تفريغ حساب وتركيب الأشكال الصيدلانية

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لجان الدفعات

- رح نحكي بعض المصطلحات الي مش familiar مثل pharma copia : - دساتير الادوية / عملية تحضير الدواء هو عبرة عن ال formula

ال formula في لغة الصناعة يعني توليفه شو يعني توليفه خليط بين المادة الفعالة والغير فعالة , حكينا الادوية بتتصرف بطريقتان الاولى عن طريق الطب .

الادوية بتنقسم لقسمين من ناحية prescription النوع الاول prescription يعني دواء اجباري يكون له وصفة والنوع الثاني non prescription

لازم نعرف انه احنا حلقة الوصل بين الطبيب والمريض

نيجي لل formula : - عبارة عن active و inactive

Pharmacopeias are reflecting the best in the current practices of medicine and pharmacy and provide suitable tests and assay procedures for demonstrating compliance with these standards in which these standards are used by regulatory agencies and manufacturers to help to ensure that these products are of the appropriate:

- identity,
- strength,
- quality,
- purity, and
- consistency.

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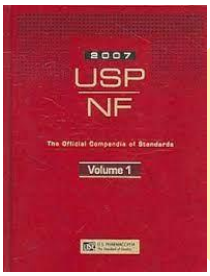
MSTS : لكل ماده في الدوا سواء كان active او inactive شو ممكن يصير لو اخذت sheet اللي بتزحلك عشان تعرف الماده اللي بدنا نحضرلها لشو مخاطرها

United States Pharmacopeia (USP)



- The **United States Pharmacopeia** (**USP**) is the official pharmacopeia of the United States, it is a combination of two official compendia that are publishes togather, the United States Pharmacopoeia (USP) and the National Formulary (NF).

- The USP/NF is published every year by **United States Pharmacopeial Convention** (usually also called the USP) who the trademark and the copyrights.

MP بعطينا اياها الطبيب ↑ NoN prescription ↑ ذي

- The Prescription and over–the–counter medicines and other health care products sold in the United States are required to follow the standards in the USP-NF. USP also sets standards for food ingredients and dietary supplements.

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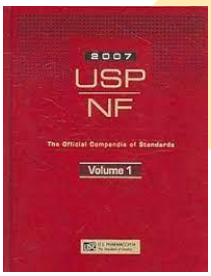
Major Sections of USP-NF

1. Preface: By-laws, changes from previous USP
2. General Notices: Definitions and assumption
3. USP Monographs :Drug substance, product standards
4. General Chapters: General test methods, information
5. Reagents: Materials used in Monographs
6. Reference Tables: Description, solubility, etc.
7. NF Monographs: Excipients
8. Dietary Supplement Monographs :Substance and product standards



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USP/NF Chapters

Chapters <795> - Pharmaceutical Compounding - Nonsterile Preparations

- Published in 2000
- Enforceable

Chapter <797> - cPharmaceutical Compounding - Sterile Preparations

- Became official in 2004.

Other Chapters

- Containers <661>
- Good Compounding Practices <1075>
- Pharmaceutical Stability <1150>
- Pharmaceutical Dosage Forms <1151>

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The British Pharmacopoeia (BP)

The BP consists of six volumes:

- Volumes I and II: Contain medicinal substances.
- Volume III: Contains formulated preparations, Blood related preparations, Immunological products, Radiopharmaceutical preparations, Surgical materials, Homeopathic preparations.
- Volume IV: Contains appendices, supplementary chapters, Infrared Reference Spectra, Index.
- Volume V: The veterinary British Pharmacopoeia.
- Volume VI: Contains CD ROM for the electronic version of the BP.

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ال injection اخطر من البلع في أخذ الدواء

Compounding (Extemporaneous) preparation is an inherently risky activity; therefore, before we proceed with this topic we need to identify the **risk levels** associated with it.

Chapter <795> classified the compounding into three main categories based on the following criteria:

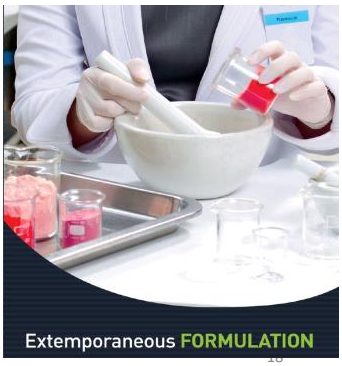
كل ما كان الدواء جرعته كبيره 500 / 1000 غالبا يكون Safe / اما اللي جرعته قليله زي عيار 1 او 5-5 يكون خطير في عنا اختلاف ذي الكريم والبومم

1. The degree of difficulty or complexity of the compounding process.
2. The stability information and warnings.
3. Packaging and storage requirements.
4. Dosage forms.
5. Complexity of calculations.
6. Local versus systemic biological disposition.
7. Level of risk to the compounder.
8. Potential for risk of harm to the patient.

الهدف علاقته بتلف أنه الدواء ممكن يتلف من الضوء او من الحرارة

دح نعطي الدواء منجيب اثره

- جوهم يدخل الجسم بسهوله لأنه دهني



antibiotic ← unpotent عكسها potent

دواء فعال بجرعه صغيره

ال compounding : - تركيب الدواء الان او حاليا ومش الدواء الي بكون في المصنع

احنا لازم نعرف انه compounding في اله 3 main categories

1 – simple :- بسيطة جدا يعني لما تيجي تحل السائل بكون معروف اذا هو simple او complex لانه بكون معروف شو هو السائل وال product عندك جاهز مش محتاج لحسابات

➢Compounding categories practice examples

➢Simple

Making a preparation that has a USP compounding monograph or that appears in a peer-reviewed journal article that contains :

- specific quantities of all components,
- compounding procedure
- equipment, and
- stability data for that formulation with
- appropriate BUDs (*Beyond-Use Dates*); or
- reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer.

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➢Moderate

Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units;

or making a preparation for which stability data for that specific formulation are not available. For instance, mixing two or more manufactured cream and the stability of the mixture is not known.

➢Complex

Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. Transdermal dosage forms and modified-release preparations are examples.

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Pharmacist who are engaged in drug or dietary supplement compounding shall be proficient in compounding and should continually expand their compounding knowledge by participating in seminars and/or studying appropriate literature.

They shall be knowledgeable about the contents of this chapter and should be familiar with:

- Pharmaceutical Dosage Forms ⟨1151⟩.
- Pharmaceutical Calculations in Pharmacy Practice ⟨1160⟩.
- Quality Assurance in Pharmaceutical Compounding ⟨1163⟩.
- Prescription Balances and Volumetric Apparatus Used in Compounding ⟨1176⟩ and ⟨1191⟩.
- Written Prescription Drug Information—Guidelines ⟨1265⟩.
- All applicable compounding laws, guidelines, and standards.

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The main compounding steps:

1. Pharmacist receives prescription or medication order.
2. Review and interpret (translate) the prescription.
3. Compounding the preparation*
4. Packaging *
5. Labelling *
6. Verification : Involves checking to ensure that all the process were appropriate and performed accurately. Additionally, the Master Formulation Record and the Compounding Record have been reviewed by the compounder to ensure that errors have not occurred in the compounding process and that the preparation is suitable for use
7. Patient counseling: The preparation is delivered to the patient or caregiver with the appropriate consultation about use, storage, and evidence of instability (visual changes, odor, etc.).

* Detailed explanation will be presented in the following slides.

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1. Prescription and Medication order.

- Both are legal orders by which the prescriber communicate with the pharmacist with regard to the treatment for a patient.
- Prescriptions are used for outpatient (on the right) and medication orders are for inpatients (on the left).

Patient: John Smith
Age: 68
Medical record number: 145693
Room: 3B-154

Date	Medication	Prescriber
8/10 8:23 am	Vancomycin 1,500 mg IV q12 hours x 3 days	B. Pajamo, MD
	D/c clindamycin 600 mg IV q6 hours	B. Pajamo, MD
8/10 9:15 am	KCl 20 mEq in 1 L 0.9%NS IV at 100 ml/hr x 1 liter	B. Pajamo, MD
	Acetaminophen 650 mg PO q6 hours prn temp >101°F	B. Pajamo, MD

B. Pajamo, M.D.
4701 Main St.
Baltimore, MD 12345

Name Jane Rusky DOB 1/5/62
Address 309 South Street Date 8/10/14

℞ Ciprofloxacin 500 mg
Sig: take 1 tab po bid x 7 days
Disp: 14 tabs

Refills 0 B. Pajamo M.D.

3. Compounding the preparation*

The compounder is responsible for ensuring that each individual incidence of compounding meets the given following criteria:

1. Evaluated the dose, safety, and intended use of the preparation for suitability in terms of, the chemical and physical properties of the components, dosage form therapeutic appropriateness and route of administration, including local and systemic biological disposition, legal limitations, if any.
2. Created a master formulation record before compounding a preparation for the first time. (This record shall be followed each time that preparation is made).
3. A Compounding Record should be completed each time a preparation is compounded.
4. Identify the materials and the equipment needed and Inspected the equipment for cleanliness and correct functioning.

5. Clean and sanitised the area dedicated to compounding.
6. Personnel engaged in compounding maintain good hand hygiene and wear clean clothing appropriate to the type of compounding performed (e.g., hair bonnets, coats, gowns, gloves, facemasks, shoes, aprons, or other items) as needed for protection of personnel from chemical exposures and for prevention of drug contamination.
7. Only one preparation is compounded at one time in a specific workspace.
8. Critical processes (including but not limited to weighing, measuring, and mixing) are verified by the compounder to ensure that procedures, when used, will consistently result in the expected qualities in the finished preparation.
9. The final preparation is assessed using factors such as weight, adequacy of mixing, clarity, odor, color, consistency, pH, and analytical testing as appropriate; and record this information in the Compounding Record (log) (Refer to chapter ⟨1163⟩).
10. Clean all equipment thoroughly and promptly, and store properly.

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4. Packaging

- The compounder shall ensure that the containers and container closures used in packaging:
  1. Meet *USP* requirements and when available, compounding monographs.
  2. Made of a material that doesn't change the quality, strength, or purity of the preparation.
  3. Stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first.
  4. Selected based on the physical and chemical properties of the preparation to avoid container–drug interaction. Some materials might have sorptive or leaching properties.
  5. Finally, the compounder need to make sure that the container is properly sealed, and the preparation is protected against damage/contamination.

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5. Labeling

The preparation container is labeled according to all applicable laws and guidelines.

➢Label on the dispensed preparation has two main functions:

1. To uniquely identify the contents of the container.
2. To ensure that patients have a clear and a concise information that enable them to take or to use their medication in the most effective and appropriate way.

➢There are two types of labels: Main label and Auxiliary label

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The Main Label

1. Name and address of the pharmacy
2. The patient's name
3. The name of the preparation, written as

quantity of preparation (50 ml, 40 tablet, 30 gm) , the name of preparation, the name of dosage form, the strength number written as whole numbers where decimal should be avoided but if the decimals are un-avoided write (zero decimal then the number, (0.5), then the unit of concentration and the source of the formula if it is an official product.

Ex: 50 mL of sodium salicylate mixture 10 % W/V BP.

1. The use of the preparation, give the patient clear and complete instructions on how to take the drug, quantity to be taken, frequency, route of administration and the method of use: Take 5mL three times daily orally after food.
2. Storage conditions: "*Store in cool place", "store in dry place", " store in dark place"*
3. The date of the compounding, written as day/ month/ year.

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