draw up 12.5mL Selenium and add to above NS bag. Mix.
- Draw up _____mL of Dipeptiven®(as per chart) and add to above NS bag. Mix.
- Final total volume= _____ mL (As per chart -Ignore overflow)
- Infusion rate _____ mL/hr.(As per chart)
- Expiry Dating= 96 hrs at room temperature.
- Generate a label and attach to bag.
- Record the volumes of Dipeptiven, Selenium and Normal Saline on the Parenteral Study Supplement Log for this patient daily.



Parenteral Supplements Worksheet Placebo

Patient will only receive normal saline

Patient CR #: _____ Patient Initials: _____ Enrollment #: _____

1. Patient's height = **Not needed for calculating dose** _____ cms
2. Normal Body Weight = (#1) minus 100 cms = **Not needed** _____ kgms
3. Dose of Dipeptiven* to be added = **0** mL
4. Dose of Selenium to be added = **0** mL
5. Total Volume to be removed from 250 ml normal saline bag before adding study supplements = **0** mL (add #3 and #4)
6. No mixing needed. The patient will receive a 250 ml bag of normal saline.
7. Record the volume of Normal Saline (=250 mls) on the Parenteral Study Supplement Log, for this patient daily.
8. Generate a label and attach to bag.



Parenteral Supplements Worksheet for patients ≥ 196 cm tall Placebo

Patient CR #: _____ Patient Initials: _____ Enrollment #: _____

Dosing:

1. Dose will consist of a 250mL NS bag with added NS to a final volume as indicated in chart below. Inherent overfill of bag to be ignored.
2. **Rate of infusion determined from chart below.** (rate may be increased up to 2x the amount on day 1 for hours missed to conform to standard dosing times)

Go to Height chart (see below. Record:

1. Patient Height _____ cm
2. Final Total Volume of bag (from chart below) _____ mL
3. Rate to be infused (from chart below) _____ mL
4. Amount of NS to be added to 250mL bag _____ mL

Height	Final total volume of bag	Rate to be infused	Amount of normal saline to be added
196 cm	253 mL	10.5 mL/hr	3 mL
198 cm	258 mL	10.8 mL/hr	8 mL
201 cm	266 mL	11.1 mL/hr	16 mL
203 cm	271 mL	11.3 mL/hr	21 mL
206 cm	278 mL	11.6 mL/hr	28 mL
208 cm	283 mL	11.8 mL/hr	33 mL
211 cm	291 mL	12.1mL/hr	41 mL
213 cm	296 mL	12.3mL/hr	46 mL

5. Retrieve 250mL bag of normal saline.
6. Add _____ mL normal saline to the above 250mL NS bag.
7. Final total volume= _____ mL (As per chart -Ignore overfill)
8. Infusion rate _____ mL/hr.(As per chart)
9. Expiry Dating= 96 hrs at room temperature.



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10. Record the volume of Normal Saline on the Parenteral Study Supplement Log, for this patient daily.
11. Generate a label and attach to bag.



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Appendix E

Parenteral Study Supplement

Study: REDOX[®]

Parenteral Component

For Clinical trial Use Only

Enrollment #:

Patient CR#/ID#:

Patient Name:

Physician:

Date:

Directions: Infuse at 10 mL/hr

Storage: keep between 15-25

Expiry:



Appendix F. Height and Dose of Dipeptiven

Ht (ft in)	Ht (cms)	Dipeptiven mls	Se mls	N/S mls	Total mls
6'0"	183	208	12.5	30	250
6'1"	185	212	12.5	25	250
6'2"	188	220	12.5	18	250
6'3"	191	228	12.5	10	250
6'4"	193	233	12.5	5	250
6'5"	196	240	12.5	---	253
6'6"	198	245	12.5	---	258
6'7"	201	253	12.5	---	266
6'8"	203	258	12.5	---	271
6'9"	206	265	12.5	---	278
6'10"	208	270	12.5	---	283
6'11"	211	278	12.5	---	291
7'0"	213	283	12.5	---	296