Applying Stability Data in Compounding Parenteral Nutrition

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INTRODUCTION

In order to apply stability data in compounding parenteral nutrition, storage times shown in the monographs of this section represent chemical and physical studies of parenteral nutrition components, stability, container material, and storage conditions. Before the official publication of the United States Pharmacopeia (USP) Chapter <797>, *Pharmaceutical Compounding – Sterile Preparations*, which set enforceable standards related to compounding sterile preparations, beyond-use dates were based primarily on chemical and physical stability, often labeling compounded parenteral nutrition for use over several weeks. The USP recognizes the risks of microbial contamination as a contributor to patient safety, and sets limits on the length of time a compounded sterile preparation (CSP) may be stored before the actual time that clinical administration to a patient starts. Pharmacists responsible for compounding and dispensing parenteral nutrition must assign a date representing the date beyond which the preparation should not be stored or used.[1] Assigning an appropriate beyond-use date (BUD) incorporates both chemical and physical factors, plus maintaining a level of quality assurance through the compounding facility's design, equipment, personnel, and processes. The final BUD placed on the CSP container label is determined by applying microbial risk guidance from the USP and data from stability studies of parenteral nutrition. Medication shortages in the United States have led to the importation of international products not previously approved by the FDA. Where applicable, imported products are included in the charts and tables displayed in this chapter.

Stability monographs for single-ingredient CSPs of a parenteral nutrition solution or additive are located in the Drug Monographs section of this book (See: Ascorbic acid, Calcium chloride, Lipid emulsion, Magnesium sulfate).

FACTORS AFFECTING EXTENDED STABILITY OF PARENTERAL NUTRITION

The stability monographs in this chapter provide data from parenteral nutrition studies and indicate the stability of the additive or solution after compounding into the parenteral nutrition formula. Stability studies occasionally assess for changes in a compounded formula's characteristics over time and do not quantify each ingredient. Admixture stability of parenteral nutrition solutions is determined by lack of precipitation, maintenance of pH, visual inspection, and changes to size and distribution of lipid particles. Study data are available for the container specified under the specific conditions noted.[2-4] For more information, refer to Table 1: Conditions Affecting Parenteral Nutrition Stability.

Injectable lipid emulsions have physical and chemical characteristics influencing stability that differ from other intravenous nutrients and fluids. Emulsion stability is included in parenteral nutrition studies to determine the final admixture's stability because emulsions are affected by other ingredients in the parenteral nutrition formula. Droplet size and distribution are essential to parenteral nutrition stability. The USP set a limit to the mean droplet size of not more than 0.5 microns, and the volume-weighted percent of fat droplets greater than 5 microns to be less

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TABLE 1: Conditions Affecting Parenteral Nutrition Stability

Stability/Influence	Description	Outcome
Chemical Changes	Calcium-phosphate precipitation[3]	• ***Increased*** risk of precipitation with any of the following: ■ High concentrations of calcium and phosphate ■ Less stable salt forms: calcium chloride, mineral form of phosphate ■ Increased pH ■ Low concentration of amino acids and dextrose with increased concentration of lipids ■ Mixing order ■ Storage time ■ Increased temperature
	Lipid peroxidation[3,5,10]	• Soy or fish oil emulsions are more susceptible to peroxidation. • ***Increased*** rate of lipid peroxidation with any of the following: room temperature, incubator temperature, and light. • ***Decreased*** rate of lipid peroxidation with either of the following: multilayered EVA bags and the presence of tocopherol.
Injectable Lipid Emulsion Stability	Formation of large droplets and aggregation[3,5,6]	• Electrolytes and trace elements contribute to aggregation. ■ Concentrations of calcium and magnesium >20 mEq/L leads to instability of the emulsion. • A pH >5 is needed for a stable emulsion. ■ Addition of acidic solutions (eg, dextrose) that decrease pH decreases emulsion stability. ■ Amino acids increase stability.
Compounding	Mixing order[2,6,7]	• For admixtures containing lipids: ■ Transfer the dextrose and amino acids to the container before adding lipid emulsion. ■ Do not inject additives directly into undiluted lipid emulsion.
Microbiological Contamination	Microbial contamination risk[1,5]	• Variables affecting microbial risk: ■ Environment (eg, engineering controls) ■ Aseptic processing (eg, personnel aseptic technique) ■ Storage conditions (eg, refrigeration, room temperature) ■ Sterile starting components ■ Sterility testing (eg, air sampling, personnel evaluation) • Infection risk is ***lower*** when parenteral nutrition is compounded into a single container and ***higher*** when lipids are infused separately.
Storage Temperature	Heat[8]	• Temperature fluctuations affect chemical reactivity, primarily hydrolysis and oxidation. ■ Heat ***increases*** the rate of hydrolysis. • A fluctuation of 10°C can change the rate of reaction.
	Freezing[8,12]	• Freezing may either break emulsions or cause a large ***increase*** in the droplet size of emulsions. • Freezing temperatures can denature proteins or cause crystallization or precipitation.
Container	Oxygen permeable	• ***Increases*** risk of oxidation of lipids and vitamin C.[5]
	Leaching	• DEHP leaching of lipophilic medications and PVC.[10]
Light Exposure	Ultraviolet light (UV)[5,8]	• Exposure to UV light may cause oxidation. • In susceptible compounds, photochemical energy creates free radicals. ■ Accelerated chemical degradation reactions of vitamins. ■ Peroxidation of lipid injectable emulsions.

TABLE 1: Conditions Affecting Parenteral Nutrition Stability (cont'd)

Stability/Influence	Description	Outcome
pH	High and low pH extremes[8]	• High and low pH extremes increase the rate of hydrolysis and oxidation. • ***Higher*** pH: ■ Increases calcium phosphate precipitation. ■ Increases emulsion stability. • ***Lower*** pH: ■ Increases calcium and phosphate solubility. ■ Destabilizes emulsions.

than 0.05%, expressed as $PFAT_5$. Formulations with a $PFAT_5$ exceeding 0.05% are at risk of destabilization over time.[10] The stability of the emulsion is dependent on the zeta potential of the emulsifier. The zeta potential refers to repulsive forces pushing lipid particles apart based on the droplet surface's negative charges. If the zeta potential is neutralized with the addition of cations or the pH decreases below 5, it could lead to coalescence, which causes the droplets to fuse and become larger.[3,10] Physical destabilization occurs in phases, starting with flocculation, creaming, and coalescence, followed by oiling out or cracking. Both flocculation and creaming result from the aggregation of lipid droplets that may or may not be visible; however, the aggregated lipid droplets can be redispersed by gently agitating the container and safely administering to a patient. If yellow or brown oil droplets are found at the surface of the CSP during a visual inspection, it is evidence of coalescence or cracking. Once an emulsion reaches these phases, the lipid droplets cannot be fully redispersed, and the admixture should not be used.[10] For a summary on emulsion instability, refer to Figure 1: Phases of Emulsion Instability.

EXTRAPOLATION CONSIDERATIONS

When the usage timeframe in the manufacturer product labeling is limited or omitted, published stability studies can potentially support extending the BUD assigned to a parenteral nutrition solution. If a referenced study does not match a specific parenteral nutrition formula's conditions, assess the individual components based on the manufacturer, electrolyte salt form, concentration, container type, storage temperature, and exposure to light to determine if the available stability data may be extrapolated. Predictions of any area of stability impart an element of risk, and the degree of accuracy depends on the extent of the difference between the CSP characteristics.[11] When several concentrations of an ingredient are studied with similar stability results, it is reasonable to expect the stability to be the same for concentrations falling within the ones tested.[9] In the absence of stability studies in a specific container, the pharmacist should consider the available container materials and compare them to the materials studied.[9] When compounding parenteral nutrition using a dual-chamber bag, considerations for concentrations of electrolytes and additives should be calculated in the final volume of the container or individual chamber. If compounding software calculates a final volume of both chambers combined, the concentrations of each chamber could exceed limitations and precipitate. If not explicitly studied, room temperature storage stability data should not be applied to refrigerated storage conditions, and refrigerated storage stability data should not be applied to room temperature storage conditions.[1] Studies performed while the preparation was protected from light cannot be extrapolated to light-exposed conditions.[12] However, stability studies of light-exposed preparations can be extrapolated to light-protected conditions. Time periods reported can only be shortened, not lengthened. For more information, refer to Table 2: Extrapolation Considerations for Compounding Parenteral Nutrition.

FIGURE 1: Phases of Emulsion Instability[3]

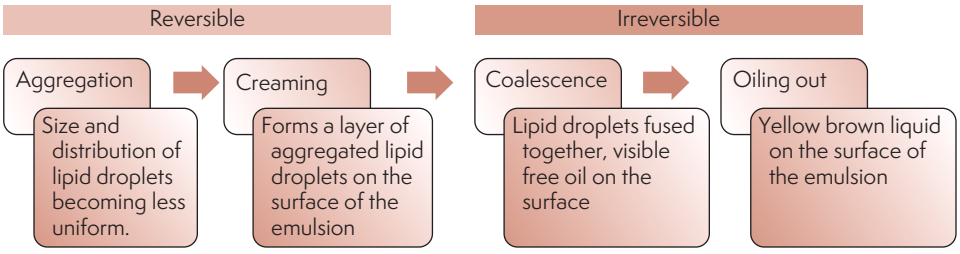

TABLE 2: Extrapolation Considerations for Compounding Parenteral Nutrition

Comparison	Considerations	Conclusions
Manufacturer	Manufacturer product studied differs from inventory[9]	• Drugs that are generically and chemically identical are expected to have the same results as those studied. • If there are differences in salt form, excipients, or solubilizing agents, the studied stability data may not be applicable.
Component	Injectable lipid emulsions[5]	• Lipid products with similar composition are expected to have similar stability to those studied. • Soy and fish oil emulsions are more susceptible to peroxidation than emulsions containing olive oil.
	Calcium gluconate vs. calcium chloride[14]	• Calcium gluconate has a lower degree of dissociation than calcium chloride. • Higher concentrations of calcium gluconate are soluble with phosphate.
	Glycerophosphate/phosphate[14]	• Glycerophosphate ***increases*** calcium phosphate solubility. • Higher concentrations of glycerophosphate are soluble with calcium.
Concentration	Several concentrations studied with similar stability results[9]	• Prediction of similar stability for a concentration falling within the range of studied concentrations is reasonable. • If there are data available in a container type and admixture with documented stability at two concentrations, concentrations falling within the two data points are acceptable. • Extrapolating stability outside the studied concentrations is not recommended due to increased risk of instability of the final solution.
Container	EVA	• Permeable to oxygen.[23]
	Multilayer EVA	• Less permeable to oxygen.[23]
	Polypropylene	• RTU formulas.[13]
	Dual-chamber/single-chamber	• Considerations for concentrations of electrolytes and additives should be calculated in the final volume of the container or individual chamber. ■ If compounding software calculates a final volume of both chambers combined, the concentrations of each chamber could exceed limitations and precipitate.
Light	Light-protected compared to light-exposed	• Do not extrapolate light-protected study results to light-exposed admixtures.[12]
	Light-exposed compared to light-protected	• Stability studies of light-exposed drugs can be extrapolated to light-protected admixtures.
Premix/RTU	RTU manufacturer expiration to compounded admixtures	• Do not extrapolate RTU manufacturer expiration dates to beyond-use dates for compounded admixtures.
Sterility	Sterility tests from CSP to CSP	• Do not extrapolate sterility studies.[1]
Temperature	Studied at two temperatures and stable at both vs. studied at only one temperature	• Temperatures should not be extrapolated without studying the admixture at the temperature desired.[1]

PREPARATION STERILITY AND QUALITY ASSURANCE

Individual organizations have to determine their own specific standard operating procedures (SOPs). In order to ensure consistent practices and reproducible results, there should be SOPs for parenteral nutrition compounding and all related processes. Consistency in compounding compliance using standardized SOPs can reduce variation and decrease the chances of preventable errors occurring. SOPs should be based on applicable laws, regulations, and accreditation standards, and they should be further individualized for the types of compounding performed and equipment used at each facility.[1]

If compounding in batches for more than one patient, a master formulation record provides specific compounding instructions and describes how the CSP was prepared.[15,16] When standardizing compounding records and master formulation records, the names, descriptions, and IDs of CSPs should be consistent.

Automated compounding devices (ACDs) can improve accuracy and efficiency in creating the parenteral nutrition formula, but they can also introduce risk or impact the sterility of a preparation. A pharmacist should ensure tubing in an ACD is not used beyond its labeled timeframe per manufacturer instructions. An appropriate flush should be done between the compounding of incompatible formulations to avoid cross-contamination. Changing or replacing products used by an ACD must be done utilizing proper aseptic techniques, and their hang time should be evaluated to ensure sterility and stability of the product. The mixing order must be considered for high-precipitation risks such as calcium and phosphates, which need to be added separately and into the largest solution volume to avoid forming precipitates during the compounding process.

ASSIGNING BEYOND-USE DATES TO COMPOUNDED PARENTERAL NUTRITION

Assigning a beyond-use date or BUD to a parenteral nutrition admixture is performed as part of the compounding process. A BUD encompasses the time period starting at the date and time of compounding through the date and time after which the start of clinical administration should not occur. Assigning an appropriate BUD requires the consideration of many factors such as chemical stability, physical properties, component compatibility, sterility, component concentrations, container type, personnel factors, environmental factors, and equipment utilized during the compounding process. BUDs are determined using a risk-based approach. The USP limits maximum BUDs to decrease risks posed to patients by requiring a labeled BUD that represents a time span before it is a risk for physical or chemical degradation, microbial contamination and proliferation, and diminished integrity of the container. The date takes into consideration the specific conditions where the parenteral nutrition admixture was compounded, the probability for microbial growth, and the time period within which it should be used.[1]

The clinical guidelines set by the American Society for Parenteral and Enteral Nutrition (ASPEN) recommend compounding parenteral nutrition formulas within macronutrient concentrations that have been studied and report consistent extended stability.[17] For more information, refer to Figure 2: Macronutrient Concentrations Exhibiting Maximum Stability.

Labels that specify the storage conditions and BUD of compounded preparations are placed on each parenteral dosage unit. Documentation of the preparation date should be part of the labeling, and include the time of compounding, if applicable, to any component of the formula. If preparation stability varies under different temperature conditions, list the BUD for each anticipated storage condition on the label. If the preparation needs to be warmed to room temperature prior to administration, the label and ancillary instruction material should describe it. If preparations are stable for less than 24 hours at room temperature, the label should be specific about the end-use time. Individuals administering parenteral nutrition should be trained to check preparations for current BUDs prior to usage. Practitioners should establish a standardized approach to labeling that is clear, concise, and meets all licensure and regulatory requirements, including USP Chapter <797> general labeling guidelines.[18]

PROFESSIONAL, REGULATORY, AND ACCREDITATION GUIDELINES

ASPEN has developed guidance documents related to parenteral nutrition. Following ASPEN guidelines decreases the risk of incompatibility or instability, while outlining in-process and end-product inspections used to confirm compounding accuracy. ASPEN recommendations are aligned with requirements for pharmacies to adhere to USP Chapter <797>, *Pharmaceutical Compounding – Sterile Preparations.*[17,19]

The Centers for Disease Control and Prevention (CDC), in their *Guidelines for the Prevention of Intravascular Catheter-Related Infections,* recommends that lipid emulsions should be infused for no longer than 12 hours when infused alone, and no longer than 24 hours as a component of a lipid containing parenteral nutrition formula. Administration sets for lipids should be changed every 24 hours.[20]

USP Chapter <729>, *Globule Size Distribution in Lipid Injectable Emulsions*, contains the methodology for manufacturers to determine the mean particle size in injectable lipid emulsions. The stability of manufactured injectable lipid emulsions is defined by limiting mean lipid globule size at no greater than 5 microns, and the percent of globules larger than 5 microns should not exceed 0.05%, expressed as $PFAT_5$. When interpreting published stability data on lipid emulsions, similar methodology should be reported and assessed before applying extended stability to a particular admixture.[10]

FIGURE 2: Macronutrient Concentrations Exhibiting Maximum Stability[17]

Container	Admixture Concentration	Room Temperature	Refrigerated Temperature
Ethylene Vinyl Acetate (EVA)	Amino acid ≥4% Dextrose ≥10% Lipid emulsion ≥2%	24 hours	9 days

USP Chapter <797>, *Pharmaceutical Compounding – Sterile Preparations*, outlines the standards and minimum required practices related to compounding sterile preparations in the United States. It provides the organizational structure, procedures, processes, and resources necessary to ensure predefined quality measures are met by facilities that compound sterile preparations. The chapter is enforceable by state boards, the FDA, and accreditation organizations.[1]

APPLYING STABILITY DATA USING COMMERCIAL PRODUCTS

When using premixed or ready-to-use (RTU) products, care must be taken to ensure all calculations and considerations regarding stability include the ingredients of all components. For example, if a concentrated commercial solution of electrolytes is used and additional individual electrolytes are admixed, the total of each component combined should be evaluated for stability. The products should be separated in the compounding process to avoid instability. Similarly, if using a premixed parenteral nutrition product and adding an additive, the pharmacist should review available data to ensure that the final solution containing all components results in a stable solution and that BUDs are appropriately adjusted based on the method of additive addition utilized (eg, pharmacy or bedside addition) and storage conditions.

Many components of parenteral nutrition and premixed solutions come in protective overwrap. If removing this overwrap before the time of compounding, dispensing, or administration, the manufacturer guidelines should be consulted to determine any potential impact on stability. For some products, the overwrap must remain intact for the labeled expiration—once the overwrap is removed, the product may be subject to impacts from hydrolysis, evaporation, or light damage.

SUMMARY

Pharmacists are responsible for dispensing parenteral nutrition admixtures that meet patients' unique clinical needs while satisfying all quality, safety, and environmental control requirements set by legislative, regulatory, and accreditation bodies. They direct all phases of preparation, storage, transportation, and administration of parenteral nutrition and maintain compliance with established standards, regulations, and best practices.

Carnitine *in Parenteral Nutrition*

Container	Formulation/ Concentration	Temperature		Light		Lipids		Refer.
		Refrig	Room	Exposed	Protected	With	Without	
Bag, Ethylene Vinyl Acetate (EVA)	100 mg/L[a]	4 d	n/a	n/a	n/a	X	X	(4)

Note

[a] Formulas: Pediatric amino acid (TPH®), dextrose, lipids (Intralipid®, ClinOleic™, Lipofundin®, SMOFlipid®, Lipidem®), electrolytes, trace elements, vitamins, and carnitine.[4]

Chromium *in Parenteral Nutrition*

Container	Formulation/ Concentration	Temperature		Light		Lipids		Refer.
		Refrig	Room	Exposed	Protected	With	Without	
Bag, Ethylene Vinyl Acetate (EVA)	[a]	7 d	24 hr	n/a	n/a	X	n/a	(2)
	[b]	7 d	48 hr	n/a	n/a	X	n/a	(22)
	[c]	7 d	48 hr	n/a	X	X	n/a	(23)
	[d]	30 d	24 hr	n/a	n/a	X	n/a	(24)
Bag, Multilayer Polypropylene[e]	[e]	7 d	48 hr	n/a	n/a	X	n/a	(13)(25)

Special Considerations: Stability studies assessed changes to characteristics of the admixture over time (pH, precipitation, visual inspection, changes to size and distribution of lipid particles), and did not measure the content of each trace element.

Notes

[a] Formulas: amino acids (Clinisol™, Prosol™, Travasol®), dextrose, lipid (SMOFlipid®), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).[2]

[b] Formulas: amino acids (Aminosyn®, Plenamine™), dextrose, lipid (SMOFlipid®), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).[22]

[c] Formulas: amino acids (Aminoplasmal®), dextrose, lipid (Intralipid®, ClinOleic™), electrolytes, and trace elements (Cr, Cu, Mn, Se, Zn).[23]

[d] Formulas: amino acids (Neonutrin), dextrose, lipid (SMOFlipid®), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).[24]

[e] Formulas: Kabiven® (RTU three-chamber bag) (amino acids, dextrose, soy-based lipid), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).[13,25]

Copper *in Parenteral Nutrition*									
		Temperature			Light		Lipids		
Container	Formulation/ Concentration	Refrig	Room	Body	Exposed	Protected	With	Without	Refer.
Bag, Ethylene Vinyl Acetate (EVA)	[a]	7 d	24 hr	n/a	n/a	n/a	X	n/a	(2)
	[b]	7 d	48 hr	n/a	n/a	n/a	X	n/a	(22)
	[c]	7 d	48 hr	n/a	n/a	X	X	n/a	(23)
	[d]	9 d	24 hr	n/a	n/a	X	X	X	(27)
	[e]	21 d	24 hr	n/a	n/a	X	n/a	X	(29)
	[f]	30 d	24 hr	24 hr	X[i]	X[i]	n/a	X	(14)
	[g]	30 d	24 hr	n/a	n/a	n/a	X	n/a	(24)
Bag, Multilayer Polypropylene[h]	[h]	7 d	48 hr	n/a	n/a	n/a	X	n/a	(13)(25)

Special Considerations: Stability studies assessed changes to characteristics of the admixture over time (pH, precipitation, visual inspection, changes to size and distribution of lipid particles), and did not measure the content of each trace element.

Notes

[a] Formulas: amino acids (Clinisol™, Prosol™, Travasol®), dextrose, lipid (SMOFlipid®), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).(2)

[b] Formulas: amino acids (Aminosyn®, Plenamine™), dextrose, lipid (SMOFlipid®), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).(22)

[c] Formulas: amino acids (Aminoplasmal®), dextrose, lipid (Intralipid®, ClinOleic™), electrolytes, and trace elements (Cr, Cu, Mn, Se, Zn).(23)

[d] Formulas: amino acid solution, dextrose, lipid, electrolytes, and trace elements (Tralement®: Cu, Mn, Se, Zn).(27)

[e] Formulas: amino acids (Aminoven®, Primene™), dextrose, electrolytes, and trace elements (Peditrace™: Cu. F, I, Mn, Se, Zn).(29)

[f] Formulas: amino acids (Aminoven®, Vaminolact®, Primene™), dextrose electrolytes, and trace elements (Peditrace™: Cu, F, I, Mn, Se, Zn).(14)

[g] Formulas: amino acids (Neonutrin), dextrose, lipid (SMOFlipid®), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).(24)

[h] Formulas: Kabiven® (RTU three-chamber bag) (amino acids, dextrose, soy-based lipid), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).(13,25)

[i] Light exposed for 30 days RF, light protected for 24 hours at 37°C.(14)

Famotidine *in Parenteral Nutrition*								
		Temperature		Light		Lipids		
Container	Formulation/ Concentration	Refrig	Room	Exposed	Protected	With	Without	Refer.
Bag, Ethylene Vinyl Acetate (EVA)	0.02, 0.05 mg/mL[a]	24 hr[a]	24 hr[a]	n/a	n/a	X	n/a	(41)
	0.02 mg/mL[b]	n/a	24 hr	X	n/a	X	n/a	(42)
	0.02, 0.04 mg/mL[c]	7 d	48 hr	X	n/a	n/a	X	(43)
	0.02 mg/mL[d]	n/a	48 hr	X	n/a	X	X	(44)
	0.02, 0.04 mg/mL[e]	n/a	72 hr	X	n/a	X	n/a	(45)
Bag, Polyvinyl Chloride (PVC)	0.02 mg/mL[f]	5 wk	n/a	n/a	X	n/a	X	(21)

Notes

[a] Stability was 48 hr total (24 hr refrigerated followed by 24 hr at room temp). Formula: amino acids (FreAmine III®), dextrose, lipid emulsion (Intralipid® 20%), electrolytes, and trace elements; no impact on emulsion stability.(41)

[b] Formula: amino acids (Novamine®), dextrose, lipid emulsion, electrolytes, vitamins, and trace elements.(42)

[c] Formula: amino acids (FreAmine III®), dextrose, electrolytes, vitamins, heparin, and trace elements.(43)

[d] Formula: amino acids (Travasol®), dextrose, lipid emulsion (Liposyn II®, Intralipid®), electrolytes, vitamins, and trace elements; no effect on emulsion stability.(44)

[e] Formula: amino acids, glucose, lipid emulsions, electrolytes, vitamins, and trace elements.(45)

[f] Formula: amino acids (Travasol®), dextrose, electrolytes, and trace elements.(21)

Folic Acid *in Parenteral Nutrition*								
		Temperature		Light		Lipids		
Container	Formulation/ Concentration	Refrig	Room	Exposed	Protected	With	Without	Refer.
Bag, Ethylene Vinyl Acetate (EVA)	[a]	n/a	24 hr	X	n/a	n/a	X	(33)
	[b][c]	48 hr	24 hr	n/a	X	X	n/a	(34)

Notes

[a] Formula: amino acids, glucose, electrolytes, vitamins, and trace elements (European products).[33]

[b] Formula: amino acids (Viamin), dextrose, lipid (SMOFlipid®), electrolytes, and vitamins.[34]

[c] Stability studies assessed changes to characteristics of the admixture over time (pH, precipitation, visual inspection, changes to size and distribution of lipid particles), and did not measure the content of each vitamin.

Heparin *in Parenteral Nutrition*								
		Temperature		Light		Lipids		
Container	Formulation/ Concentration	Refrig	Room	Exposed	Protected	With	Without	Refer.
Bag, Polyvinyl Chloride (PVC)	3, 5, 10, 20 units/mL[a]	21 d	n/a	n/a	n/a	n/a	X	(26)
Unspecified	77 units/mL[b]	n/a	24 hr	n/a	n/a	n/a	n/a	(28)

Notes

[a] Formula: amino acids (+/–)[c] (Travasol®), dextrose, electrolytes, and trace elements; longer stability with amino acids included in formula.[26]

[b] Neonatal Parenteral Nutrition unspecified.[28]

[c] (+/–) indicates that sample was mixed both with and without the nutrient.

Iron *in Parenteral Nutrition*								
		Temperature		Light		Lipids		
Container	Formulation/ Concentration	Refrig	Room	Exposed	Protected	With	Without	Refer.
Bag, Ethylene Vinyl Acetate (EVA)	0.7-1.9 mg/L[a][f][h]	7 d	24 hr	n/a	n/a	X	n/a	(2)
	0.8 mg/L[b][f][h]	30 d	24 hr	n/a	n/a	X	n/a	(24)
Bag, Multilayer Polypropylene[c]	0.43-1.1 mg/L[c][f][h]	7 d	48 hr	n/a	n/a	X	n/a	(13)(25)
Unspecified	100 mg/L[d][i]	n/a	18 hr	n/a	n/a	n/a	X	(30)
Vial, Glass	2 mg/L[e][i]	48 hr	48 hr	n/a	n/a	X	n/a	(31)

Notes

[a] Formulas: amino acids (Clinisol™, Prosol™, Travasol®), dextrose, lipid (SMOFlipid®), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).[2]

[b] Formulas: amino acids (Neonutrin), dextrose, lipid (SMOFlipid®), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).[24]

[c] Formulas: Kabiven® (RTU three-chamber bag) (amino acids, dextrose, soy-based lipid), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).[13,25]

[d] Formulas included amino acids (Travasol®), dextrose, electrolytes, vitamins (+/–)[g], and trace elements (+/–)[g].[30]

[e] Formulas included amino acids (Travasol®), dextrose, lipid emulsions (Intralipid®, Liposyn II®), electrolytes, and heparin.[31]

[f] Stability studies assessed changes to characteristics of the admixture over time (pH, precipitation, visual inspection, changes to size and distribution of lipid particles), and did not measure the content of iron.[2,24,25]

[g] (+/–) indicates that sample was mixed both with and without the nutrient.

[h] Concentration: expressed as mg/L of ferric chloride.

[i] Concentration: expressed as mg/L of iron dextran.

Manganese *in Parenteral Nutrition*									
		Temperature			Light		Lipids		
Container	Formulation/ Concentration	Refrig	Room	Body	Exposed	Protected	With	Without	Refer.
Bag, Ethylene Vinyl Acetate (EVA)	[a]	7 d	24 hr	n/a	n/a	n/a	X	n/a	(2)
	[b]	7 d	48 hr	n/a	n/a	n/a	X	n/a	(22)
	[c]	7 d	48 hr	n/a	n/a	X	X	n/a	(23)
	[d]	9 d	24 hr	n/a	n/a	X	X	X	(27)
	[e]	21 d	24 hr	n/a	n/a	X	n/a	X	(29)
	[f]	30 d	24 hr	24 hr	X[i]	X[i]	n/a	X	(14)
	[g]	30 d	24 hr	n/a	n/a	n/a	X	n/a	(24)
Bag, Multilayer Polypropylene[h]	[h]	7 d	48 hr	n/a	n/a	n/a	X	n/a	(13)(25)

Special Considerations: Stability studies assessed changes to characteristics of the admixture over time (pH, precipitation, visual inspection, changes to size and distribution of lipid particles), and did not measure the content of each trace element.

Notes

[a] Formulas: amino acids (Clinisol™, Prosol™, Travasol®), dextrose, lipid (SMOFlipid®), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).[2]

[b] Formulas: amino acids (Aminosyn®, Plenamine™), dextrose, lipid (SMOFlipid®), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).[22]

[c] Formulas: amino acids (Aminoplasmal®), dextrose, lipid (Intralipid®, ClinOleic™), electrolytes, and trace elements (Cr, Cu, Mn, Se, Zn).[23]

[d] Formulas: amino acid solution, dextrose, lipid, electrolytes, and trace elements (Tralement®: Cu, Mn, Se, Zn).[27]

[e] Formulas: amino acids (Aminoven®, Primene™), dextrose, electrolytes, and trace elements (Peditrace™: Cu, F, I, Mn, Se, Zn).[29]

[f] Formulas: amino acids (Aminoven®, Vaminolact®, Primene™), dextrose electrolytes, and trace elements (Peditrace™: Cu, F, I, Mn, Se, Zn).[14]

[g] Formulas: amino acids (Neonutrin), dextrose, lipid (SMOFlipid®), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).[24]

[h] Formulas: Kabiven® (RTU three-chamber bag) (amino acids, dextrose, soy-based lipid), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).[13,25]

[i] Light exposed for 30 days RF, light protected for 24 hours at 37°C.[14]

Selenium *in Parenteral Nutrition*									
		Temperature			Light		Lipids		
Container	Formulation/ Concentration	Refrig	Room	Body	Exposed	Protected	With	Without	Refer.
Bag, Ethylene Vinyl Acetate (EVA)	[a]	7 d	24 hr	n/a	n/a	n/a	X	n/a	(2)
	[b]	7 d	48 hr	n/a	n/a	n/a	X	n/a	(22)
	[c]	7 d	48 hr	n/a	n/a	X	X	n/a	(23)
	[d]	9 d	24 hr	n/a	n/a	X	X	X	(27)
	[e]	21 d	24 hr	n/a	n/a	X	n/a	X	(29)
	[f]	30 d	24 hr	24 hr	X[i]	X[i]	n/a	X	(14)
	[g]	30 d	24 hr	n/a	n/a	n/a	X	n/a	(24)
Bag, Multilayer Polypropylene[h]	[h]	7 d	48 hr	n/a	n/a	n/a	X	n/a	(13)(25)

Special Considerations: Stability studies assessed changes to characteristics of the admixture over time (pH, precipitation, visual inspection, changes to size and distribution of lipid particles), and did not measure the content of each trace element.

Notes

[a] Formulas: amino acids (Clinisol™, Prosol™, Travasol®), dextrose, lipid (SMOFlipid®), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).[2]

[b] Formulas: amino acids (Aminosyn®, Plenamine™), dextrose, lipid (SMOFlipid®), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).[22]

[c] Formulas: amino acids (Aminoplasmal®), dextrose, lipid (Intralipid®, ClinOleic™), electrolytes, and trace elements (Cr, Cu, Mn, Se, Zn).[23]

[d] Formulas: amino acid solution, dextrose, lipid, electrolytes, and trace elements (Tralement®: Cu, Mn, Se, Zn).[27]

[e] Formulas: amino acids (Aminoven®, Primene™), dextrose, electrolytes, and trace elements (Peditrace™: Cu, F, I, Mn, Se, Zn).[29]

[f] Formulas: amino acids (Aminoven®, Vaminolact®, Primene™), dextrose electrolytes, and trace elements (Peditrace™: Cu, F, I, Mn, Se, Zn).[14]

[g] Formulas: amino acids (Neonutrin), dextrose, lipid (SMOFlipid®), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).[24]

[h] Formulas: Kabiven® (RTU three-chamber bag) (amino acids, dextrose, soy-based lipid), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).[13,25]

[i] Light exposed for 30 days RF, light protected for 24 hours at 37°C.[14]

Trace Elements *in Parenteral Nutrition*									
		Temperature			Light		Lipids		
Container	Formulation/ Concentration	Refrig	Room	Body	Exposed	Protected	With	Without	Refer.
Bag, Ethylene Vinyl Acetate (EVA)	[a]	7 d	24 hr	n/a	n/a	n/a	X	n/a	(2)
	[b]	7 d	48 hr	n/a	n/a	n/a	X	n/a	(22)
	[c]	7 d	48 hr	n/a	n/a	X	X	n/a	(23)
	[d]	9 d	24 hr	n/a	n/a	X	X	X	(27)
	[e]	21 d	24 hr	n/a	n/a	X	n/a	X	(29)
	[f]	30 d	24 hr	24 hr	X[i]	X[i]	n/a	X	(14)
	[g]	30 d	24 hr	n/a	n/a	n/a	X	n/a	(24)
Bag, Multilayer Polypropylene[h]	[h]	7 d	48 hr	n/a	n/a	n/a	X	n/a	(13)(25)

Special Considerations: Stability studies assessed changes to characteristics of the admixture over time (pH, precipitation, visual inspection, changes to size and distribution of lipid particles), and did not measure the content of each trace element.

Notes

[a] Formulas: amino acids (Clinisol™, Prosol™, Travasol®), dextrose, lipid (SMOFlipid®), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).[2]

[b] Formulas: amino acids (Aminosyn®, Plenamine™), dextrose, lipid (SMOFlipid®), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).[22]

[c] Formulas: amino acids (Aminoplasmal®), dextrose, lipid (Intralipid®, ClinOleic™), electrolytes, and trace elements (Cr, Cu, Mn, Se, Zn).[23]

[d] Formulas: amino acid solution, dextrose, lipid, electrolytes, and trace elements (Tralement®: Cu, Mn, Se, Zn).[27]

[e] Formulas: amino acids (Aminoven®, Primene™), dextrose, electrolytes, and trace elements (Peditrace™: Cu, F, I, Mn, Se, Zn).[29]

[f] Formulas: amino acids (Aminoven®, Vaminolact®, Primene™), dextrose electrolytes, and trace elements (Peditrace™: Cu, F, I, Mn, Se, Zn).[14]

[g] Formulas: amino acids (Neonutrin), dextrose, lipid (SMOFlipid®), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).[24]

[h] Formulas: Kabiven® (RTU three-chamber bag) (amino acids, dextrose, soy-based lipid), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).[13,25]

[i] Light exposed for 30 days RF, light protected for 24 hours at 37°C.[14]

Vitamin A *in Parenteral Nutrition*									
		Temperature			Light		Lipids		
Container	Formulation/ Concentration	Refrig	Room	Body	Exposed	Protected	With	Without	Refer.
Bag, Ethylene Vinyl Acetate (EVA)	[a]	24 hr	24 hr	24 hr	X	n/a	X	n/a	(35)
	[b]	6 d	24 hr	n/a	X	X	X	n/a	(36)
	[c]	20 d	n/a	n/a	X	X	X	X	(37)
Bag, Polyvinyl Chloride (PVC)	[c]	20 d	n/a	n/a	X	X	X	X	(37)
Vial, Glass	[c]	20 d	n/a	n/a	X	X	X	X	(37)

Notes

[a] Formula: amino acids, glucose, lipid emulsion, electrolytes, vitamins, and trace elements (European products).[35]

[b] Form: Retinyl palmitate. Formula: amino acids, glucose, lipid emulsion (Intralipid®), electrolytes, vitamins, and trace elements (European products); refrigerated samples were protected from light; stability defined as greater than 80% of initial concentration. Room temperature storage followed 6 d refrigeration.[36]

[c] Formula: amino acids, glucose, lipid emulsion, electrolytes, vitamins (MVI-12®), and trace elements (+/–)[d] (European products); stability defined as greater than 80% of initial concentration.[37]

[d] (+/–) indicates that sample was mixed both with and without the nutrient.

Vitamin B1 *in Parenteral Nutrition*								
		Temperature		Light		Lipids		
Container	Formulation/ Concentration	Refrig	Room	Exposed	Protected	With	Without	Refer.
Bag, Ethylene Vinyl Acetate (EVA)	[a]	4 d	n/a	n/a	X	X	n/a	(36)
	[b]	n/a	24 hr	X	n/a	n/a	X	(33)
Bag, Multilayer Polypropylene[d]	[c]	72 hr	72 hr	X	X	n/a	X	(38)

Notes

[a] Form: thiamine. Formulas: amino acids, glucose, lipid emulsion (Intralipid®), electrolytes, vitamins, and trace elements (European products); stability defined as greater than 80% of initial concentration.[36]

[b] Form: thiamine hydrochloride. Formulas: amino acids, glucose, electrolytes, vitamins, and trace elements (European products).[33]

[c] Formulas: amino acids, dextrose, electrolytes, trace elements, pediatric multivitamins, high concentration calcium, and organic phosphate (Brazilian products).[38]

[d] Polypropylene, polyethylene, polyester multilayer container.[38]

Vitamin B2 *in Parenteral Nutrition*								
		Temperature		Light		Lipids		
Container	Formulation/ Concentration	Refrig	Room	Exposed	Protected	With	Without	Refer.
Bag, Ethylene Vinyl Acetate (EVA)	[a]	6 d	24 hr	X	X	X	n/a	(36)
Bag, Multilayer Polypropylene[c]	[b]	72 hr	72 hr	X	X	n/a	X	(38)

Notes

[a] Form: riboflavin. Formula: amino acids, glucose, lipid emulsion (Intralipid®), electrolytes, vitamins, and trace elements (European products); stability defined as greater than 80% of initial concentration. Room temp studied followed 6 d refrigerated.[36]

[b] Formula: amino acids, dextrose, electrolytes, trace elements, pediatric multivitamins, high-concentration calcium, and organic phosphate (Brazilian products).[38]

[c] Polypropylene, polyethylene, polyester multilayer container.[38]

Vitamin B3 *in Parenteral Nutrition*								
		Temperature		Light		Lipids		
Container	Formulation/ Concentration	Refrig	Room	Exposed	Protected	With	Without	Refer.
Bag, Ethylene Vinyl Acetate (EVA)	[a]	4 d	n/a	n/a	X	X	n/a	(36)

Note

[a] Form: nicotinamide. Formulas: amino acids, glucose, lipid emulsion (Intralipid®), electrolytes, vitamins, and trace elements (European products); stability defined as greater than 80% of initial concentration.[36]

Vitamin B5 *in Parenteral Nutrition*								
		Temperature		Light		Lipids		
Container	Formulation/ Concentration	Refrig	Room	Exposed	Protected	With	Without	Refer.
Bag, Ethylene Vinyl Acetate (EVA)	[a]	4 d	n/a	n/a	X	X	n/a	(36)

Note

[a] Form: pantothenate. Formula: amino acids, glucose, lipid emulsion (Intralipid®), electrolytes, vitamins, and trace elements (European products); stability defined as greater than 80% of initial concentration.[36]

Vitamin B6 *in Parenteral Nutrition*								
		Temperature		Light		Lipids		
Container	Formulation/ Concentration	Refrig	Room	Exposed	Protected	With	Without	Refer.
Bag, Ethylene Vinyl Acetate (EVA)	[a]	4 d	n/a	n/a	X	X	n/a	(36)
	[b]	n/a	24 hr	X	n/a	n/a	X	(33)
Bag, Multilayer Polypropylene[d]	[c]	72 hr	72 hr	X	X	n/a	X	(38)

Notes

[a] Form: pyridoxine. Formulas: amino acids, glucose, lipid emulsion (Intralipid®), electrolytes, vitamins, and trace elements (European products); stability defined as greater than 80% of initial concentration.[36]

[b] Form: pyridoxine hydrochloride. Formulas: amino acids, glucose, electrolytes, vitamins, and trace elements (European products).[33]

[c] Formulas: amino acids, dextrose, electrolytes, trace elements, pediatric multivitamins, high-concentration calcium, and organic phosphate (Brazilian products).[38]

[d] Polypropylene, polyethylene, polyester multilayer container.[38]

Vitamin B12 *in Parenteral Nutrition*								
		Temperature		Light		Lipids		
Container	Formulation/ Concentration	Refrig	Room	Exposed	Protected	With	Without	Refer.
Bag, Ethylene Vinyl Acetate (EVA)	[a]	4 d	n/a	n/a	X	X	n/a	(36)

Note

[a] Form: cyanocobalamin. Formulas: amino acids, glucose, lipid emulsion (Intralipid®), electrolytes, vitamins, and trace elements (European products); stability defined as greater than 80% of initial concentration.[36]

Vitamin C *in Parenteral Nutrition*								
		Temperature		Light		Lipids		
Container	Formulation/ Concentration	Refrig	Room	Exposed	Protected	With	Without	Refer.
Bag, Ethylene Vinyl Acetate (EVA)	[a]	24 hr	24 hr	n/a	X	X	n/a	(39)
Bag, Multilayer Polypropylene[d]	[c]	72 hr	48 hr	X	X	n/a	X	(38)
Bag, Multilayer Polypropylene[e]	[b]	48 hr	48 hr	X	n/a	X	n/a	(40)

Notes

[a] Formulas: amino acids (Aminoplasmal®), dextrose, lipid (Lipofundin®), and electrolytes.[39]

[b] Formulas: amino acids, dextrose, lipid, electrolytes, trace elements, and multivitamins.[40]

[c] Formulas: amino acids, dextrose, electrolytes, trace elements, pediatric multivitamins, high-concentration calcium, and organic phosphate (Brazilian products).[38]

[d] 3-layer container; polypropylene, polyethylene, polyester.[38]

[e] 6-layer container with ethylene vinyl acetate gas-impermeable layer.[40]

Vitamin D *in Parenteral Nutrition*								
		Temperature		Light		Lipids		
Container	Formulation/ Concentration	Refrig	Room	Exposed	Protected	With	Without	Refer.
Bag, Ethylene Vinyl Acetate (EVA)	[a]	24 hr	24 hr	n/a	X	X	n/a	(2)(32)
Bag, Multilayer Polypropylene	[b]	24 hr	24 hr	n/a	X	X	n/a	(13)(25)(32)

Notes

[a] Formulas: amino acids (Clinisol™, Prosol™, Travasol®), dextrose, lipid (SMOFlipid®), electrolytes, trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn), and vitamins (Infuvite®).[2] After addition of multiple vitamins for injection, use within 24 hours.[32]

[b] Formulas: Kabiven® (RTU three-chamber bag) (amino acids, dextrose, soy-based lipid), electrolytes, trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn), and vitamins (Vitalipid®).[13,25] After addition of multiple vitamins for injection, use within 24 hours.[25,32]

Vitamin E *in Parenteral Nutrition*									
		Temperature			Light		Lipids		
Container	Formulation/ Concentration	Refrig	Room	Body	Exposed	Protected	With	Without	Refer.
Bag, Ethylene Vinyl Acetate (EVA)	[a]	6 d	24 hr	n/a	X	X	X	n/a	(36)
	[b]	72 hr	72 hr	72 hr	X	n/a	X	n/a	(35)
	[c]	20 d	n/a	n/a	n/a	X	X	X	(37)
Bag, Polyvinyl Chloride (PVC)	[c]	20 d	n/a	n/a	n/a	X	X	X	(37)
Vial, Glass	[c]	20 d	n/a	n/a	n/a	X	X	X	(37)

Notes

[a] Formulas: amino acids, glucose, lipid emulsion (Intralipid®), electrolytes, vitamins, and trace elements (European products); refrigerated samples were protected from light; stability defined as greater than 80% of initial concentration. Room temperature storage followed 6 d refrigeration.[36]

[b] Formulas: amino acids, glucose, lipid emulsion, electrolytes, vitamins, and trace elements (European products).[35]

[c] Formulas: amino acids, glucose, lipid emulsion, electrolytes, vitamins (MVI-12®), and trace elements (+/–)[d] (European products); stability defined as greater than 80% of initial concentration.[37]

[d] (+/–) indicates that sample was mixed both with and without the nutrient.

Vitamin K *in Parenteral Nutrition*								
		Temperature		Light		Lipids		
Container	Formulation/ Concentration	Refrig	Room	Exposed	Protected	With	Without	Refer.
Bag, Ethylene Vinyl Acetate (EVA)	[a]	20 d	n/a	n/a	X	X	X	(37)
Bag, Polyvinyl Chloride (PVC)	[a]	20 d	n/a	n/a	X	X	X	(37)
Vial, Glass	[a]	20 d	n/a	n/a	X	X	X	(37)

Notes

[a] Vitamin K1; Formula: amino acids, glucose, lipid emulsion, electrolytes, vitamins (MVI-12®), and trace elements (+/–)[b] (European products); stability defined as greater than 80% of initial concentration.[37]

[b] (+/–) indicates that sample was mixed both with and without the nutrient.

Zinc *in Parenteral Nutrition*									
		Temperature			Light		Lipids		
Container	Formulation/ Concentration	Refrig	Room	Body	Exposed	Protected	With	Without	Refer.
Bag, Ethylene Vinyl Acetate (EVA)	[a]	7 d	24 hr	n/a	n/a	n/a	X	n/a	(2)
	[b]	7 d	48 hr	n/a	n/a	n/a	X	n/a	(22)
	[c]	7 d	48 hr	n/a	n/a	X	X	n/a	(23)
	[d]	9 d	24 hr	n/a	n/a	X	X	X	(27)
	[e]	21 d	24 hr	n/a	n/a	X	n/a	X	(29)
	[f]	30 d	24 hr	24 hr	X[i]	X[i]	n/a	X	(14)
	[g]	30 d	24 hr	n/a	n/a	n/a	X	n/a	(24)
Bag, Multilayer Polypropylene[h]	[h]	7 d	48 hr	n/a	n/a	n/a	X	n/a	(13)(25)

Special Considerations: Stability studies assessed changes to characteristics of the admixture over time (pH, precipitation, visual inspection, changes to size and distribution of lipid particles), and did not measure the content of each trace element.

Notes

[a] Formulas: amino acids (Clinisol™, Prosol™, Travasol®), dextrose, lipid (SMOFlipid®), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).(2)

[b] Formulas: amino acids (Aminosyn®, Plenamine™), dextrose, lipid (SMOFlipid®), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).(22)

[c] Formulas: amino acids (Aminoplasmal®), dextrose, lipid (Intralipid®, ClinOleic™), electrolytes, and trace elements (Cr, Cu, Mn, Se, Zn).(23)

[d] Formulas: amino acid solution, dextrose, lipid, electrolytes, and trace elements (Tralement®: Cu, Mn, Se, Zn).(27)

[e] Formulas: amino acids (Aminoven®, Primene™), dextrose, electrolytes, and trace elements (Peditrace™: Cu, F, I, Mn, Se, Zn).(29)

[f] Formulas: amino acids (Aminoven®, Vaminolact®, Primene™), dextrose electrolytes, and trace elements (Peditrace™: Cu, F, I, Mn, Se, Zn).(14)

[g] Formulas: amino acids (Neonutrin), dextrose, lipid (SMOFlipid®), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).(24)

[h] Formulas: Kabiven® (RTU three-chamber bag) (amino acids, dextrose, soy-based lipid), electrolytes, and trace elements (Addamel™: Cr, Cu, F, Fe, I, Mn, Mo, Se, Zn).(13,25)

[i] Light exposed for 30 days RF, light protected for 24 hours at 37°C.(14)

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