

MEDICATION STABILITY & STORAGE


Administration of parenteral medications (e.g., intravenous infusions, injections) should begin immediately following preparation—ideally within one (1) hour of beginning preparation.


If extenuating circumstances preclude immediate administration, manufacturer guidelines regarding stability and storage must be followed. However, it is important to note:


- **Storage must not exceed four (4) hours** *unless* the product was prepared in an environment with at least ISO Class 5 air quality in accordance with United States Pharmacopeia (USP) General Chapter <797> pharmacy standards for compounding sterile products.


This is true even if storage/stability information in product labeling indicates that prepared medications may be stored for durations that exceed four (4) hours.

Stability and storage duration data supplied in FDA-approved labeling typically:

 Refers to chemical and/or physical stability

 Does not consider preparation procedures used (e.g., aseptic technique)

 Does not refer to microbiological purity or safety

 Does not consider environmental conditions (e.g., ISO air classification)

The longer a prepared medication is stored before administration, the more time microbial pathogens—which may be introduced via contamination during preparation—have to replicate. While the medication molecules themselves may be physically stable beyond 4 hours, the infection risk is too great.

This guide is for informational not intended to supersede guidance from the FDA, USP, state/local health departments, or other regulatory authorities

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STORAGE AND STABILITY DURATION OF COVID-19 ANTIBODY THERAPIES BASED ON PREPARATION ENVIRONMENT

COVID-19 Antibody Product	Preparation Environment Air Quality	Maximum Length of Time Product May Be Stored	
		Room Temperature (20°C to 25°C or 68°F to 77°F)	Refrigerated (2° to 8°C or 36° to 46°F)
bamlanivimab + etesevimab	Non-ISO classified air (e.g., clinical area)	4 hours	4 hours
	ISO Class 5 or cleaner (e.g., pharmacy cleanroom)	7 hours	24 hours
casirivimab + imdevimab	Non-ISO classified air (e.g., clinical area)	4 hours	4 hours
	ISO Class 5 or cleaner (e.g., pharmacy cleanroom)	4 hours	36 hours
sotrovimab	Non-ISO classified air (e.g., clinical area)	4 hours	4 hours
	ISO Class 5 or cleaner (e.g., pharmacy cleanroom)	4 hours	24 hours