Compatibility and Stability Considerations for PN

Compounding Checklist

PRACTICE TOOL

The American Society for Parenteral and Enteral Nutrition (ASPEN) champions evidence-based practices that support parenteral nutrition (PN) therapy across varying patient populations, disease states, and practice settings. The appropriate use of PN aims to maximize clinical benefit while minimizing the potential risks.

This checklist promotes PN compounding safe practices by the pharmacy staff to prepare optimal PN formulations, particularly with regard to compatibility and stability issues. See the ASPEN competencies model for order review and compounding to ensure that staff are verified to perform these functions safely. Use this checklist along with companion checklists on PN prescribing, order review, and administration.

Automated Compounding Device (ACD) Setup

- ☐ Use vendor-validated setup for ACD.
- ☐ Perform initial ACD setup using 2 staff members:
  - Use independent double-check process
  - Use printed check
  - Verbally affirm all component products and base solutions including:
    - » name
    - » concentration
    - » container size
- ☐ Use barcode technology and pharmacy workflow software to verify products during setup and product replacement.
- ☐ Inspect integrity of each component product.
- ☐ Trace tubing from the source container to the port where it attaches to the ACD during initial setup and with each change in the source container.
- ☐ Verify all empty containers when multiple containers of a single component product are used.
- ☐ Use ACD to deliver all PN component products that are approved in the device manual.
- ☐ Consider use of photoprotection measures.
- ☐ Minimize potential incompatibilities in the central tubing by separating potentially interacting components and/or using an adequate volume of a compatible universal ingredient flush as available in between. See table below of potential physicochemical interactions between PN components.
- ☐ Note the final PN weight variance within an acceptable tolerance margin for the ACD (e.g., ≤5%), does not necessarily mean that critical active ingredient concentrations fall within expected limits.
- ☐ Any changes made to the ACD database, alerts, or mixing sequence should be performed by a qualified professional, in keeping with those parameters set and validated by the ACD manufacturer.

PN Component Product	Potential Physicochemical Interaction
Lipid injectable emulsion	Dextrose, high-dose monovalent (sodium or potassium), divalent (calcium or magnesium) minerals, and acidic components (L-cysteine, dextrose)
Calcium gluconate/chloride	Phosphate-containing component
Potassium acetate	Magnesium sulfate
Copper*	L-cysteine and ascorbic acid
Selenium**	Ascorbic acid
Ascorbic acid	Copper, manganese, and zinc sulfate
Folic acid	Acidic components

Abbreviation: PN, parenteral nutrition Reprinted from Boullata JI, et al. * as cupric chloride ** as selenious acid

Continued on next page

aspen® American Society for Parenteral and Enteral Nutrition

Manual Compounding

☐ Use manual compounding when:

- The volume of PN component to be mixed is less than the ACD can accurately deliver.
- There is an interaction between a PN component and a component of the ACD (e.g., regular insulin and tubing).
- There is a chemical reaction between PN component(s) that cannot be mitigated by sequencing the addition of ingredients.
- There is a shortage of a specific PN component or ACD device and manual compounding is part of a conservation measure.

☐ Verify and inspect manual additive vials and syringes with the additive prior to adding to PN (Do not use proxy methods of verification such as syringe pull-back method).

☐ Use check list or sign-off sheet for manual additives.

☐ Mix each additive thoroughly across the bulk of PN fluid before the next additive.

☐ Consider the example of an acceptable mixing sequence of components in table below to reduce the risk of incompatibility or instability.

Sequence of Mixing	PN Component Product	Notes
1	Amino acids	–
2	Dextrose	–
3	Sterile water for injection	–
4	Phosphate salt(s)	–
5	Other electrolytes (sodium, potassium, or magnesium)	Separate potassium acetate from magnesium sulfate
6	Trace elements	–
7	Vitamins	Except for PN at home, when added last by patient/caregiver just before infusion
8	Calcium gluconate	The preferred source of calcium when using inorganic phosphate salts
9	Lipid injectable emulsion	If appropriate

Abbreviation: PN, parenteral nutrition Reprinted from Boullata JI, et al.

Standardized, Commercial - Parenteral Nutrition Products (Multi-chambered Bag [MCB] PN Products)

☐ Activate the bag (break seal or remove bar between the chambers), mix components, and then add other PN components within compatibility and stability limits prior to labeling and dispensing from pharmacy.

☐ Reach out to manufacturers to determine number of times bags can be accessed/punctured and any other best practices with additives, including stability/compatibility information.

Prior to Dispensing Any PN Admixture

☐ Review and compare PN order, label on PN product and compounding label prior to dispensing.

☐ Visually inspect PN for any leaks, gross particulates, or emulsion instability (e.g., oiling, streaking, color changes, clumping, or separation), although these may only become apparent hours later.

☐ The PN admixture will include a beyond use date on the label based on formulation compatibility and stability as well as sterility, and be maintained under refrigeration until administration.

For full recommendations, rationale, and references, go to:

- Boullata JI, Salman G, Mirtallo JM, et al. Parenteral nutrition compatibility and stability: Practical considerations. *Nutr Clin Pract.* 2024;39(5):1150-63.
- Ayers P, Adams S, Boullata J, Gervasio J, Holcombe B, Kraft M, et al. ASPEN parenteral nutrition safety consensus recommendations. *JPEN J Parenter Enteral Nutr.* 2014;38: 296-333.
- Boullata JI, Holcombe B, Sacks G, et al. Standardized competencies for parenteral nutrition order review and parenteral nutrition preparation, including compounding: the ASPEN model. *Nutr Clin Pract.* 2016 Aug;31(4):548-55.

Note: This content has been developed based on ASPEN Board Approved documents. The information presented here is for use by healthcare professionals to inform other clinicians and/or patients/caregivers. Recommendations provided here do not constitute medical or other professional advice and should not be taken as such. To the extent that the information presented here may be used to assist in the care of patients, the primary component of quality medical care is the result of the professional judgment of the healthcare professionals providing care. The information presented here is not a substitute for the exercise of professional judgment by healthcare professionals. Circumstances and patient specifics in clinical settings may require actions different from those recommended in this document; in those cases, the judgment of the treating professional should prevail. Use of this information does not in any way guarantee any specific benefit in outcome or survival. This tool is intended to supplement, but not replace, professional training and judgment.

Supported by Baxter *and* FRESENIUS KABI