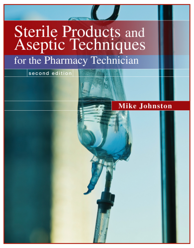
Sterile Products and Aseptic Techniques
for the Pharmacy Technician



CHAPTER 1

Introduction to Sterile Products

Types of Compounded Drugs

- Nonsterile
  - Oral medications
  - Topical medications
- Sterile
  - Injections
  - Intravenous admixtures

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Parenteral Routes

Overview

- Any route that bypasses GI tract
- Most commonly associated with injection
- Drugs given parenterally must be sterile

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Parenteral Routes (cont’ d)

Advantages

- Rapid onset of action
- More accurate control of drug levels
- Good for irritant medications
- Large volumes can be administered

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Parenteral Routes (cont’ d)

Disadvantages

- Most dangerous: once injected, can’ t be retrieved
- Can be painful
- Must use aqueous solution & aseptic technique

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Common Parenteral Routes

Intradermal

- Injection into dermis (top layer of skin)
- Used for skin tests for allergies & tuberculosis
- Should not exceed 0.1 mL
- Small-gauge needle required

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Common Parenteral Routes (cont' d)

Subcutaneous

- Injection into fatty subcutaneous tissue of skin
- Allows slow, continuous absorption
- Smaller-gauge needle required
- Maximum injection volume = 2 mL
- Sites: upper arm, top of thigh, buttock, abdomen

Common Parenteral Routes (cont' d)

Subcutaneous (cont' d)

- Minimal pain & discomfort
- Used for self-administration of insulin, epinephrine

Common Parenteral Routes (cont' d)

Intramuscular

- Injection deep into large muscle mass
- Sites: buttock, thigh, upper arm
- Faster-acting than subcutaneous
- Maximum injection volume = 5 mL
- Volumes over 3 mL should be divided into 2 shots
- Big disadvantage: pain

Common Parenteral Routes (cont' d)

Intravenous

- Injection directly into bloodstream
- Fastest parenteral route
- Preferred route for irritating drugs (quick dilution)
- Not as limited by volume
- Restricted by patient' s age & physical state

Other Parenteral Routes

Intracardiac

- Injection directly into cardiac muscle or heart
- Used in emergencies
- Epinephrine
  - Most common intracardiac drug
  - Available in pre-filled syringe
  - Injected with 3.5 in. needle to penetrate chest wall

Other Parenteral Routes (cont' d)

Epidural

- Injection into space between spinal cord & vertebrae
- Used to treat neurologic pain & inflammation
- Commonly contains narcotic drug & anesthetic

Other Parenteral Routes (cont’d)

Epidural (cont’d)

- Must compound with preservative-free materials
  - Preservatives can cause paralysis

Other Parenteral Routes (cont’d)

Intrathecal

- Injection into space surrounding spinal cord
- Used mainly for
  - Spinal Anesthesia
  - Pain Management
  - Chemotherapy

Other Parenteral Routes (cont’d)

Intrathecal (cont’d)

- Also used for cerebral palsy drugs (baclofen)
- Drugs must be preservative-free

Other Parenteral Routes (cont’d)

Intraperitoneal

- Injection into
  - Peritoneal cavity
  - Abdominal organ
    - Kidney
    - Liver
    - Bladder
- Requires 4 to 6 in. needle

Other Parenteral Routes (cont’d)

Intra-arterial

- Injection into artery leading to desired organ
- Used for
  - Diagnostic procedures
  - Chemotherapy

Other Parenteral Routes (cont’d)

Intraocular

- Injection into eye
- Used to treat eye infections unresponsive to traditional treatments

Other Parenteral Routes (cont’d)

Intrapleural
- Injection into pleural cavity (lungs)
- Used to treat
  - Infections
  - Cancers of pleural cavity

Intravenous Infusions

Peripheral Line (Catheter) Access
- Veins in arms, legs, hands, feet
- Most common in hospital setting
- Temporary, as can be dislodged easily
- Must flush regularly with normal saline/heparin
  - To clean line
  - To prevent blood coagulation

Intravenous Infusions (cont’d)

Peripheral Line (Catheter) Access (cont’d)
- Most common IV drug type compounded by PTs

Intravenous Infusions (cont’d)

Central Line (Catheter) Access
- Veins in
  - Neck (jugular)
  - Chest (subclavian)
  - Arm (superior vena cava: central vein)

Intravenous Infusions (cont’d)

Central Line (Catheter) Access (cont’d)
- Used
  - When peripheral access is unavailable
  - For long-term administration
  - To administer caustic substances (chemo)
  - To administer highly concentrated TPN

Intravenous Infusions (cont’d)

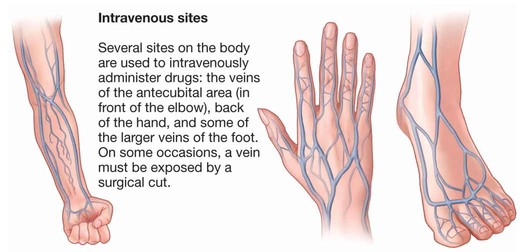
Types
- IV Push
  - (10 mL or less)
  - Injection from syringe into vein
- Continuous Infusion
  - (250 mL or more)
  - Infused at constant rate over longer admin. time

Intravenous Infusions (cont’d)

Types (cont’d)

- Intermittent Infusion (IV Piggyback)
  - <250 mL
  - Infused at scheduled, short (<1 hr) intervals

Intravenous Administration (cont’d)



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Aseptic Technique

- All drugs injected parenterally must be sterile
- Sterile = no contamination
- Contaminants
  - Bacteria
  - Pyrogens
  - Particulate matter

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Aseptic Technique (cont’d)

- Aseptic technique: only way to ensure products are sterile

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Aseptic Technique (cont’d)

- Proper Hygiene
- Proper Garbing
- Maintaining Proper
  - Equipment
  - Manipulations
  - Procedures
- Improper asepsis can contaminate products

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Aseptic Technique (cont’d)

- Consumption of contaminated drugs can cause:
  - Phlebitis
  - Sepsis

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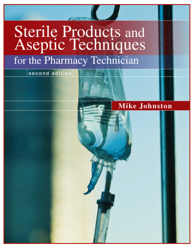

CHAPTER 2

USP 797 Guidelines: Compounding Areas and Equipment

USP 797

- Stringent regulations of aseptic preparations
- Covers
  - Compounding personnel responsibilities
  - Microbial contamination risk factors
  - Personnel training & evaluation
  - Immediate use compounded sterile products
  - Single-dose & multi-dose containers

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USP 797 (cont' d)

- Covers (cont' d)
  - Hazardous drugs
  - Verification of compounding accuracy
  - Elements of quality control
  - Release checks & tests
  - Storage & beyond-use dating
  - Maintaining sterility, purity, & stability
  - Patient or caregiver training

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USP 797 (cont' d)

- Covers (cont' d)
  - Patient monitoring & adverse events reporting
  - Quality assurance program

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Facilities and Clean Room

Six ISO Air Environment Categories

- Class 3: ≤35.2 particles ≥0.5 micron per m^3
- Class 4: ≤352 particles ≥0.5 micron per m^3
- Class 5: ≤3,520 particles ≥0.5 micron per m^3

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Facilities and Clean Room (cont' d)

Six ISO Air Environment Categories

- Class 6: ≤35,200 particles ≥0.5 micron per m^3
- Class 7: ≤352,000 particles ≥0.5 micron per m^3
- Class 8: ≤3,520,000 particles ≥0.5 micron per m^3

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Facilities and Clean Room (cont'd)

Clean Room

- Ante-area or anteroom
  - Class 8 or better
  - Area for hand washing & dressing
  - Ingredients & supplies gathered here
  - Order entry & labeling performed here
- Buffer area
  - Location of primary engineering control (PEC)
  - Class 7 or better

Facilities and Clean Room (cont'd)

Clean Air Space

- Compound at least 6 in. inside edges of PEC
- Keep blower on at all times
- Clean PEC with sterile water & 70% IPA
- Positive-pressure room
- Only one door; keep shut
- Not for storage

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Facilities and Clean Room (cont'd)

Primary Engineering Controls

- Class 5 device or room
- For exposure of critical sites when compounding
- Types
  - Laminar airflow workbench (LAFW)
  - Biological safety cabinet (BSC)
  - Compounding aseptic isolator (CAI)

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Laminar Airflow Workbench

- For most nonhazardous aseptic compounding
- Contaminants minimized by constant air filtration
- Hood creates particle-free working environment
- Air is blown horizontally toward front of hood

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Laminar Airflow Workbench (cont'd)

- Includes prefilter & high-efficiency particulate air (HEPA) filter

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Laminar Airflow Workbench (cont'd)

FIGURE 2-4 Laminar airflow hood

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Biological Safety Cabinet

- For hazardous compounding (chemotherapy)
- Room air is sucked into grills & filtered
- Filtered air is blown vertically down from hood top
- HEPA filter should be tested every 6 months

Biological Safety Cabinet (cont’d)

FIGURE 2-5 Biological safety cabinet

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Compounding Aseptic Isolator

- Class 5 environment
- Can be used in lieu of clean room
- Self-contained environment
- Sterile products manipulated via glovebox system
- Supplies introduced via transfer chamber
- For nonhazardous compounding
- Special version (CACI) used for hazardous CSPs

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Other Clean Room Supplies

- Sink
- Sharps containers
- Refrigerator/freezer with thermometer
- Infusion devices
- Disinfectant cleaning solutions
- Hand washing agents
- Disposable, lint-free towels or wipes
- Filters & filtration equipment

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Personal Protection Equipment

- Hair cover
- Shoe covers
- Gloves
- Mask
- Beard cover
- Gown
- Scrubs

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Personal Protection Equipment (cont’d)

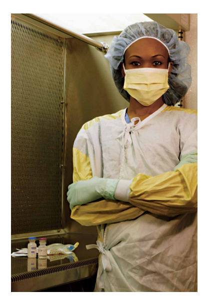

FIGURE 2-7 IV Technician dressed in sterile clothing

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Needles

Parts of a Needle

- Lumen: hollow space inside needle
- Bevel: sharp, pointed end of needle
- Heel: rounded, bottom part of needle
- Hub: part that attaches to syringe

Needle Specifications

- Needle length: ranges from 3/8 to 3-1/2 in.

Needles (cont' d)

- Gauge: size of opening of needle
  - The larger the gauge, the smaller the opening
  - Range: from 28 to 16

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Parts of a Needle

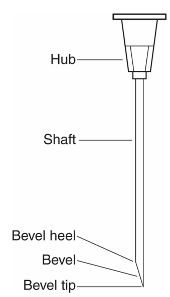

FIGURE 2-16 Parts of a needle

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Syringes

Parts of a Syringe

- Tip: where needle is attached
- Barrel: where fluid is held
- Plunger: slides in & out of barrel

Types of Syringes

- Luer-lock: needle screws onto syringe
- Slip tip: needle slides onto syringe

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Needle Lengths

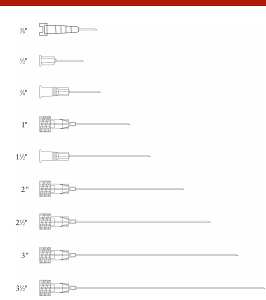

FIGURE 2-17 Needle lengths

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Other Compounding Supplies

- Ampule
- Single dose vial
- Sticky mats
- Vials
- Filters (membrane, depth, in-line)
- IV tubing (primary, vented)
- Empty evacuated containers

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Other Compounding Supplies (cont’ d)

- Viaflex bags
- Leur-to-leur connectors
- Dispensing pins
- Mini-bags or advantage
- Syringe caps
- Port adapters (male adapters)
- IVA seals (foil port covers)

Other Compounding Supplies (cont’ d)

- Auxiliary labels
- Dark bags
- Red sharps containers
- Vented spike adapters

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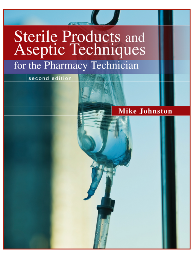

CHAPTER 3

Aseptic Calculations

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IV Additive Dosage Calculations

- Used to calculate correct quantity of drug to be withdrawn & transferred
- Use basic ratio & proportion
- Basic equation
- Drug Concentration Available (What You Have) = Dose or Volume Ordered (What You Need)

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IV Additive Dosage: Example

Rx: Gentamicin 120 mg IVPB q12h
Drug Available: Gentamicin 40 mg/mL, 2-mL vial

How much drug must be drawn up for each dose?

Set up the ratio proportion: $\frac{40\text{ mg}}{\text{mL}} = \frac{120\text{ mg}}{X\text{ mL}}$

Cross-multiply: $40(X) = 120$

Divide by 40: $X = 3$

Therefore, the technician must withdraw **3 mL** for a 120-mg dose which will require two stock vials.

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Diluent, Powder, & Reconstitution

- Many drugs in powder form must be reconstituted
- Volume of diluent often must be calculated
- Formula
- DV + PV = FV
- DV = diluent volume
- PV = powder volume
- FV = final volume

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Reconstitution: Example

The 1-g antibiotic vial states "Reconstitute with 3.3 mL of sterile water for a final volume of 4 mL." What is the powder volume in the vial?

Insert the diluent volume of 3.3 mL and the final volume of 4 mL into the formula:

$$3.3 + PV = 4$$

To solve, we need to have the unknown variable (PV) by itself on one side of the equal sign. To do this, we have to subtract 3.3 from each side:

$$3.3 + PV(-3.3) = 4 - 3.3$$
$$PV = 0.7$$

Therefore the powder volume is 0.7 mL.

Milliequivalents

- Unit of measure used with TPNs
- Calculate using ratios & proportions
- Example
- Electrolyte: NaCl
- Stock vial: 4 mEq/mL
- Rx order: 40 mEq
- How many mL of NaCl 4 mEq/mL should be added to TPN?

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Milliequivalents: Example

ELECTROLYTE	STOCK VIAL	RX ORDER	HOW MANY mL?
NaCl	4 mEq/mL	40 mEq	________

Using the information provided, set up a ratio and proportion to solve:

$$\frac{4 \text{ mEq}}{1 \text{ mL}} = \frac{40 \text{ mEq}}{x}$$

Cross-multiply: $40 = 4x$

Divide both sides by 4: $X = 10$

So 10 mL of NaCl 4 mEq/mL should be added to the TPN.

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IV Flow Rates

- Commonly expressed in mL/hr or gtts/min
- IV rate (mL/hr): speed an IV solution is infused
- Drip rate (gtts/min): speed IV admin. set is calibrated to achieve IV rate
- Formula
  - Volume to be infused (mL) = mL/hr
  - Infusion time (hours)

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IV Flow Rates: Example

Rx: D5W 1 L q6h. What is the IV rate?

$1000 \text{ mL}/6 \text{ hr} = 166.67 \approx 167 \text{ mL/hr}$

IMPORTANT: IV rates should always be rounded to the nearest whole number (mL), as decimal values cannot be accurately measured.

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IV Frequency or Schedule

- Time it takes to infuse specific volume of solution
- Usually expressed in hours
- Always round down to nearest whole number in hrs

FORMULA

$$\frac{\text{Total Volume to Be Infused (mL)}}{\text{IV Rate (mL/hr)}} = \text{q\_hr}$$

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IV Frequency/Schedule: Example

Rx: NS 1 L to be infused at 145 mL/hr. What is the frequency of a 1-L IV bag?

$$\frac{1000 \text{ mL}}{145 \text{ mL/hr}} = 6.9\text{hr}$$

Therefore, a 1-L bag will last 6 hr, or the frequency is 6q7h.

IV Drip Rates

- Used to calibrate IV administration set to ensure correct infusion of IV solution
- Drop factor: drops/mm delivered in IV set
- Microdrip IV sets: calibrated at 60 gtts/mL
- Macrodrip IV sets: calibrated at 10 or 20 gtts/mL

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IV Drip Rates (cont'd)

FORMULA

$$\frac{\text{Volume to Be Infused (mL)}}{\text{Infusion Time (min)}} \times \text{IV Set Drop Factor} = \frac{\text{Drops}}{\text{Minute}}$$

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IV Drip Rates: Example

Rx: Infuse D5W 500 mL over 4 hr with an IV set with a drop factor of 10 gtt/mL. What is the drip rate?

First, determine the total time to infuse 500 mL:

$$4 \text{ hr} \times 60 \text{ min/hr} = 240 \text{ min}$$

Set up the formula:

$$\frac{500 \text{ mL}}{240 \text{ min}} \times \frac{10 \text{ gtt}}{\text{mL}} = x \frac{\text{gtt}}{\text{min}}$$

Cancel like units before multiplying:

$$\frac{500 \not{\text{mL}}}{240 \text{ min}} \times \frac{10 \text{ gtt}}{\not{\text{mL}}} = x \frac{\text{gtt}}{\text{min}}$$

Multiply 500 × 10, then divide by 240, and the resulting answer will be in gtt/min:

$$5000/240 = 20.8 \approx 21 \text{ gtt/min}$$

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Percent Concentrations

- Used to determine % strength of active ingredient
- Amount of active ingredient in 100 mL or g of CSP

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Percent Concentrations (cont'd)

FORMULAS

$\text{w/w\%} = \frac{\text{g}}{100 \text{ g}}$ = number of grams of the drug in 100 g of final product, which means that if you have a 10% (w/w) preparation, you have 10 g of active ingredient in every 100 g of final product.

$\text{w/v\%} = \frac{\text{g}}{100 \text{ mL}}$ = number of grams of the drug in 100 mL of final product, which means that if you have a 20% (w/v) preparation, you have 20 g of active ingredient in every 100 mL of final product.

$\text{v/v\%} = \frac{\text{mL}}{100 \text{ mL}}$ = number of milliliters of the drug in 100 mL of the final product, which means that if you have a 30% (v/v) preparation, you have 30 mL of active ingredient in every 100 mL of final product.

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Percent Concentrations: Example

How many grams of dextrose are in 1 L of D50W?

By definition, D50W means that 50 g of dextrose are in 100 mL of final product. Therefore, using the definition of percentage strength, we can set up a ratio proportion to calculate how many grams of dextrose are in 1 L of D50W as follows:

$$\frac{50 \text{ g}}{100 \text{ mL}} = \frac{X \text{ g}}{1000 \text{ mL}}$$

Cross-multiply:

$$100X = 50{,}000$$

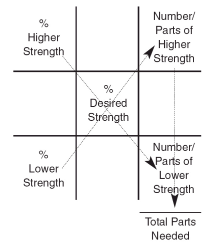
Divide by 100:

$$X = 500$$

Therefore, 1 L of D50W contains 500 g of dextrose.

Alligations

- Used to calculate amount of each product in mix
- Use alligation grid



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Alligations: Example

70 (higher conc)		25
	30 (desired conc)	
5 (lower conc)		40

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Electrolytes Added to TPNs

- TPNs
  - Given by IV when nutrients can't be consumed orally
  - Balanced mix of carbs, protein, fats, minerals, electrolytes, vitamins, & water

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Electrolytes Added to TPNs (cont'd)

- Electrolytes
  - Charged ions in solution
  - Maintain acid-base balance in body fluids
  - Control body water volume
  - Regulate metabolism

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Electrolytes Added to TPNs: Example

Determine the volume needed for each of the following electrolytes.

NaCl

Stock vial concentration = 4 mEq/mL

Milliequivalents ordered = 60 mEq

Volume needed: 60 mEq/4 mEq = 15 mL

Na phosphate

Stock vial concentration = 4 mEq/mL

Milliequivalents ordered = 40 mEq

Volume needed: 40 mEq/4 mEq = 10 mL

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Mike Johnston
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Dilution Technique

- Dilution is required for medications with tiny dosages
- Dilute 1 mL of concentrate with 9 mL of sterile water for injection

Dilution Technique (cont'd)

Example

Rx: Insulin dilution to 10 U/mL

Take 1 mL from a stock vial containing 100 U/mL and inject it into an empty sterile vial. Add 9 mL of sterile water for injection. What is the resulting concentration?

Answer: 100 U/10 mL or 10 U/1 mL.

If a patient requires a dose of three units once daily, what volume should be injected?

$$\frac{10\ \text{U}}{1\ \text{mL}} :: \frac{3\ \text{U}}{x\ \text{mL}} = 0.3\ \text{mL}$$