D.PHARM • SECOND YEAR

अस्पताल एवं नैदानिक फार्मेसी

अध्याय 5

अस्पताल में कम्पाउंडिंग

हिंदी अध्याय नोट्स



COMPOUNDING IN HOSPITALS

परिभाषा

Hospital compounding, valid order और authorized procedure के अनुसार identified patient या approved hospital need के लिए medicine की preparation, mixing, assembling, altering, packaging और labelling है।

कब आवश्यकता होती है

- Suitable commercial strength या dosage form उपलब्ध न हो।
- Patient को अलग concentration, flavour, vehicle या route चाहिए।
- Safe administration के लिए medicine reconstitute या dilute करनी हो।
- Hospital policy के अनुसार frequently used preparation का validated batch चाहिए।

Compounding genuine therapeutic need पूरी करे; suitable available product को बिना reason copy न करे।



COMMON FORMS

Oral liquids • powders • creams / ointments / gels • capsules • sterile syringes या infusions • pediatric और geriatric preparations।

ESSENTIAL REQUIREMENTS

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

BULK COMPOUNDING AND QUALITY CONTROL

1 कच्चे माल की जाँच और तौलन्ना



Raw materials की पहचान और तौल

2 मिश्रण (Mixing)



सही क्रम में uniform होने तक mix

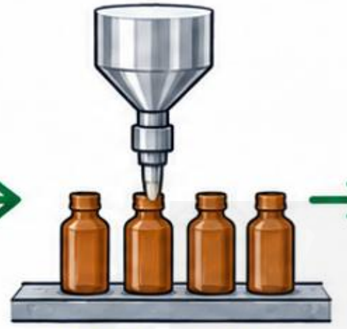
3 In-process check

IN-PROCESS QC
(Appearance / uniformity)



मिश्रण की गुणवत्ता की जाँच

4 Filling (भरना)



Suitable containers में fill

5 Closure (बंद करना)



Containers को close करना

6 Labeling (लेबल लगाना)



सही label लगाना

7 Final check और release

FINAL QC
(Full testing / release)



Final quality check और release decision

BULK COMPOUNDING

Approved master formula से raw materials द्वारा multiple doses या batch तैयार करना। Examples: ORS powder, standard oral liquids, creams, ointments और validated pediatric dilutions।

BATCH PROCESS

1. Master formulation record review और batch quantity calculate।
2. हर ingredient की identity, quality और expiry verify।
3. Accurate weigh या measure; actual quantities record।
4. Correct order में uniform होने तक mix।
5. In-process checks।
6. Suitable containers में fill, close और label।
7. Batch record, yield, release decision और storage complete।

QUALITY CONTROL

- Appearance / colour
- relevant odour
- clarity
- uniformity
- pH
- weight या volume
- container closure
- label
- required microbial / sterility testing
- applicable potency या assay।

TRACEABILITY

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

IV ADMIXTURE SERVICE

परिभाषा

IV admixture, controlled aseptic conditions में एक या अधिक sterile medicines को compatible sterile diluent या infusion fluid के साथ मिलाकर बनी sterile preparation है।

OBJECTIVES

- Correct dose और concentration • sterility • compatibility • stability • accurate label • safe administration।

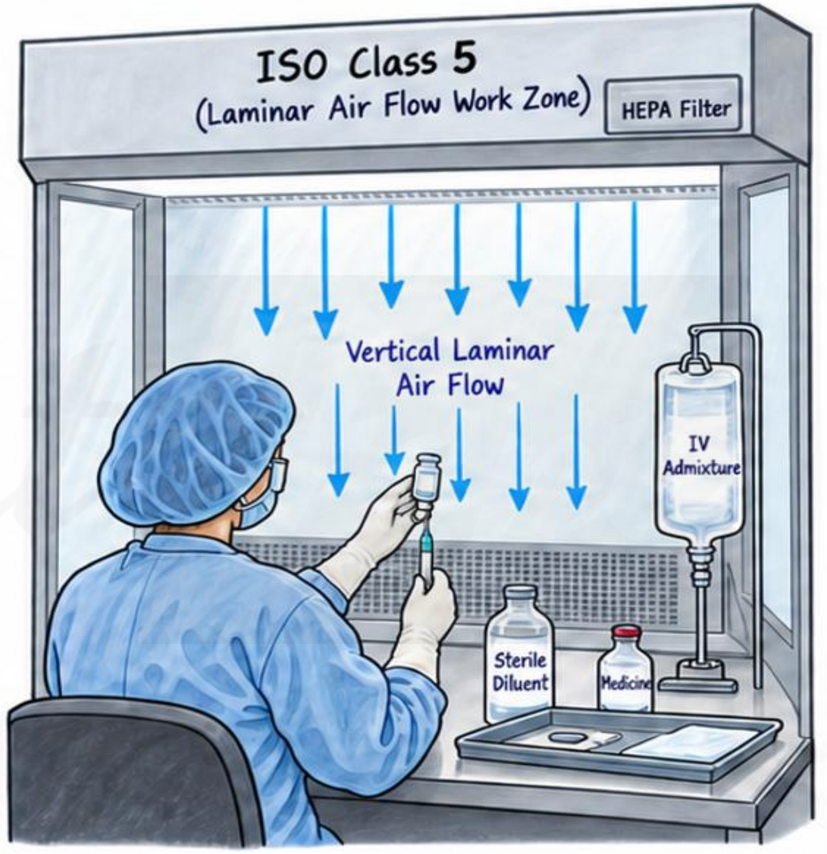
COMPONENTS

Active medicine + compatible diluent / base जैसे 0.9% sodium chloride या 5% dextrose + prescribed approved additives।

FACILITY AND PERSONNEL

- Trained, competency-assessed pharmacists और technicians।
- ISO Class 5 work zone देने वाला suitable primary engineering control, applicable standard के required controlled surrounding area में।
- Hazardous drugs के लिए biological safety cabinet या containment system।
- Environmental cleaning, monitoring, equipment certification और complete records।

Note: पूरे room को ISO Class 5 तभी कहें जब वह वास्तव में उसी तरह designed और certified हो।



Aseptic Manipulation within ISO Class 5 Primary Engineering-Control Work Zone

SAFE WORKFLOW

1. Order और patient review
2. calculations
3. compatibility check
4. materials gather और disinfect
5. aseptic manipulation
6. visual inspection
7. label
8. independent verification
9. protected delivery

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