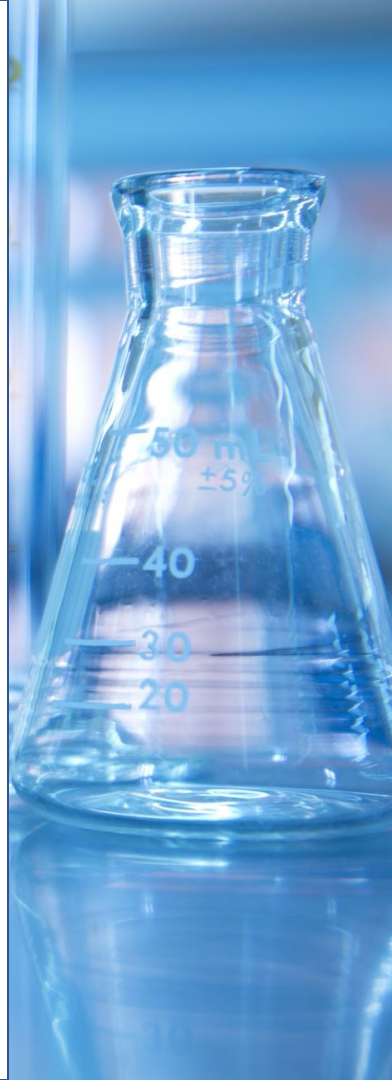
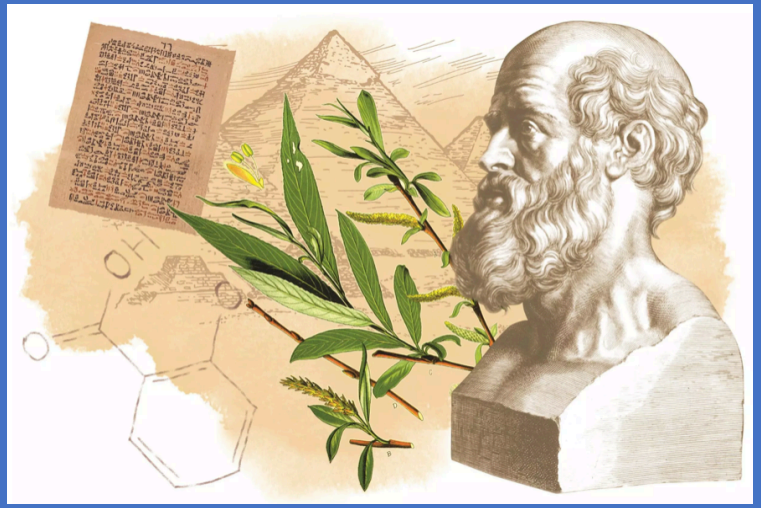
ملاحظة : هاد شرح للمادة أكثر من كونه تفريغ لانه الدكتورة ما خلصت عن السلايدات
والامتحان رح يكون منهم

Introduction to Pharmaceutical Compounding





History of Pharmacy Profession

It is impossible to specify when humans first started to mix materials and formulate preparations that produced either perceived or real therapeutic effects. However, it is known that the compounding of medicinal preparations from animal, vegetable (liquorice, mustard, myrth) , and opium and mineral sources has been practised in a sophisticated form by ancient civilisations such as The Ancient Egyptians, Mesopotamian civilisations, the Ancient Greek.

- ما بنعرف عن بالمشت صناعة الادوية و العلاجات
- كان منهم مركبات ليها تأثير ومنهم مركبات مش فعالة
- مصدر المواد : حيوانات / خضار / أفيون / معادن
  - كان شكلها معقد
- الخضار مثل : عرق السوس / الخردل / myrrh
- من الحضارات اللي كانت تركب ادوية : المصرية
  - اليونان
  - العراق (مابين النهرين)

Definition of Pharmaceutical Compounding

Based on United States Pharmacopeia (USP-NF) chapter <795>: pharmaceutical compounding—nonsterile preparations, compounding can be defined as :

''The preparation, mixing, assembling, altering, packaging, and labeling of a drug, drug-delivery device, or device in accordance with a licensed practitioner's prescription, medication order, or initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice".

مصطلح nonsterile هي تراكيب عادي لو كانت فيها جراثيم أو بكتيريا لانها تستخدم في اماكن من الجسم ما بتحتاج تعقيم كامل

الترجمة الحرفية : مستحضرات غير معقمة

← التعريف مبني على الفارماكوبيا الأمريكية اختصارها USP-NF

← تعريف الـ (مستحضرات غير معقمة أو تراكيب صيدلانية) مأخوذ من الشابتر 795

ترجمة التعريف: تحضير وخلط وتجميع وتعديل وتغليف ووضع ملصقات على دواء أو جهاز توصيل دواء أو جهاز آخر وفقًا لوصفة طبية أو أمر دواء أو مبادرة من ممارس مرخص بناءً على العلاقة بين الممارس والمريض والصيدلي والمركب في سياق الممارسة المهنية.

Why Extemporaneous compounding is needed:

معناها الحرفي مرتجل بس Extemporaneous

Extemporaneous compounding مصطلح هذه العبارة التركيبية والمقصود

تحضير الدواء لمريض معين بشكل فوري داخل الصيدلية

الأمثلة على أوقات بنحتاج نحضر دواء بالسلايد اللي بعده

- **Pediatric patients** requiring diluted adult strengths of drugs.

- Patients needing an oral **solution or suspension** of a product that is only available in another form.

- Patients with **sensitivity** to dyes, preservatives, or flavoring agents found in commercial formulations.

- Dermatological formulations with fortified (strengthened) or diluted concentrations of commercially available products.

- Compounding for **animals.**

- **Reconstitution** of a lyophilised powder to form a simple solution

- In hospital compounding involves the preparation of IV admixtures, parenteral nutrition solutions, and radiopharmaceuticals

- In home health care compounding requires the preparation of syringes and other devices for home-infusion administration

- المرضى الأطفال
- معلق دوائي: سائل فيه الدواء
- صلب موزع بالسائل متى ذاب فيه
- حساسية
- صبغة
- مواد حافظة
- منكهات
- تركيبات تجارية (من المصانع)
- جلدية
- لها مركز المادة
- إعادة تكوين
- مسحوق مجفف بالتجميد
- محاليل تغذية وريدية
- خلطات الوريد
- الأدوية المشعة

- في المستشفيات في أدوية لازم تتحضر الأشعة بالجهة نوى
- لما المريض يتعالج بالبيت بدل المستشفى في أدوية لازم تتحضر بوقتها

- ١ حيانا الأطفال يحتاجوا دواء بس يكون مخفف من جرعة البالغين
- لما مريض يحتاج دواء بس بده اياه بشكل oral solution أو oral suspension
- المريض اللي عنده حساسية من أي مكونات الدواء
- أمراض جلدية أدويتها بدها تخفيف أو تركيز
- مركبات أو أدوية الحيوانات
- إعادة تركيب دواء من مسحوق مجفف بالتبريد ليصير محلول (غالباً عشان يزيد مدة الصلاحية أو يحافظ على Stability)

اعادة التحضير

What is Reconstitution?

Some drugs must be stored in powdered form because they rapidly lose their power once they are mixed into a solution. These drugs will then have to be **reconstituted**, or mixed with a liquid, called the **diluent**, before they can be administered.

- بعض الادوية ثباتها قليل أو لا يكون Stability
لما يصير تتخزن ك سائل

بتخزنها بالصيدلية كمادر ولما يجتاجها مريض بنعيد تحضيرها بأنه نخضفها أو نحولها لسائل

Example


NDC 0002-1497-01
VIAL No. 767
Lilly
℞
KEFZOL®
STERILE
CEFAZOLIN
SODIUM, USP
Equiv. to
500 mg
Cefazolin
تحذير
CAUTION—Federal (U.S.A.) law prohibits dispensing without prescription.
For I.M. or I.V. Use
Dosage—See literature.
To prepare solution add 2 ml Sterile Water for Injection or 0.9% Sodium Chloride Injection. Provides an approximate volume of 2.2 ml (225 mg per ml)
SHAKE WELL
Protect from Light
Prior to Reconstitution: Store at Controlled Room Temperature 59° to 86°F (15° to 30°C)
After Reconstitution: Store in a refrigerator. For Storage Time - See Accompanying Literature. If kept at room temperature, use within 24 hours.
Lyophilized
WV 4520 AMX

Dosage form (Preparation)

Active Pharmaceutical ingredient (API):

Any substance or mixture of substances intended to be used in the compounding of a drug preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body.

Added substances

Ingredients that are necessary to compound a preparation but are not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms *inactive ingredients, excipients,* and *pharmaceutical ingredients.*

General Principles of Compounding

1. Personnel are appropriately trained and are capable of performing and qualified to perform their assigned duties. Such training should be documented.

2. Compounding ingredients of the appropriate identity, purity, and quality are purchased from reliable sources and are properly stored according to manufacturer specifications or *pharmacopeial* standards.

3. Bulk component containers are labeled with appropriate Occupational Safety and Health Administration (OSHA) hazard communication labels*, and Material Safety Data Sheets (MSDS)* are available to compounding personnel for all drugs and chemicals used in compounding.

4. All equipment used in compounding is clean, properly maintained, and used appropriately.

* Refer to the PDF documents provided with the lecture notes on MS Teams

تكملة اللي فوق

General Principles of Compounding

1. The compounding environment is suitable for its intended purpose; and procedures are implemented to prevent cross-contamination, especially when compounding with drugs (e.g., hazardous drugs and known allergens like penicillin) that require special precautions.

2. Only authorised personnel are allowed in the immediate vicinity of the drug compounding operations.

3. There is assurance that processes are always carried out as intended or specified and are reproducible.

4. Compounding conditions and procedures are adequate for preventing errors.

5. All aspects of compounding are appropriately documented.

6. Adequate procedures and records exist for investigating and correcting failures or problems in compounding, testing, or the preparation itself.

- بيئة تحضير مناسبة - تطبيق اجراءات لمنع التلوث المتبادل خاصة مع ادوية معينة
- فقط للموظفين المصرح لهم يدخلوا المكان
- ضمان أنه العمليات مخطط لها وقابلة للتكرار
- اجراءات كافية لمنع الاخطاء
- كل شيء يكون موثق
- التحقيق بحالات الفشل وتصحيح المشاكل

Grades of Materials used in compounding

I. Pharmacopeial grade:

Meets USP/NF or BP standards

II. American Chemical Society (ACS) grade:

Meets the specifications of the Reagent Chemicals Committee of the American Chemical Society. ACS requires the chemicals to be at least 95% pure. Hence, materials of this grade considered of high quality.

III. Analytical grade (AR):

Very high purity reagents.

IV. High-performance liquid chromatography (HPLC) grade:

Very high purity.

Used in high pressure chromatography.

V. Ultra Performance Liquid Chromatography (UPLC) grade :

Very high purity.

Used in UPLC.

دستور الادوية

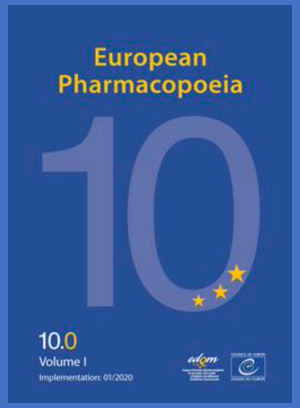
Pharmacopeias

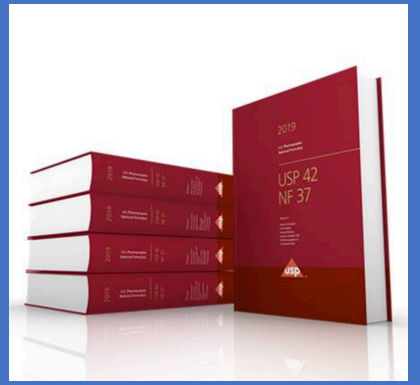
The term pharmacopeia originates from the Greek word pharmakon, meaning drug, and poiein, meaning make.

1. **The British Pharmacopoeia (BP)**
2. **The European Pharmacopoeia (Ph Eur)***
3. **The unites States Pharmacopoeia (USP)**

صاد

صاد موجود بـ





*The European Pharmacopoeia (Ph Eur) is included in the British Pharmacopoeia which is available online

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, as well as strength, quality, purity, and consistency.

الفارماكوبيا هو دستور للادوية عبارة عن معايير
بيتبعوها بتصنيع الادوية عشان كل الدرجة بهاي الدول
تكون اكيد آمنة وهش كل حد يصنع بكيفه

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 publishesd every year by **United States Pharmacopeial Convention** (usually also called the USP) who the trademark and the copyrights.

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.

Major Sections of USP-NF

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

USP/NF Chapters

مستحضرات غير معقمة (شرحت معناها بالمحاضرة قبل)

Chapters <795> - Pharmaceutical Compounding - Nonsterile Preparations

- Published in 2000
- Enforceable

يعني أنه قانونيًا ملزمين بتطبيقه

مستحضرات معقمة

Chapter <797> - cPharmaceutical Compounding - Sterile Preparations

- Became official in 2004.

Other Chapters

- Containers <661> لمعايير العبوات
- Good Compounding Practices <1075>
- Pharmaceutical Stability <1150> العلاقة باستقرار المواد
- Pharmaceutical Dosage Forms <1151> اشكال الادوية ومعاييرها

The British Pharmacopoeia (BP)

- Volumes I and II: Contain medicinal substances. يحتوي على المواد الطبية

- Volume III: Contains formulated preparations, Blood related preparations, Immunological products, Radiopharmaceutical preparations, Surgical materials, Homeopathic preparations.

- Volume IV: Contains appendices الحق, supplementary فصول اضافية chapters, Infrared Reference Spectra, Index.

- Volume V: The veterinary British Pharmacopoeia. البيطري

- Volume VI: Contains CD ROM for the electronic version of the BP. CD النسخة الالكترونية

تحضير آني

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.

← عملية تحضير المركبات الصيدلانية عملية خطيرة وفي مستويات لهاد الخطر صنفها الـ USP الأمريكي

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

الخطر بتقسم لـ 3 مستويات أو درجات
هاي معايير التقييم اللي بناء عليها بنحدد مستوى الخطر

1. The degree of difficulty or complexity of the compounding process. ١. صعوبة تركيب الدوا
2. The stability information and warnings. ٢. الـ stability
3. Packaging and storage requirements. ٣. التغليف والتخزين اللي بيحتاجه الدوا عشان نحافظ عليه
4. Dosage forms. ٤. شكل الدوا (كريم، تابلت،...)
5. Complexity of calculations. ٥. تعقيد الحسابات عشان نعمله
6. Local versus systemic biological disposition. ٦. المكان اللي بيستهدفه الدوا (يعني بنحط موضعي ولا بستهدف الجسم كله ولا لجهاز معين بالجسم)
7. Level of risk to the compounder. ٧. مستوى خطورته على الشخص اللي بصنعه
8. Potential for risk of harm to the patient. ٨. خطورته على المريض (الآثار الجانبية أو المخاطر المحتملة)

مستوى الخطر: معقد
الصيدلاني يركب مركب
يحتاج بيئة خاصة وتدريب
ومعدات معينة

مستوى الخطر: متوسط
انه الصيدلي يقل مركب
وفي غالباً معلومة ناقصة

١. يتطلب حسابات خاصة
٢. معلومات ناقصة عن
الثباتية أو اي اشي ثاني

مستوى الخطر: بسيط
الصيدلي يعتمد على مصدر
موثوق بتركيب الدوا
يوفر كل المعلومات

يكون
اله دستور تركيب بال USP
أو
نشر بمقال علمي بمجلة موثوقة
لهم شروط المقال
١. يحدد الكميات للمواد
٢. يحدد خطوات التحضير
٣. يبين الثباتية وتاريخ الانتهاء

➢ 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 and equipment, and stability data for that formulation with appropriate BUDs; or reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer.

منتجات دوائية جاهزة

➢ 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.

لم شكل صيدلاني
لمادة تمتص عبر الجلد

لم مستحضر ذو تحرر معدل
(ما بعرف ايش يعني المهم تحفظها ت)

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.

Compounding categories practice examples

The main compounding steps:

الخطوات الرئيسية للتحضير الصيدلاني

١. نستلم الوصفة الطبية
٢. نقرأها نفسرها ونحللها
٣. نحضر التركيبة المطلوبة
٤. نغلف الدوا
٥. بنحط الليبل ومعلومات الدوا
٦. نتأكد انه عملنا كل اشي صح
٧. بنحكي للمريض كل شي عن a. الاستخدام
b. التخزين
c. علامات إذا الدوا مزبت

1. Pharmacist receives prescription or medication order.
2. Review and interpret (translate) the prescription.
3. Compounding the preparation*
4. Packaging *
5. Labelling *

بنشرح عنهم اكثر بالمحاضرات الجاية

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

السجلين المذكورين للتأكد من عدم وقوع أخطاء بالتحضير

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.).

هقدم الوحاية مناسبة

* Detailed explanation will be presented in the following slides.

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*

Rx

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

Refills *0*

B. Pajamo M.D.

1. تقييم الجرعة، والأمان، والاستخدام المقصود للتركيبة لضمان ملاءمتها من حيث: الخصائص الكيميائية والفيزيائية للمكونات، والملاءمة العلاجية للشكل الصيدلاني، وطريقة الإعطاء (بما في ذلك

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.

2. اذا اول مرة بنعمل المركب لازم نعمله سجل تركيب ولازم نتبع السجل كل مرة بنرجع نعمل التركيبة

3. اذا هو اول مرة لازم نرجع للسجل الخاص بالتركيبة

4. تحدد المواد والمعدات اللي بنحتاجها وتتأكد من نظافة كلشي وانها بتشتغل مع

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.

4. Packaging

➢ The compounder shall ensure that the containers and container closures used in packaging:

شروط لازم نتأكد منها انها بالعبوات والغطيتهم موجودة

1. Meet *USP* requirements and when available, compounding monographs.

١. بتنطبق عليها شروط USP و المونوغرام اذا كان انها مونوغراف

2. Made of a material that doesn't change the quality, strength, or purity of the preparation.

٢. مصنوعة من مواد ما بتأثر على الدوا

3. Stored off the floor, handled and stored to prevent contamination, and rotated so that the oldest stock is used first.

منع التلوث

٣. تخزن بعيداً عن الارض وعن التلوث ونستخدم الاقدم أولاً

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.

بنختار العبوة المناسبة اللي ما تتفاعل مع المحتوى اللي رح تنحط فيه

5. Finally, the compounder need to make sure that the container is properly sealed, and the preparation is protected against damage/contamination.

نتأكد انه العلبة مغلقة و محمية من التلوث والتلف

5. Labeling

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

➢ Label on the dispensed preparation has two main functions:

وظيفتين د الليبل
١. التعريف بمحتويات العلبة
٢. معلومات بتساعد المريض عن استخدام الدواء

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

The Main Lable

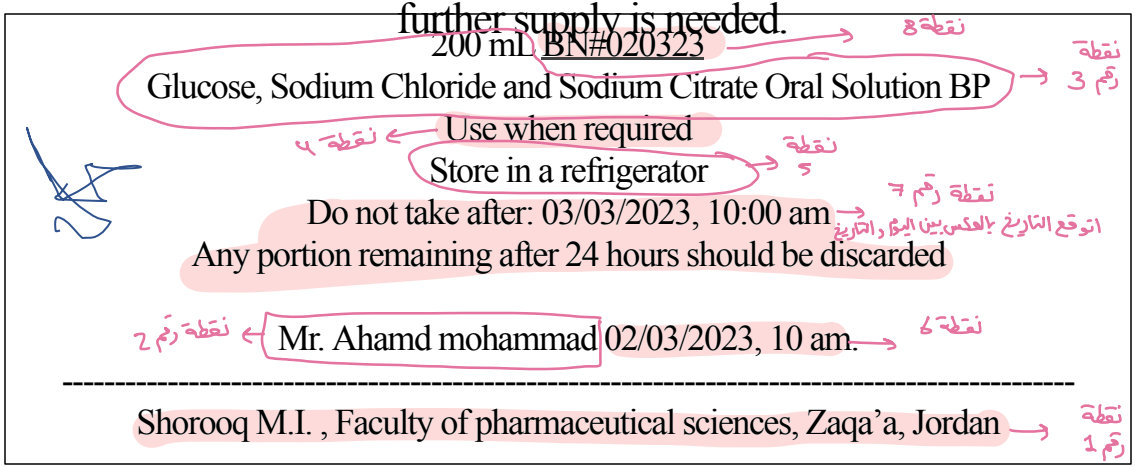
1. Name and address of the pharmacy
2. The patient's name
3. The name of the preparation, written as quantity of preparation (50 ml, 40 tablet, 30 gm) the name of preparation, the name of dosage form, the strength number written as whole numbers where decimal should be avoided but if the decimals are 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.
4. 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.
5. Storage conditions: "*Store in cool place", "store in dry place", " store in dark place"*
6. The date of the compounding, written as day/ month/ year.

الانتهاء هام

7. Beyond-Use Date (BUD): The date after which a compounded preparation shall not be used; determined from the date the preparation is compounded according to references, this time is different from expiry date which is longer, written as day/month/year.

تاريخ عدم الاستخدام مختلف عن تاريخ الانتهاء

2. The prescription reference number: number written on the prescription and on the container, this allows the record to be traced easily if the patient brings the container and not the prescription when a further supply is needed.



اسئلة على الدقة بس صون مقارنة بين النقاط النظرية وبين تطبيقها

Stability

Stability

- The extent to which a dosage form retains the same properties and characteristics that it possessed at the time of its manufacture.

Expiration date

- The date until which the manufacturer can guarantee of the safety and full potency of a drug- usually determined after extensive study of the product's stability.

Beyond-use dates

- Used for compounded preparations only and are generally in the order of "days" or "months."

Shelf life

- Length of time a packaged drug will last without deteriorating

تحديد

كيف نحدد الـ BUD لـ non-sterile ؟ عندي ٣ أقسام : (الشرح بالسلايد اللي بعده)

Assigning a Beyond-Use Date

For non-sterile compounded preparations that have no stability data; the following BUD are assigned:

1. **For Nonaqueous liquids and solid formulations**

سائلة بس مافيها ماء أو رطوبة

If the source of the active drug is a manufactured drug product, the beyond-use date is not later than 25% of the time remaining until the drug product's expiration date, or 6 months, whichever is earlier.

If the source of the active drug is a USP or NF substance, the beyond-use date is not later than 6 months.

2. **For Water containing formulations**

When prepared from ingredients in solid form, the beyond-use date should be not later than 14 days when stored at cold temperature.

3. **For all other formulations**

The beyond-use date is not later than the intended duration of therapy or 30 days, whichever is earlier.

BUD for non-sterile

Non aqueous liquid or solid

- Manufactured
  - محضره من المصنع
  - بنشوف المدة الباقية لتاريخ الانتهاء
  - وبنوخذ 25% منها
  - هسا بنقارن مين اقصر هاي المدة ولا 6 أشهر ؟
  - بنوخذ المدة الاقصر يسنهم بتكون هي الـ BUD
- اذا كان مصدر المادة الفعالة من USP أو الـ NF
  - مباشرة الـ BUD 6 أشهر

water-containig formulation

- مباشرة بعرف الـ BUD 14 يوم
- بس! في شرطين
  1. تم تحضيرها من مادة صلبة
  2. نحفظها بدرجة حرارة باردة

بقية الـ formulations

- اذا مدة العلاج اقل من 30 يوم
  - بتكون مدة العلاج هي الـ BUD
- اذا مدة العلاج اكثر من 30 يوم
  - الـ BUD بكون 30 يوم

Storage Requirements

* يس لازم نحفظهم

Term	Definition*
Freezer	-25°C to -10°C
Protect from Freezing	Store above 0°C
Cold	temperature not exceeding 8°C
Refrigerator	Between 2°C and 8°C
Cool	Between 8°C and 15°C
Room Temperature (Ambient temperature)	Temperature in the working environment
Controlled Room Temperature	Thermostatically controlled at 20°C to 25 0C
Warm	Between 30° and 40°C
Excessive Heat =	temperature above 40° C
Dry place	A place that does not exceed 40% average relative humidity at 20°C
Do not refrigerate:	the storage temperature of 20°–25°C
Protect from light	The article must be packaged in a light resistant Container.

- *USP Chapter 〈659〉 Packaging And Storage Requirements

كل اللي فوق كانوا المهم علاقة بال main label

Auxiliary Labels

- The auxiliary labels: arranged (توضع) on the other side of the container, these labels are cautionary (تحذيرية) or advisory (ارشادية) depending on the type of dosage form.
  - Needed to provide supplementary information regarding (تتعلق) proper and safe administration, use, or storage of the formulation (الادارة الآمنة والصحيحة)
- *'keep out of reach of children" for oral use" "for external use", "not to be taken orally", "flammable", "not to be swallowed", and "shake the bottle before use".* (أمثلة)
- (Controlled substances (مواد خاضعة للرقابة)) from schedules II,III, and IV must carry an auxiliary label stating "Caution: Federal Law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed"

المواد من الجداول ٢ و٣ و٤ من USP لازم يحطوا هاد التنبيه على الليبل الارشادي

ممنوع اعطاء المواد لاي حد غير المريض اللي انوصفله

Auxiliary Labels Examples

Preparations lables and packaging examples

حفظ

Auxiliary labels	Packaging	Color of print	Type of preparation
For oral use	Plain bottle(glass, plastic)	Black	Oral solutions (ORS,Elixir,syrups)
Not to be taken orally, for ear use only	Fluted hexagonal glass dropper bottle or plastic squeeze bottle قطارة زجاجية سداسية مضلعة أو زجاجة بلاستيك قابلة للعصر	Red	Ear drops
Not to be taken orally, for eye use only, sterile till open	Fluted hexagonal glass dropper bottle or plastic squeeze bottle	black	Eye drops
Not to be taken orally, for nasal use only	Fluted hexagonal glass dropper bottle or plastic squeeze bottle	black	Nasal drops
For external use only	Fluted bottle (glass, plastic)	Red	External solutions(antiseptic, lotions)

Caution !

Reviewing and understanding the prescription as well as labeling the compounded preparation involve a “language” that must be learned and utilised to assure the quality and the efficacy of the preparation and to avoid any errors that will put the patient life at risk.

مراجعة وفهم الوصفة ووضع الملصق بيتضمنوا لغة لازم تكون ناصمينها

Care must be taken when interpreting any abbreviation, some abbreviations are prone to misinterpretation, so their use is not encouraged

نتبه واحنا بنفسر الاختصارات للمريض عشان ماينفهم اي شي خطأ ويروح فيها

https://www.ismp.org , the website for the institute of safe medication practices provide lists and tools to help preventing medication errors.

هاد الموقع فيه اشهر الاخطاء اللي بتصير بين الصيدلاني والمريض وكيف نتجنبها

Prescription abbreviations in Pharmacy

اختصارات

Abbreviations in pharmacy cover the following aspects:

الاشياء اللي بنعملها اختصار هي:

1. Route of administration طريقة الاعطاء
2. Dosage Form الشكل الصيدلاني
3. Frequency or times of administration وقت الاعطاء والتكرار (يعني كم مرة باليوم)
4. Dosage كم الجرعة

الجداول تحت فيها الاختصارات وطبعا حفظ ومعاهم كمان اختصارات وحدات القياس

1. *Route of Administration* Abbreviations

Abbreviation	Latin term	Meaning	
IM	-	Intramuscular	حقن عضلي
IV	-	Intravenous	حقن وريدي
p.o.	Per os	By Mouth, Orally	من طريق الفم
SL	-	Sublingually, Under the tongue	تحت اللسان
ad	Auris Dextra	Right ear	الاذن اليمنى
a.s. or a.l.	Auris Sinister, Auris Laeva	Left ear	الاذن اليسرى
a.u.	Auris Utraque	Each ear	كل اذن (يعني الاثنتين)
o.d.	Oculus Dexter	Right eye	العين اليمين
o.s.	Oculus Sinister	Left eye	العين اليسار
o.u.	Oculus Uterque	Both eyes	العينتين

3. *Time of Administration Abbreviations*

Abbreviation	Latin term	Meaning
ac	Ante Cibum	Before meals
pc	Post Cibum	After meals
hs	Hora Somni	At bedtime
qd	Quaque Die	Every day
prn	Pro Re Nata	As needed
qid	Quater In Die	Four times a Day
tid	Ter In Die	Three times a Day
bid	Bis In Die	Two times a Day

4. *Dosage Form Abbreviations*

elix □ elixir

Supp □ suppository

ung □ ointment

tab □ tablet

Cap □ capsule

sol □ solution

susp □ suspension

Measurement Abbreviations

I, II, III □ 1,2,3

gm □ Gram

gr □ Grain

L □ Liter

mg □ microgram

µg (mcg)□ microgram

meq □ milliequivalent

ml □ milliliter

qs □ a sufficient quantity

Label wording instructions

تعليمات الكتابة على الليبل (سواء الـ main أو الثاني)

باختصار لازم نكتب كل اشي بالتفصيل حتى لو اشي بديهي

تحديد الجرعة اللي رح يتناولها

1. **Indicate the dosage form to be administered.**
   "Take one capsule every day" instead of "Take one every day".

مثال صح — مثال خطأ

2. **Use words NOT of numbers.**
   "Take one capsule every day" instead of "Take 1 capsule every day"

3. **Specify the route of administration if the medication is not intended for oral use.**
   "Insert one suppository vaginally every night at bedtime"

4. **Specify which side is to receive the medication if more than one organ is present.**
"Instill two drops in left eye daily" instead of "instill two drops daily"

5. **Do not use abbreviations.**
الا ختصارات
"Take two capsules twice a day" and not "Take two caps twice a day.

6. **Use familiar words**
Teaspoonful or 10 mL
ملعقة صغيرة
طبعا لما نشتغل بصيدلية بنكتب بالعربي
لانه الهدف توصيل المعلومة واضحة للمريض

7. **Specify the amount of active ingredient per dosage unit.**
نكتب نسبة المادة الفعالة بالدواء
Amoxicillin 250mg/5ml, Phenergan 25mg/ suppository.

8. **When dispensing medications in bulk, such as solutions, suspensions, emulsions, ointments, or creams, express the amount of active ingredients as a percentage strength.**
الادوية اللي بتيجي بكمية كبيرة بنعبر عن كمية المادة الفعالة بنسبة مؤوية
Hydrocortisone cream 1%, Betadine solution 2%.

9. **When writing direction for use, start with a verb,** Take, instill, inhale, insert, or apply. And **Indicate the route of administration,** apply to affected area. Take one tablet by mouth. Insert rectally. Place one tablet under the tongue.
نكتب طريقة أخذ الدواء بفعل أمر وتوضح الطريقة مثل ادهن المنطقة المصابة
تناول قرص واحد عن طريق الفم

At last:

Don’t add information!

Never add information based on what you assume the prescriber meant. The prescriber has knowledge of the patient’s condition that you don’t.

1

!Don't add information

Never add information based on what you assume the prescriber meant

The prescriber has knowledge of the patient's conditions that you don't

ما تضيف معلومات بس لانك افترضت انها صح الطبيب ادرى

Check against the original!

During the fill process, always refer to the original prescription first and then refer to the label.

2

Check against the original!

During the fill process, always refer to the original prescription first and then refer to the label.

لما تحضر الدواء دايما ارجع للوصفة الطبية بعدها لـ الليبل

هاد عنوان الـثـابتّ الجاي

Equipment used Pharmaceutical Compounding

Types of Equipment

Measuring

ادوات قياس

- Balance, weights, weighing containers, volumetric glassware (graduates, pipets, flasks, syringes).

محقن

Mixing

خلط

- Beakers, Erlenmeyer flasks, spatulas, funnels, sieves, mortar and pestle.

منخل

Molding

ادوات التشكيل
أو القوالب

- Hot plates, suppository molds, capsule shells, ointment slabs.

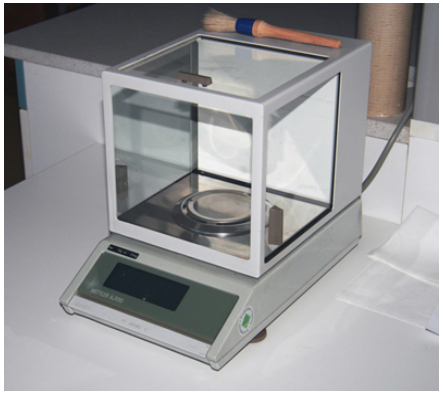
قالب التحاميل
كبسولات فارغة
لتحضير المراهم

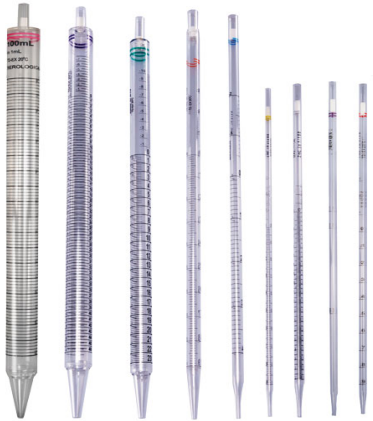
Packaging

تغليف

- Prescription bottles, capsule vials, suppository boxes, ointment jars.


STAINLESS STEEL
JAPAN






10
20
30
40
50
60
ml
70


1000 10ml

Pharmaceutical Calculations

As we mentioned earlier, compounding **is an inherently risky activity.** One of the greatest sources for error in prescription compounding is in the area of pharmacy calculations. There is no place for ignorance in this area and an individual how are incompetent to do the necessary calculations should not be involved in pharmaceutical compounding.

A misplaced decimal or "estimated" value for a medication can have serious consequences including death.

كما ذكرنا سابقاً، تُعد الصيدلة التركيبية (Compounding) نشاطاً ينطوي بطبيعته على مخاطر. ويُعد مجال **الحسابات الصيدلانية** أحد أكبر مصادر الخطأ في تحضير الوصفات التركيبية.

لا يوجد مكان للجهل في هذا المجال، وأي فرد يفتقر للكفاءة اللازمة لإجراء الحسابات الضرورية **يجب ألا يشارك** في عملية التحضير الصيدلاني. إن وضع فاصلة عشرية في غير مكانها أو استخدام قيمة "تقديرية" للدواء يمكن أن يؤدي إلى عواقب وخيمة، بما في ذلك الوفاة.

حكي مش مهم و مقدمة لا ممكن الباي بس مي ترجمته

هاد موقع للاخبار
وهاي مقالة عليه برضه مش مهمة

Chemists fined over deadly medicine

Helen Carter

Thu 2 Mar 2000 02.17 GMT

Two Boots pharmacists who dispensed a peppermint solution which killed a four-day-old baby were fined yesterday after they admitted supplying defective medicine.

The medicine given to Matthew Young, from Runcorn, Cheshire, contained 20 times too much chloroform. He suffered a heart attack and brain damage, and died in hospital 18 days later.

At Chester crown court yesterday a verdict of not guilty to manslaughter was ordered against pharmacist Lisa Taylor-Lloyd, 27, and Ziad Kattab, 25, a trainee pharmacist, who were fined £1,000 and £750 respectively after they admitted supplying the solution.

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'He was gaslighting

Thank you!

Any questions?