D.PHARM • SECOND YEAR

Hospital & Clinical Pharmacy

CHAPTER 5

Compounding in Hospitals

ENGLISH CHAPTER NOTES



DIPLOMA IN PHARMACY

COMPOUNDING IN HOSPITALS

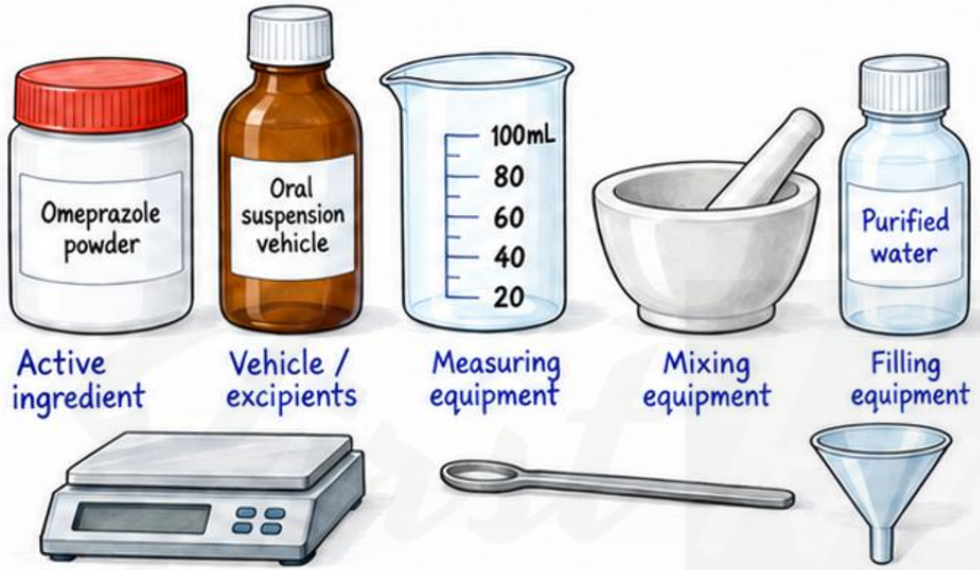
1. PRESCRIPTION

Hospital Pharmacy Date: 12/04/2024

Patient: Child, 5 years
Weight: 20 kg

Rp:
Omeprazole oral suspension
2 mg/mL
Give 10 mL twice daily
Quantity: 100 mL
For oral use

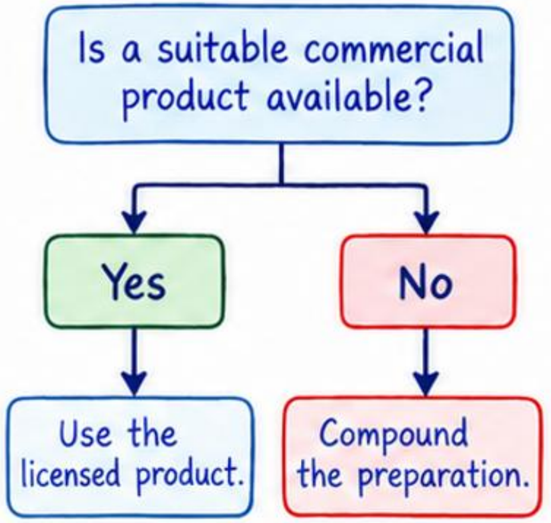
2. INGREDIENTS AND EQUIPMENT



3. FINISHED PREPARATION



4. WHEN IS COMPOUNDING NEEDED?



DEFINITION

Hospital compounding is the preparation, mixing, assembling, altering, packaging and labelling of a medicine for an identified patient or an approved hospital need, according to a valid order and authorized procedure.

WHEN IT IS NEEDED

- No suitable commercial strength or dosage form is available.
- A patient needs a different concentration, flavour, vehicle or route.
- A medicine must be reconstituted or diluted for safe administration.
- A validated batch of a frequently used preparation is required by hospital policy.

COMMON FORMS

Oral liquids • powders • creams / ointments / gels • capsules • sterile syringes or infusions • pediatric and geriatric preparations.

ESSENTIAL REQUIREMENTS

Approved formula • suitable ingredients • accurate calculation and measurement • trained staff • clean / controlled area • compatible container • complete label • beyond-use date • storage instructions • batch / patient traceability • quality checks.

IMPORTANT: Compounding should solve a genuine therapeutic need, not copy a suitable available product without reason.

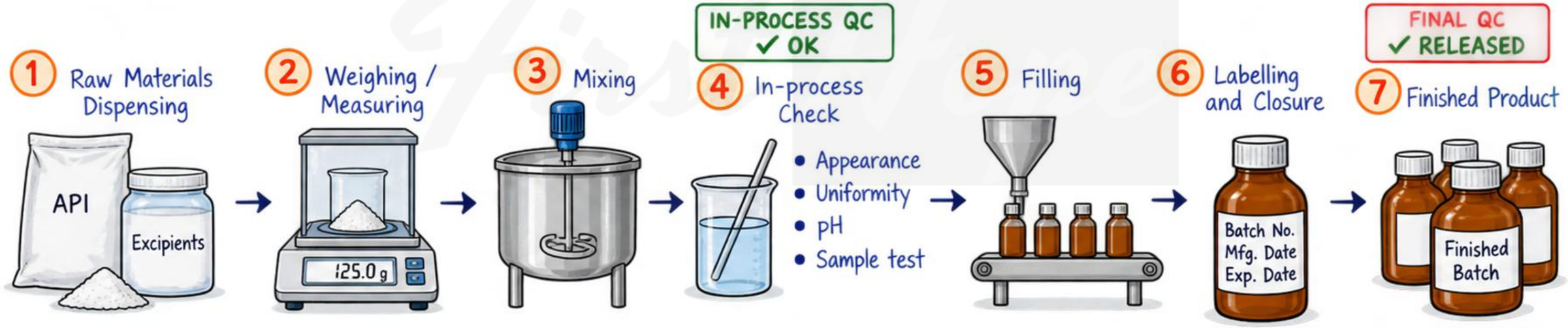
BULK COMPOUNDING AND QUALITY CONTROL

BULK COMPOUNDING

Preparation of multiple doses or a batch from raw materials using an approved master formula. Examples include ORS powder, standard oral liquids, creams, ointments and validated pediatric dilutions.

BATCH PROCESS

1. Review master formulation record and calculate batch quantity.
2. Verify identity, quality and expiry of every ingredient.
3. Accurately weigh or measure; record actual quantities.
4. Mix in the correct order until uniform.
5. Perform in-process checks.
6. Fill into suitable containers, close and label.
7. Complete batch record, yield, release decision and storage.



QUALITY CONTROL

- Appearance / colour • odour where relevant • clarity • uniformity
- pH • weight or volume • container closure • label • microbial / sterility testing when required • potency or assay when applicable.

TRACEABILITY

- Formula number • ingredients and lot numbers • operator and checker
- date / time • batch number • theoretical and actual yield
- test results • beyond-use date • distribution / recall record.

IV ADMIXTURE SERVICE

DEFINITION

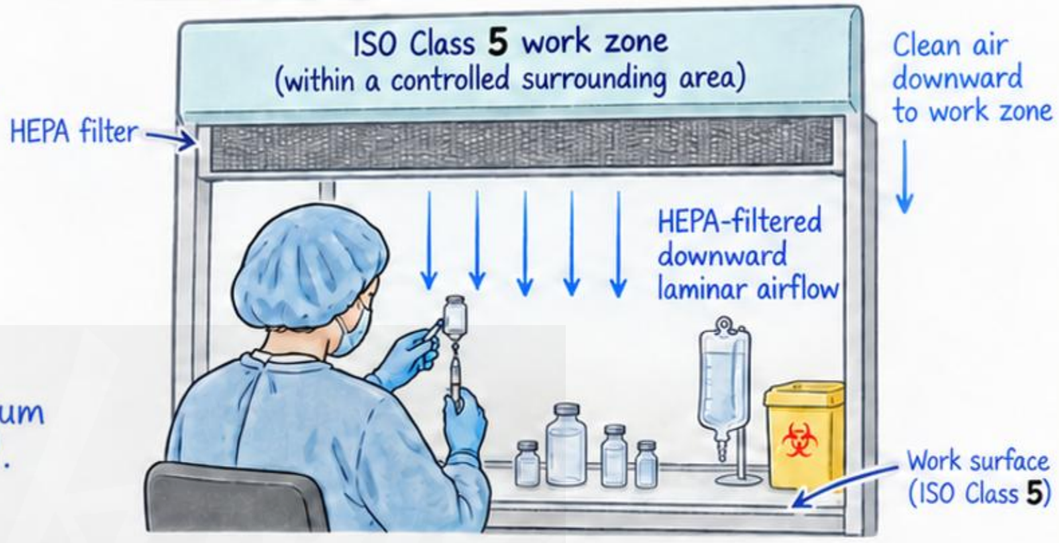
An IV admixture is a sterile preparation made by combining one or more sterile medicines with a compatible sterile diluent or infusion fluid under controlled aseptic conditions.

OBJECTIVES

• Correct dose and concentration • sterility • compatibility • stability • accurate label • safe administration.

COMPONENTS

Active medicine + compatible diluent / base such as 0.9% sodium chloride or 5% dextrose + approved additives when prescribed.



SAFE WORKFLOW



Order and patient review → calculations → compatibility check → gather and disinfect materials → aseptic manipulation → visual inspection → label → independent verification → protected delivery

FACILITY AND PERSONNEL

- Trained, competency-assessed pharmacists and technicians.
- An appropriate primary engineering control providing an ISO Class 5 work zone, located in a controlled surrounding area required by the applicable standard.
- Biological safety cabinet or containment system for hazardous drugs.
- Environmental cleaning, monitoring, equipment certification and complete records.

Do not call the whole room ISO Class 5 unless it is actually designed and certified that way.

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