



لجان الرفعات

DISPENSING



MORPHINE ACADEMY

MORPHINE
ACADEMY

Pharmaceutical Compounding- Introduction

Dr. Saja Hamed

The origin of the pharmacy profession

- Compounding of medicinal preparations from material of animal, vegetable and mineral sources has been practiced Ancient Egypt, Greece, Rome and the Arabian culture
- Opium, myrrh, and liquorice
- History of Pharmacy Profession (wikipedia)

عبارة عن مصادر المواد الطبيعية الي كانوا بيعتمدو عليها في الطب في السنين القديمة

صيدلية (جردانة)
تأسست في عام 1923
المؤسس لها الصيدلاني عبد الرحيم جردانة
صيدلية (الصباغ)
تأسست في عام 1934
المؤسس لها الصيدلاني سليم محمد تحسين الصباغ

أول صيدليتين فتحوا في عمان
+
طلبت منا الدكتورة نبحت عن
اللقاء مع الدكتور محمد تحسين
سليم موجود على الصفحة
الرسمية لكلية العلوم الصيدلانية
على الفيس

Compounding

- **Extemporaneous compounding**

- On-demand preparation of a drug product. حسب الطلب
- According to a physician's prescription. وصفة طبية
- Meets the unique needs of an individual patient. وطبيعاً لازم يلبي الإحتياجات لكل مريض

- **Manufacturing**

- The production or processing of a drug in a **LARGE** quantity by various mechanisms. الإنتاج المعالجة متنوعه الآليات

والفرق بيناتهم بالكمية يعني
Extemporaneous compounding يكون لمريض واحد فقط
Manufacturing تكون من الشركة لكافة الناس بكميات كبيرة

Definitions

- Chapter <1075> Good Compounding Practices in the USP-NF defines compounding as:
“ the preparation, mixing, assembling, packaging, or labeling of a drug or device in accordance with a licensed practitioner’s prescription under an initiative based on the practitioner/patient/pharmacist/compounder relationship in the course of professional practice”

هي عبارة عن تحضير و خلط و تعبئة دواء حسب وصفة طبية مرخصة بناءً على العلاقة بين الطبيب والمريض والصيدلاني

Compounding is NOT manufacturing in the legal sense

وعنا بالاردن JFDA

- Manufacturing is the mass production of drug products that have been approved by the Food and Drug Administration (FDA).
These products are sold to pharmacies, health care practitioners or others authorized under state and federal law to resell them.
إنتاج متسلسل
مؤسسة الغذاء والدواء
ممارسي الرعاية الصحية مثل الدكتور الصيدلاني
او غيرهم ممن يحق بموجب قانون الولاية والقانون الفيدرالي إعادة بيعهم
- Manufacturing is defined in USP/NF as: تعريف تاني كمان مفصل اكثر:
“the production, propagation, conversion, or processing of a drug or device, either directly or indirectly, by extraction of the drug from substances of natural origin or by means of chemical or biological synthesis.....”
إنتاج
تكاثر
تحويل
معالجة
استخلاص
أصل طبيعي

الجوانب التنظيمية

Regulatory Aspects of Compounding

كتابين فيهم كل شيء بيتعلق بال compending من أنظمة ومعلومات

Pharmacopoeias and Formularies

- Regulations and information related to compounding are found in **Pharmacopoeias and Formularies**
- These are books that contain the standards for the drug other related substances, tests, formulas, doses, storage conditions etc.
 من ظروف التخزين والجرعات والصيغ والاختبارات
- These books are referred to collectively as drug compendia.
- These books are revised from time to time to introduce the latest information available.

وتُعرف هذه الكتب بدساتير الأدوية

وطبعًا تتجدد من وقت لآخر عشان تعطينا دائمًا أحدث نسخة
لأنه العلم بطبيعته مُتجدد

Pharmacopoeias and Formularies

Common drug compendia أمثلة على دساتير الأدوية

- ◆ The United States pharmacopoeia (USP) الأمريكي
- ◆ British pharmacopoeia (BP) البريطاني
- ◆ European pharmacopoeia (Ph. Eur.) الأوروبي
- ◆ The pharmacopoeia of Japan الياباني
- ◆ International pharmacopoeia (Available online) الدولي
- ◆ The Indian pharmacopoeia الهندي

USP

- The term pharmacopeia comes from the Greek *pharmakon*, meaning *drug*, and *poiein*, meaning *make*, and the combination indicates any recipe or formula or other standards required to make or prepare a drug.

وهاد الاسم

جاء من اليونان

هي عبارة عن دستور أدوية يحتوي على كافة المتطلبات للأدوية

USP

دستور الأدوية الأمريكي

- The United States Pharmacopeia (USP) is the official pharmacopeia of the United States, ^{نشرت} published dually with the National Formulary as the USP-NF. The **United States Pharmacopeial Convention** (usually also called the USP) is the nonprofit organization that owns the trademark and copyright to the USP-NF and publishes it every year.

يمكن نحكي هذه

أقسام الأدوية

والفرق بيناتهم انه OTC بتعطيها للمريض بدون وصفة طبية

زي البندول مثلاً بس مش معناته بدون استشارة الصيدلاني

أما prescription لازم بوصفة طبية حتى تعطيها للمريض



② اختصارها OTC

- Prescription and over-the-counter medicines and other

③

Control drug

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.

أما هذه بتكون للأدوية التي تحتاج لوصفة خاصة نتيجة الإدمان عليها

أما هذه مكملات غذائية وليست دواء

USP

اعتمدت على المعايير التالية

- The USP and NF adopt standards for:

- drug substances, خصائص المادة الفعالة التي يدي استخدامها لتصنيع الدواء
- pharmaceutical ingredients, أي مواد أخرى غير المادة الفعالة أو ما يعرف بال (excipient) المادة المساعدة
- and dosage forms أشكال الجرعات الهدف أنه تعكس أفضل الممارسات في الطب والصيدلة وتوفر الاختبارات والتحاليل المناسبة لإثبات الامتثال لهذه المعايير

reflecting the best in the current practices of medicine and pharmacy and provide suitable tests and assay procedures for demonstrating compliance with these standards

- 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.

الهيئات التنظيمية مثل FDA

الشركات المصنعة

القوة

الجودة

نقاء

تناسق

لازم التأكد إنها بالهوية والشكل المناسب

Pharmacopoeias and Formularies

USP/NF

- Each general chapter is assigned a number appears in brackets
- <1> to <999> → are considered requirements and official monographs and standards **legally enforceable by the FDA.**
- <1000> to <1999> are considered informational
- <2000> and above → apply to nutritional supplements

Chapters

- **Chapters <795> - called Pharmaceutical Compounding - Nonsterile Preparations** الأدوية غير المعقمة

- Published in 2000

← نُشِرَ وتعني أنها أقل تعقيمًا عند حدٍ معين لأنه هناك جراثيم ممنوعة لأنها مُمرضة

- Enforceable يعني لازم التنفيذ

- **Chapter <797> - called Pharmaceutical Compounding - Sterile Preparations,** الأدوية المعقمة

- Became official in 2004.

→ مثل الإبر أو قطرة العين أو أي شيء بدي ادخله داخل الجسم

أصبح رسميًا

- **Other Chapters**

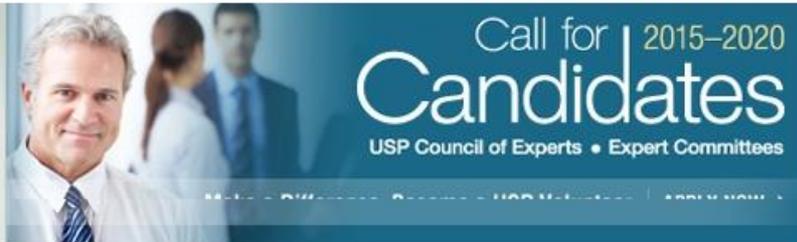
- Containers <661>
- Good Compounding Practices <1075>
- Pharmaceutical Stability <1150>
- Pharmaceutical Dosage Forms <1151>

شباتر أخرى مهمة تتعلق بالcompounding

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Our Mission

USP's mission is to improve global health through public standards and related programs that help ensure the quality, safety, and benefit of medicines and foods.



Call for **2015-2020**
Candidates
USP Council of Experts • Expert Committees



Standards Updates

[USP-NF](#)[Reference Standards](#)[Food Chemicals Codex](#)

Review these updates to the USP-NF.

- [Compounded Preparations Title Changes \(29-Aug-2014\)](#)
- [Two New Intent to Revise Notices \(25-Jul-2014\)](#)
- [Seven New Revision Bulletins \(25-Jul-2014\)](#)
- [Six New Interim Revision Announcements \(25-Jul-2014\)](#)
- [USP 38-NF 33 Revisions, Deferrals and Cancellations & IRA Commentaries \(25-Jul-2014\)](#)

Saja Hamed, Ph.D

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7/14/2025

موجود في المكتبة الطبية

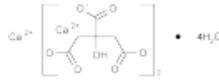
British pharmacopoeia
دستور الأدوية البريطاني



A sample of USP-NF monograph ^{دراسة}

تحتوي هذه
الدراسة على كل
التفاصيل لهذه
المادة من التركيبة
وشو تعريفه
وإلى آخره ولازم
أول ما نشترئها
نعمل عليها
اختبارات حسب
المعايير عشان
نضمن الفعالية
والجودة عشان
لو صار أي خطأ
ما نضطر
نسحب كل
الوصفات بل
الشكوك فيها
فقط

Calcium Citrate



$C_{12}H_{18}Ca_2O_{14} \cdot 4H_2O$ 570.49
1,2,3-Propanetricarboxylic acid, 2-hydroxy-, calcium salt (2:3), tetrahydrate;
Calcium citrate (3:2), tetrahydrate [5785-44-4].

DEFINITION

Calcium Citrate contains four molecules of water of hydration. When dried at 150° to constant weight, it contains NLT 97.5% and NMT 100.5% of $Ca_3(C_6H_5O_7)_2$.

IDENTIFICATION

- A.**
Analysis: Dissolve 0.5 g in a mixture of 10 mL of water and 2.5 mL of 2 N nitric acid. Add 1 mL of mercuric sulfate TS, heat to boiling, and add 1 mL of potassium permanganate TS.
Acceptance criteria: A white precipitate is formed.
- B.**
Sample: 0.5 g of Calcium Citrate
Analysis: Ignite completely the *Sample* at as low a temperature as possible, cool, and dissolve the residue in dilute glacial acetic acid (1:10). Filter, and add 10 mL of ammonium oxalate TS to the filtrate.
Acceptance criteria: A voluminous white precipitate that is soluble in hydrochloric acid is formed.

ASSAY

PROCEDURE

Sample solution: Dissolve 350 mg of Calcium Citrate, previously dried at 150° to constant weight, in 12 mL of 0.5 M hydrochloric acid, and dilute with water to about 100 mL.
Analysis: While stirring the *Sample solution*, add 30 mL of 0.05 M edetate disodium VS from a 50-mL buret. Add 15 mL of 1 N sodium hydroxide and 300 mg of hydroxy naphthol blue, and continue the titration to a blue endpoint. Each mL of 0.05 M edetate disodium is equivalent to 8.307 mg of calcium citrate ($Ca_3(C_6H_5O_7)_2$).
Acceptance criteria: 97.5%–100.5% on the dried basis

IMPURITIES

and 10 mL of 0.2 M edetate disodium. If necessary, adjust with 1 N sodium hydroxide or 1 N hydrochloric acid to a pH of 5.5. Transfer to a 100-mL volumetric flask, and dilute with water to volume. This solution contains 0.05 µg/mL of fluoride.

Linearity solution B: Transfer 5.0 mL of the *Standard solution* to a 250-mL plastic beaker, and proceed as directed for *Linearity solution A* beginning with "Add 50 mL of water,". This solution contains 0.25 µg/mL of fluoride.

Linearity solution C: Transfer 10.0 mL of the *Standard solution* to a 250-mL plastic beaker, and proceed as directed for *Linearity solution A* beginning with "Add 50 mL of water,". This solution contains 0.50 µg/mL of fluoride.

Sample solution: Transfer 1.0 g of Calcium Citrate to a 100-mL beaker. Add 10 mL of water and, while stirring, 10 mL of 1 N hydrochloric acid. When dissolved, boil rapidly for 1 min, transfer the solution to a 250-mL plastic beaker, and cool in ice water. Add 15 mL of 1.0 M sodium citrate and 10 mL of 0.2 M edetate disodium, and adjust with 1 N sodium hydroxide or 1 N hydrochloric acid to a pH of 5.5. Transfer this solution to a 100-mL volumetric flask, and dilute with water to volume.

Electrode system: Use a fluoride-specific, ion-indicating electrode and a silver-silver chloride reference electrode connected to a pH meter capable of measuring potentials with a minimum reproducibility of ±0.2 mV (see pH (791)).

Analysis

Samples: *Linearity solution A*, *Linearity solution B*, *Linearity solution C*, and *Sample solution*
Transfer 50 mL of each *Linearity solution A*, *Linearity solution B*, and *Linearity solution C* to separate 250-mL plastic beakers, and measure the potential of each solution with the *Electrode system*. Between each reading wash the electrodes with water, and absorb any residual water by blotting the electrodes dry. Plot the logarithms of the fluoride concentrations (0.05, 0.25, and 0.50 µg/mL, respectively) versus potential to obtain a Standard response line.
Transfer 50 mL of the *Sample solution* to a 250-mL plastic beaker, and measure the potential with the *Electrode system*. From the measured potential and the Standard response line determine the concentration, *C*, in µg/mL, of fluoride ion in the *Sample solution*. Calculate the percentage of fluoride in the specimen taken by multiplying *C* by 0.01.

Acceptance criteria: NMT 0.003%

LIMIT OF ACID-INSOLUBLE SUBSTANCES

Sample solution: Dissolve 5 g of Calcium Citrate by heating with a mixture of hydrochloric acid and water (10:50) for 30 min

بالمختصر المفيد أنه كل دولة لها دستور الأدوية الخاص فيها وأي دولة ما عندها بتعتمد على معايير دستور دولة أخرى

- Over the years, a number of countries have published their own pharmacopeias,
- Including the United Kingdom, France, Italy, Japan, India, Mexico, Norway, and the former Union of Soviet Socialist Republics.
والمكسيك والهند واليابان وإيطاليا وفرنسا مثل المملكة المتحدة والنرويج والإتحاد السوفيتي
- These pharmacopeias and the *European Pharmacopeia (EP or Ph Eur)* are used within their legal jurisdictions and by multinational pharmaceutical companies that develop and market products internationally. وأنه لازم نتبع معايير كل دولة الخاصة فيها عند تصنيع الدواء فيها
- Countries not having a national pharmacopeia frequently adopt one of another country for use in setting and regulating drug standards.
- For example, Canada, which does not have its own national pharmacopeia, has traditionally used USP–NF standards

USP/NF

- The point of origin for many regulations
- Its guidelines can be legally enforced by the Food and Drug Administration (FDA)
- Established in 1820 ^{تأسست USP} to set uniform standards for the medications prescribed by physicians and to publish compendia of these standards
- NF was first published in 1888 ^{نُشرت NF} by APA ^{American Psychological Association} listing standardized formulas including the ingredients and their quantities required for compounding
- In 1975 ^{اشترت} the USP purchased the NF
- Today the USP/NF is an independent organization
^{عبارة عن منظمة مُستقلة مع بعض}

Official compounded formulations

وأكد يحتوي USP على أكثر الدراسات على التراكيب والوصفات المستخدمة في الصيدليات

- USP contains monograph of most commonly compounded preparations used in pharmacy practice that has the advantage ^{يتميز بـ} of:

- USP testing ^{اختبارات}
- Quality assurance ^{ضمان الجودة وسوف يأتي شرحه لاحقاً}
- “beyond use date” assignment ^{شبيه تاريخ الانتهاء بس هذا التاريخ بحطه الصيدلاني لما يقوم بتحضير الدواء في الصيدلية}



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هو عبارة عن دواء سائل يحتوي على مضاد حيوي يسمى (sulfanilamid) وفي عام 1937 قامت شركة أمريكية بخلطه مع مادة ethylene glycol (مادة سامة تسببت في وفاة الكثير من الناس) لتصنيعه على شكل سائل (Elixir) لذلك وبسبب هذه الحادثة صدر إقرار قانون الغذاء والدواء الأمريكي في عام 1938

Elixir sulfanilamide

From Wikipedia, the free encyclopedia

Elixir sulfanilamide was an improperly prepared sulfanilamide medicine that caused mass poisoning in the United States people. The public outcry caused by this incident and other similar disasters led to the passing of the 1938 Federal Food

History [edit]

Aside from the Pure Food and Drug Act of 1906 and the Harrison Act of 1914 banning the sale of some narcotic drugs, the States of America ensuring the safety of new drugs until Congress enacted the 1938 Food, Drug, and Cosmetic Act in re

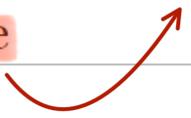
In 1937, S. E. Massengill Company, a pharmaceutical manufacturer, created a preparation of sulfanilamide using diethyl preparation "Elixir Sulfanilamide".^[3] DEG is poisonous to humans and other mammals, but Harold Watkins, the company (Though the first case of a fatality from ethylene glycol occurred in 1930 and studies had been published in medical journals its toxicity was not widely known prior to the incident.)^{[1][4]} Watkins simply added raspberry flavoring to the sulfa drug which marketed the product. Although animal testing should have been routine in most drug company operations, Massengill performed premarket safety testing of new drugs.

The company started selling and distributing the medication in September 1937. By October 11, the American Medical Association by the medication. The Food and Drug Administration was notified, and an extensive search was conducted to recover the assisted on a research project that verified that the excipient DEG was responsible for the fatal adverse effects. At least

The owner of the company, when pressed to admit some measure of culpability, infamously answered, "We have been so results. I do not feel that there was any responsibility on our part."^[6] Watkins, the chemist, committed suicide while awaiting

A woman wrote to U.S. President Roosevelt and described the death of her daughter: "The first time I ever had occasion caring for her little grave. Even the memory of her is mixed with sorrow for we can see her little body tossing to and fro

يُستخدم في الروديتر تب (Radiator) السيارة



FDA

- Congress responded with passage of the Federal Food, Drug, and Cosmetic Act of 1938 and the creation of the FDA to administer and enforce it. إقرار القانون الفيدرالي للغذاء والدواء ومستحضرات التجميل لعام 1938 وإنشاء إدارة الغذاء والدواء لإدارة وتنفيذ هذا القانون.

- The 1938 act prohibits the distribution and use of any new drug or drug product without the prior filing of a **new drug application (NDA)** and approval of the FDA. منتج دوائي جديد دون تقديم طلب دواء جديد (NDA) وموافقة (FDA) بحظر توزيع واستخدام أي دواء أو

- It became the responsibility of the FDA to either grant or deny permission to manufacture and distribute a new product after reviewing the applicant's filed data on the product's ingredients, methods of assay and quality standards, formulation and manufacturing processes, preclinical (animal, tissue, or cell culture) studies including pharmacology and toxicology, and clinical trials on human subjects. مكوّنات المنتج عمليات الصياغة متابعة طرق التحليل ومعايير الجودة الدراسات ما قبل السريرية علم الأدوية علم السموم عمليات التصنيع التجارب السريرية على البشر

صارت مسؤولية FDA أنه توافق أو ترفض تصنيع الدواء لأنه لازم يكون في فعالية ومأمونية حسب معايير معينة ومراجعة كافة التفاصيل

Why Compound?

نعمل جرعات مخففة للأطفال عشان الذي يتوفر فقط للكبار

- **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. لو المريض ما بقدر يبلع حبة الدواء بدنا دواء على شكل محلول
- **Patients with sensitivity** to dyes, preservatives, or flavoring agents found in commercial formulations. المريض عنده حساسية من نوع معين من الادوية أو مادة
- **Dermatological formulations** with fortified (strengthened) or diluted concentrations of commercially available products. ^{معيّنة}خلطات جلدية
- **Compounding for animals**. أو حتى تركيبات للحيوانات
- **Reconstitution** of a lyophilized powder to form a simple solution الدواء الذي يتكون من مسحوق ونقوم بخلطه مع سائل
- **In hospital compounding** involves the preparation of **IV admixtures, parenteral nutrition solutions, and radiopharmaceuticals** محاليل التغذية الوريدية Intravenous
من خلال الوريد المواد الصيدلانية المشعة
- **In home health care compounding** requires the preparation of syringes and other devices for home-infusion administration يمكن مش موجودة عنا بس هي عبارة عن بيوت مجهزة لرعاية المريض وعمل جميع الإجراءات اللازمة من جرعات مسكنة مختلفة

تُسمى عملية تحويل الدواء الى مسحوق Lyophilization (التجميد بالتجفيف) أو اسم المسحوق Lyophilized powder

- **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.

يلزمننا تخزين بعض الأدوية على شكل مسحوق لأنها تفقد فعاليتها بسرعة بمجرد خلطها في محلول لذلك تُعرف هذه العملية بخلط المسحوق مع السائل الذي يسمى المُخفِّف أو (ماء مقطرة) distilled water قبل الاستخدام لحفظها أطول فترة أكبر

NDC 0002-1497-01
VIAL No. 767

يعني إبرة

Prescription

بوصفة طبية

اسم الشركة

Lilly

الاسم التجاري

KEFZOL®

معقم

الاسم العلمي أو generic name (الاسم العام)

**STERILE
 CEFAZOLIN
 SODIUM, USP**

Equiv. to

500 mg

التركيز

Cefazolin

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
 Eli Lilly & Co., Indianapolis, IN 46206, U.S.A.
 Exp. Date/Control No.

NDC 0002-1497-01
VIAL No. 767



KEFZOL®

**STERILE
CEFAZOLIN
SODIUM, USP**

Equiv. to

500 mg

Cefazolin

CAUTION—Federal (U.S.A.) law prohibits dispensing without prescription.

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Lyophilized

WV 4520 AMX

Eli Lilly & Co., Indianapolis, IN 46205, U.S.A.
Exp. Date/Control No.

تفاصيل أكثر عن الدواء وكيف يتم تحضيره
ولأيش يُستخدم والتعليمات والجرعات المناسبة
يعني زي مكتوب أنه بنحلوا في 2ml ماء معقم

Categories of compounding

Compounding:

فئات

TABLE 1.1: CATEGORIES OF COMPOUNDING

Category	Compounding Activity
1	Nonsterile – Simple Mixing of two or more commercial products.
2	Nonsterile – Complex Compounding with the bulk drug substance or when calculations required.
3	Sterile – Risk Level I See Chapter <797> Pharmaceutical Compounding – Sterile Preparations.
4	Sterile – Risk Level II See Chapter <797> Pharmaceutical Compounding – Sterile Preparations.
5	Sterile – Risk Level III See Chapter <797> Pharmaceutical Compounding – Sterile Preparations.
6	Radiopharmaceuticals Preparation of radiopharmaceuticals.
7	Veterinary Preparation of veterinary pharmaceuticals.

هدول بدهم مستوى أعلى من التدريب لانه
مش اي حدا بقدر يعملهم لانه لها شروط
خاصة

General compounding considerations: Questions to ask before, during, and after the compounding process

في البداية لازم نأخذ القرار
بالعمل لأنه ممكن الدواء
المكتوب يكون عليه مثلاً
إشكاليات والدكتور مش
عارف أو مسحوب من
السوق

قبل ما تبدأ لازم تتأكد من
كل المواد موجودة والمادة
الفعالة وأدوات القياس

وبعدين لازم تعمل التغليف وتحط ملصق عليه
اسمك والاسم العلمي للدواء والتفاصيل كاملة
وما ننسى **beyond-use-date**

وبعد ما اتخلص بذك تعرف
ويكون عندك العلم الكافي
كيف تشرح للمريض مثلاً
كيف يستخدم الدواء وطريقة
التخزين والمحافظة عليه

Decision to
compound
the
formulation

Considerations
before
beginning the
compounding
process

Considerations
as the
prescription is
being
compounded

Considerations
after
compounding

Compounding- Is it for every one?

- A pharmacist is legally licensed to compound, but is the pharmacist technically qualified to compound?

هل احنا عنجد مؤهلين ؟ هون لازم يكون معنا كصيادلة دورات وشهادات تُوهلنا انه نقدر نعمل compounding

- Compounding resources:-

مصادر

- American Pharmacist Association (APhA) جمعية الصيادلة الأمريكية

- American College of Apothecaries (ACA) الكلية الأمريكية للصيادلة

- National Community Pharmacists Association (NCPA) الرابطة الوطنية لصيادلة المجتمع

-etc



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ASK THE EXPERTS

COMPOUNDING

FREQUENTLY ASKED QUESTIONS

SPECIALTY PHARMACY

TOPICS IN PRACTICE

PATIENT OUTREACH TOOLS

SAFETY NET PROVIDERS

Featured



Mansour's health kiosks enhance patient care



Bernhardt treats pedes oncology patients

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الأنظمة التي لازم نتبعهم في compounding

Compounding Regulations Applies

- Personnel
- Facilities and Equipment أدوات مرافق
- Ingredient Standards المكونات المعيارية
- Quality Assurance and Quality Control ضمان الجودة مراقبة الجودة
- Packaging and Storage التغليف التخزين
- Documentation and Record Keeping التوثيق التسجيل

Quality Assurance

هي كل الخطوات التي تضمن الدواء بطريقة صحيحة من البداية للنهاية ومنع حدوث المشاكل بدلاً من اكتشافها لاحقاً ويعمل (قبل وأثناء عملية التصنيع)

◆ أمثلة

التأكد من مصادر المواد الخام معتمدة
كتابة ومراجعة الإجراءات والتعليمات (SOPs)
التحقق من نظافة المصنع ونظام التصنيع

Quality Control

هو اختبار وفحص المنتج بعد تصنيعه للتأكد أنه مطابق للمواصفات والكشف عن الأخطاء إذا صارت يعمل (بعد الانتهاء من عملية التصنيع)

◆ أمثلة

اختبار شكل الحبة أو لونها
فحص درجة الحموضة PH
التأكد من تاريخ الانتهاء

Ingredient Standards

- **USP/NF** يعني اذا مكتوب عند مكونات الدواء هيك معناته انها توافق المعايير التي وضعها دستور الأدوية الأمريكي ودستور الوطني التركيبي
 - Meets standards set by the USP/NF.
- **ACS reagent** أما إذا كان مكتوب هذه فمعناته إنه يلبي مواصفات لجنة الكواشف الكيميائية للجمعية الكيميائية الأمريكية
 - High purity + نسبة نقاء المادة عالية
 - Meets specifications of the Reagent Chemicals Committee of the American Chemical Society.
- **AR (analytical reagent)** وإذا مكتوب هيك بكون نسبة النقاء أعلى
 - Very high purity.
- **HPLC** أما هذه بتكون نسبة النقاء غالباً فيها أعلى من AR ويستخدم في الضغط المرتفع
 - Very high purity.
 - Used in high pressure chromatography.

Record Keeping

هاد بحكي عن التعليمات والخطوات المسجلة الي لازم تتبعتها قبل ما تبدأ العمل
(يعني زي كتاب الوصفات تبع الطبخ) 😊

• Formulation Record

- Formulas and procedures (i.e., recipes) for what should happen when a formulation is compounded.

• Compounding Record

أما هاد عبارة شو عمل الصيدلاني بالزبط على أرض الواقع وهو بعمل الوصفة
الطبية وشو وزن وشو خلط بالتفاصيل (زي مثلاً كم بيضة فعلياً حطيت بالكيس) 😊

- A record of what actually happened when the formulation was compounded.

• Standard Operating Procedures (SOPs)

التعليمات المُعتمَدة للتشغيل

- Equipment maintenance, equipment calibration, handling and disposal of supplies, etc.

مثل SOPs لصيانة المعدات

أو معايرتها

أو التعامل معها

• Material Safety Data Sheets (MSDSs)

- Ingredients records with certificates of purity.

أما هذه من اسمها بتحكي عن السلامة والأمان وهي عبارة عن ملف معلومات كيف تتعامل
مع المواد والادوات وتحمي حالك وكيف اتخزنها وتتخلص منها بطريقة أمنة

Major areas within the chapter

Compounding records and documents

Purpose:

الغاية أنه نحفظ السجلات ونتأكد إنها مكتوبة عشان يقدر كل شخص يعملها بنفس الطريقة الصحيحة ونتجنب الأخطاء

1. To meet record keeping requirements

2. To enable another compounder to duplicate the preparation

● Compounding record contains: على إيش بتحتوي هذه السجلات

- Sources and lot numbers of the ingredients من مصادر وأرقام المواد
- Calculations والحسابات عشان إذا صار أي خطأ يرجع ويتأكد منها
- Processes used والعمليات المستخدمة
- Results of any testing done نتائج أي اختبارات
- An assigned beyond used date وطبعاً هذا اللي يشبه تاريخ الإنتهاء
- Identification numbers كل دواء له رقم محدد
- Name of the compounder اسم الصيدلاني أو اللي عمل الوصفة
- Quantity of the preparation compounded و كمية المستحضر المركب

اسم الشركة المُزودة



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MATERIAL SAFETY DATA SHEET

اسم المادة

SOYBEAN OIL

MSDS

مثال على MSDSs

- Material Safety Data Sheet: (MSDSs):

They are needed for all drug substances or bulk → أو قلنا اسمها أو excipient أو inactive ingredient chemicals located in the compounding pharmacy.

1. PRODUCT NAME AND COMPANY IDENTIFICATION

Product Name:	SOYBEAN OIL
Product Use:	Personal Care Formulations
Company Name:	Natural Sourcing
Company Address:	341 Christian Street, Oxford, CT 06478, USA
Date Issued:	1/1/2008
Emergency Telephone Number:	Chemtec Tel: (800) 262-8200

2. COMPOSITION/INGREDIENT INFORMATION

Ingredients:	
Vegetable Oil Triglycerides	100%
Hazardous Components:	None
CAS #:	

3. HAZARDS IDENTIFICATION

Routes of Entry	
Eye Contact: هون بحكي إذا	Mild irritation may occur
Skin Contact: قرب على العين أو	May cause irritation in sensitive individuals with prolonged exposure
Ingestion:	Food Grade
Inhalation: الجلد شو بصير	Inhalation of fine mist may effect respiratory system

4. FIRST AID MEASURES

Eyes:	Flush with plenty of water or eye wash solution for 15 minutes. Get medical attention if irritation persists.
Skin:	Wash with soap and flush with plenty of water
Ingestion:	N/A
Inhalation:	Remove to fresh air and seek medical attention
Medical Conditions Generally Aggravated by Exposure:	None

5. FIRE FIGHTING MEASURES

Flash Point (Method Used):	> 550°F Close Cup
Flammable Limits	
LEL:	Low
UEL:	Low
Extinguishing Media:	Dry Chemical, Carbon Dioxide, Foam
Special Firefighting Procedures:	Cool containers exposed to flame with water. Limit the spread

نقطة الإشتعال

Major areas within the chapter

Quality control

زي ما شرحنا قبل أنه لازم كل الخطوات تكون مدققة والمنتج النهائي مطابق للمواصفات الصحيحة

- All the paperwork from the first step through the final preparation should be reviewed, along with observing the final finished preparation
- **Standard Operating Procedures (SOPs)** are documents that describe how to perform routine tasks in the environment of formulation development, purchasing, compounding, testing, maintenance, materials handling, quality assurance, and dispensing

هي عبارة عن وثائق مكتوبة تشرح خطوة بخطوة المهام الروتينية كيف تعمل أي عملية داخل مصنع أو مختبر والهدف هو التأكد أن كل شيء كل مرة ينفذ بنفس الطريقة وطبعاً هي مش بس للصيدلة هي في كل مكان

Standard operating procedure

From Wikipedia, the free encyclopedia

For the 2008 documentary film by this name, see *Standard Operating Procedure* (film).

The term **standard operating procedure**, or **SOP**, is used in a variety of different contexts, including healthcare, aviation, engineering, education, industry, and military.

The U.S. **military** sometimes uses the term **Standing** — rather than **Standard — Operating Procedure**, because a military SOP refers to a unit's unique procedures, which are not necessarily standard to another unit. "Standard" could imply that there is one (standard) procedure to be used across all units.

Contents [hide]

- 1 Clinical research and practice
- 2 See also
- 3 References
- 4 External links

Clinical research and practice [edit]

In clinical research, the *International Conference on Harmonisation* (ICH) defines SOPs as "detailed, written instructions to achieve uniformity of the performance of a specific function". SOPs get usually applied in pharmaceutical processing and for related clinical studies. There the focus is always set on repeated application of unchanged processes and procedures and its documentation, hence supporting the segregation of origins, causes and effects. Further application is with triage, when limited resources get used according to an assessment on ranking, urgency and staffing possibilities.^[1] Study director is mainly responsible for SOPs. The Quality Assurance Unit are individuals who are responsible for monitoring whether the study report and tests are meeting the SOP. SOPs can also provide employees with a reference to common business practices, activities, or tasks. New employees use an SOP to answer questions without having to interrupt supervisors to ask how an operation is performed.^[2] The international quality standard ISO 9001 essentially requires the determination of processes (documented as standard operating procedures) used in any manufacturing process that could affect the quality of the product.^[3]

مفصلة
مكتوبة

- "detailed, written instructions to achieve uniformity of the performance of a specific function". SOPs get usually applied in pharmaceutical processing and for related clinical studies where the focus is always set on repeated application of unchanged processes and procedures and its documentation
- The Quality Assurance Unit are individuals who are responsible for monitoring whether the study report and tests are meeting the SOP
- SOP's can also provide employees with a reference to common business practices, activities, or tasks. New employees use an SOP to answer questions without having to interrupt supervisors to ask how an operation is performed

وهم الأشخاص التي حكيما عنهم بيتأكدوا. من كل الخطوات والاختبارات حسب SOP

و تُوفّر للموظفين مرجعًا لممارسات المهام الشائعة و يستخدمها الموظفون الجدد للإجابة على الأسئلة دون الحاجة إلى مقاطعة المشرفين لسؤالهم عن كيفية تنفيذ العملية.

تُطبق SOP عادةً في معالجة الأدوية والدراسات السريرية ذات الصلة، حيث يُركز دائمًا على التطبيق المتكرر للعمليات والإجراءات غير المتغيرة وتوثيقها.

Major areas within the chapter

Verification

التحقق

يعني حتى لو انت متأكد من عملك لازم يكون في شخص بيتحقق من كل اشي حسب الشروط الصحيحة

- Involves checking to ensure that all the process were appropriate and performed accurately

الإستشارة الي بقدمها للمريض مني كصيدلاني

Patient counseling

يعني انت كوظيفتك كصيدلاني لازم تحكي للمريض عن الدواء وكل شيء يأخذه بالتفصيل وكيف يحافظ عليه

- Patients should be counseled about use, storage, and evidence of instability (visual changes, odor, etc.)

هذه درجات حرارة التخزين بتكون مكتوبة على الدواء لازم اتكون حافظهم

Storage Temperature Definitions

- Freezer =
- Protect from Freezing =
- Cold =
- Refrigerator =
- Cool =
- Room Temperature =
- Controlled Room Temperature =
- Warm =
- Excessive Heat =
- -20° C to -10° C
- Store above 0° C
- Any temperature not exceeding 8° C
- Between 2° C and 8° C
- Between 8° C and 15° C
- Temperature in the work area
- Thermostatically controlled at 20° C to 25 °C
- Between 30° and 40° C
- Any temperature above 40° C

Stability

- **Stability** الثبات وهي المدة التي يبقى الدواء محافظاً على خصائصه وفعاليتها من أول ما صُنِعَ وبناءً عليها بنحدد تاريخ الإنتهاء
 - The extent to which a dosage form retains the same properties and characteristics that it possessed at the time of its manufacture.
- **Expiration date** تاريخ الإنتهاء المكتوب من المصانع وغالباً بتكون المدة أطول من beyond-use-date وبيتغير فعالية وأمان هذا الدواء بعد هذا اليوم المحدد
 - 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** هذا التاريخ الذي يشبه تاريخ الإنتهاء الذي يكتبه الصيدلاني الذي يقوم بعمل الوصفة الطبية وبناءً على حسابات معينة يقوم بوضع هذا التاريخ على الدواء
 - Used for compounded preparations only and are generally in the order of “days” or “months.”
- **Shelf life** أما هذا هو عبارة عن مدة الحياة تبعت الدواء قبل ما يتدهور وتُحسب من تاريخ الإنتاج الي تاريخ الإنتهاء
 - Length of time a packaged drug will last without deteriorating

يعني لو مصدر المادة الفعالة الي بدنا نستخدمه أصلاً عبارة عن منتج دوائي موجود له تاريخ انتهاء فبكون beyond-use-date للدواء الجديد الي بدنا انحصره ، 0.25% من تاريخ انتهاء المنتج الدوائي ، يعني مثلاً لو كان سنة فبكون للدواء الجديد 3 أشهر ، أو بنحطه من 6 أشهر أو حتى أقل

Assigning a Beyond-Use Date

تركيبة صلبة أو هو سائل بس لا يحتوي على الماء

• Nonaqueous liquids and solid formulations

- 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.

أما لو كانت المادة الفعالة أصلاً مادة خام حسب USP فبكون beyond - use date

مش أكثر من 6 أشهر

• 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.

أما اذا كانت التركيبة تحتوي على الماء أو بتكون بودرة واحنا بنخلطها مع الماء المقطر بكون

• For all other formulations

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

وأي تركيبة ثانية غير هيك بكون beyond-use date كحد 30 يوم أو أقل

Major areas within the chapter

The compounding process

بدنا نتبع 13 خطوة واحنا بنعمل compounding عشان نقلل الخطأ

Thirteen steps needed to consider to minimize error:

1. Judge the suitability of the prescription to be compounded in terms of its safety and intended use. Determine what legal limitations are applicable?
بالأول زي ما حكينا بدنا انقرر أنه الوصفة صحيحة ومناسبة وأمنة انه نعملها
2. Perform necessary calculations (see <1160> Pharmaceutical calculations in prescription compounding>)
نعمل الحسابات الضرورية
3. Identify equipment needed
تحديد المعدات المطلوبة
4. Wear the proper attire and wash hand
طبعا لازم نجهز حالنا ونلبس ملابس ملائمة
5. Clean the compounding area and needed equipment
ونظف المكان والأدوات قبل ما تبدأ

Major areas within the chapter

The compounding process

6. Compound only one prescription at one time in a specified compounding area بالنسبة لهذه النقطة كثير مهمة لازم نلتزم بعمل كل وصفة على جدا وما انخربهم ببعض ابدأ
7. Assemble all necessary material to compound the prescription جمع كل المواد الي رح تحتاجها قدامك عشان ما تتخربط
8. Compound the preparation following the formulation record or prescription, according to the art and science of pharmacy وطبعاً لازم تتبع الإرشادات والتعليمات المكتوبة بالتفصيل
9. Assess weight variation, adequacy of mixing, clarity, odor, color, consistency, and pH as appropriate. بنقيم الوزن والخلط والوضوح والرائحة واللون والتناسق وPH
10. Annotate the compounding log and describe the appearance of the formulation والتوقيع وكتابة اسم من قام بالعمل واسم التركيبة وتاريخ اليوم

Major areas within the chapter

The compounding process

11. Label the prescription containers to include the following items:

محتويات ملصق الدواء

- Name of the preparation اسم الوصفة
- Internal identification number رقم معين لكل دواء
- Beyond used date
- Initials of the compounder who prepared the label أول أحرف من اسم الصيدلاني أو من قام بصنعها
- Any storage requirements أي متطلبات للتخزين
- Any other statements required by law أي أشياء قانونية بتتعلق بهذا الدواء

Major areas within the chapter

The compounding process

12. Sign and date the prescription, affirming that all procedures were carried out to ensure uniformity, identity, strength, quantity and purity
وَقَعَ عَلَى الوَصْفَةِ الطَّبِيبِيَّةِ وَسَجَّلَ تَارِيخَهَا، مُؤَكِّدًا أَنَّ جَمِيعَ الإِجْرَاءَاتِ قَدْ نُفِّذَتْ لِضَمَانِ التَّطَابُقِ وَالْقُوَّةِ وَالْكَمِّيَّةِ وَالنَّقَاءِ.
13. Clean all equipment thoroughly and promptly, and store properly
وَطَبَعًا التَّنْظِيفَ بَعْدَ الإِنْتِهَاءِ

Types of Equipment

ينصك تفتح على كل وحدة على الانترنت وتشوف كل وحدة كيف شكلها

• Measuring أدوات القياس

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

ميزان

• Molding أدوات الصب

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

زي الغاز

عشان انسخن

عليه الاشياء

هي القوالب تبعت

تشكيل التحاميل

الكبسولات الفارغة الي

بنحط فيها المادة الفعالة

للدواء

• Packaging أدوات التغليف

• Mixing أدوات الخلط

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

قمع

مناخل أو غرابيل

علب الادوية

البلاستيكية

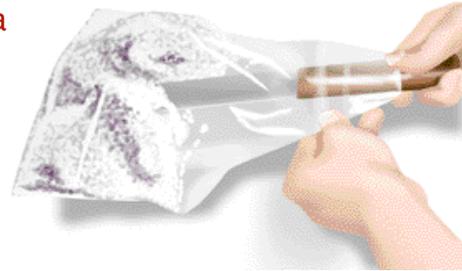
- Prescription bottles, capsule vials, suppository boxes, ointment jars.



balance



spatula



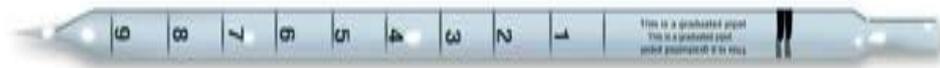
ointment slabs



pestle

mortar

Small Volumetric Equipment



Calibrated pipette



Single volume pipettes

Syringe



graduated cylinder



Labeling, Record Keeping, and Cleanup

- After compounding
 - The product **must be labeled** with a prescription label, and **a careful record** of the compounding operation should be kept.
- Once the compounding operation is finished
 - The equipment and area should be cleaned.
 - Everything should be returned to their proper places in storage.
- Compounding should never be rushed.

لا تكون متسرعاً

Prescription vs. medication orders vs. medication administration records

Prescriber information
 معلومات الطبيب
Prescriber information:
 Name, title, office address, and telephone number

Name and address of patient
 معلومات المريض
Name and address of patient:
 Other patient information such as age or weight is optional, but sometimes important, e.g., a child's weight.

Signa
 طريقة الاستخدام
Signa:
 This comes from the latin word signa, meaning "to write." It is abbreviated to sig and indicates what directions for use should be printed on the label.

Refill instructions
DAW:
 Dispense As Written and/or Generic Substitution Allowed instructions (optional)

Drug Enforcement Agency (DEA) registration number of prescriber:
 (required for all controlled substances) **Date**
Date: تاريخ وصف الدواء
 The date the prescription was written.

Inscription
 تركيبة الدواء
Inscription:
 Name (brand or generic), strength of medication.

Note: If a compound is prescribed, a list of ingredients and directions for mixing is included.

Signature of prescriber
 توقيع الطبيب
Signature of prescriber:
 (not required on a verbal prescription)

Note: Prescriptions are written in ink, never in pencil.

FIGURE 3.1: SAMPLE PRESCRIPTION

Handwritten entries on the form:
 Jacquelyn Hyde, MD
 123 Upendown Rd.
 Nowhere, NC 27000
 Phone: 555-1234
 DEA# AH0079411
 NAME: Dan D. Lyon
 DATE: 2/18/08
 ADDRESS: 123 Jackla Lane
 PHONE: 555-5678
 R
 Acetaminophen 325 mg
 Alcohol USP 15 ml
 Cherry Syrup q.s. 90 ml
 Up to (q.s.)
 SIG: 1/2 tsp. q4-6h prn
 REFILLS: 1
 Jacquelyn Hyde
 DISPENSE AS WRITTEN
 PRODUCT SELECTION PERMITTED

Prescription Sample

وهذا شكل ثاني للوصفة الطبية بس مكتوبة الكترونياً

TUFTS UNIVERSITY SCHOOL OF DENTAL MEDICINE
One Kneeland Street
Boston, MA 02111
655-999-9999

Name: Jane Doe
Age: 28
Address: 10 Kneeland Street
Boston, MA 02111
Date: 12/03/06

Drug: Amoxicillin 500 mg / capsule
Directions: 500 mg qid x 5 days
Quantity: 20
Refills: 0 (zero)

DEA #: XX55372

Signature:

Print Name:

INTERCHANGE is mandated unless the practitioner
Writes the words "NO SUBSTITUTION" in this space

دراسة تايم

DOCTOR'S ORDERS

PATIENT IDENTIFICATION
 00000000000000000000
 SMITH, JOHN
 12/04/1950
 DR. P. JOHNSON

DATE	TIME	DOCTOR'S ORDERS	SIGNATURE	DATE/TIME
12/18	1400	Admit patient to 4th floor Pneumonia, Dehydration Ad. Safe-Hives		
		Order CBC, Urine-T, blood cultures stat Start LE @ 125 mg for 2X qd Dr Johnson x3333		
12/18	1600	Temp 45 Cmg po q4 - Hots PEN for Temp > 38 Percocet 5/325 PO q 4 hrs prn break through pain Verbal order Dr Johnson! P. Smith, RN		
12/18	2000	Start ciprofloxacin 500 mg po bid Multivitamin po qd Percocet 12.5 mg 2X q 6 hrs prn cough Order OMR for this a.m. Dr Johnson x3333		

FIGURE 3.2: SAMPLE MEDICATION ORDER

COMMUNITY HOSPITAL
 Medication Administration Record

Room/Bed: 477-01 Room (Nurse) 02141000 to 0700 to 020000
 Patient: SMITH, JOHN
 Account #: 0000000000 Diagnosis: PNEUMONIA, DEHYDRATION
 Sex: M Height: 5'11" Weight: 75KG
 Age: 55Y Verified by: Susie Smith, RN
 Doctor: JOHNSON, P

Medicine: PENICILLIN → RASH

	0700-1100	1400-1800	1900-0700
LACTATED RIBBLEN 1 LITER BAG DOSE: 125 ML/HR IV Q 8HRS ORDER #2	800 JD	1400 JS	2000
MULTIVITAMIN TABLET DOSE: 1 TABLET PO QD ORDER #4	1800 JS 2000 P 1400 JD		
CIPROFLOXACIN 500 MG TABLET DOSE: 500MG PO BID ORDER #1	1800 JD	2000 JS	
ACETAMINOPHEN 325 MG TABLET DOSE: 650 MG PO Q 4-6 HRS PRN FOR TEMP > 38C ORDER #7	1500 JD		

Initial / Signature: SS, Susie Smith, RN Initial / Signature: _____
 JD, Jane Doe, RN _____
 _____ _____

FIGURE 3.3: SAMPLE MEDICATION ADMINISTRATION RECORD (MAR)

Prescription vs. medication orders vs. medication administration records

- Both convey necessary information to the pharmacists but are used in different patient care settings
للمرضى العاديين الي يكون معهم وصفة طبية من الدكتور وانت كصيدلاني بتعطيهم الدواء المكتوب
- Prescriptions are used for outpatient care
- Medication orders:
أما هذه بتكون للمرضى المقيمين (عند السرير تبعه) في المستشفى ويكون فيها الادوية الي اخذها المريض وكل التحاليل وتعليمات الدخول والخروج
 1. are used to order medications in hospitals
 2. Contain orders for procedures, laboratory tests, nursing instructions, and discharge instructions
- Medication Administration Record (MAR): it documents when and what medications were administered to a patient

أما هذه بس بتوثق متى وما هي الأدوية التي تم إعطاؤها للمريض خلال دخوله المستشفى

Review and interpretation

- Once the pharmacist has received an order he must:
 1. Review and interpret (translate) the prescription
 2. Accurately weigh and measure all components
 3. Use appropriate compounding techniques to convert individual components into a finished formulation
 4. Properly package and label the formulation
 5. Deliver the formulation to the correct patient with adequate instructions for administration and storage

Review and interpretation

- Reviewing, interpreting, and labeling the prescription involves a “language” that must be learned and utilized
- Abbreviations:
 - ^{اختصارات} Latin abbreviations
 - ^{اسم الدواء} Drug name abbreviations
 - ^{طبية} Medical abbreviations

Please refer to tables 3.1-3.2 and 3.3 for examples

Common misinterpreted abbreviations

- Care must be taken when interpreting any abbreviation
- Some abbreviations are prone to mis-interpretation so their use is not encouraged

يجب توخي الحذر عند تفسير أي اختصار
بعضها عرضة للتفسير الخاطئ

- The institute of Safe Medication Practices (www.ismp.org) maintains an online resource that provide lists and tools to help prevent medication errors



Institute for Safe Medication Practices

A Nonprofit Organization Educating the Healthcare Community and Consumers About Safe Medication Practices

[Home](#) [Support ISMP](#) [Newsletters](#) [Webinars](#) [Report Errors](#) [Educational](#) [Store](#) [Consulting](#) [FAQ](#) [Tools](#) [About Us](#) [Contact](#)



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This website is for use by healthcare professionals. Consumers can access our consumer website [here](#).

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2015

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2014-15

Targeted Medication Safety Best Practices for Hospitals

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Labeling

- **Extemporaneous preparations:** preparations done by the pharmacist in his own small lab.
- Pharmaceutical formulations must be suitably contained , protected and labeled.
- There are two types of labels: ^{الاساسية} Main and ^{المساعدة} Auxiliary
- Label on the dispensed medicine has two main functions:
 - to uniquely identify the contents of the container. تحديد محتويات الدواء
 - to ensure that patients have clear and concise information which enable them to take or to use their medication in the most effective and appropriate way. عشان يفهم المريض كل شيء عن الدواء واذا نسي كيف يأخذه

Main Label

مكونات الملصق الأساسي

- Name and address of the pharmacy
- The patient name
- 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. رقم خاص بالصيدلية
- The date of issue: the date of preparation written as day/ month/ year
- The name of 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's an official one .e.g 50 ml of sodium salicylate mixture 10 %W/V B.P.C. تركيز المادة الفعالة في التركيبة الانتباه على الاصفار والفواصل في التراكيذ المصدر المعتمد British pharmaceutical codex
- Instructions: 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.
- Storage conditions: "Store in cool place", "store in dry place", "store in dark place"
- BUD: this time is for extemporaneous prepared formula is arbitrary which according to references, this time is different from expiry date which is long compared with short shelf life, written as day/month/year.

Beyond-use date

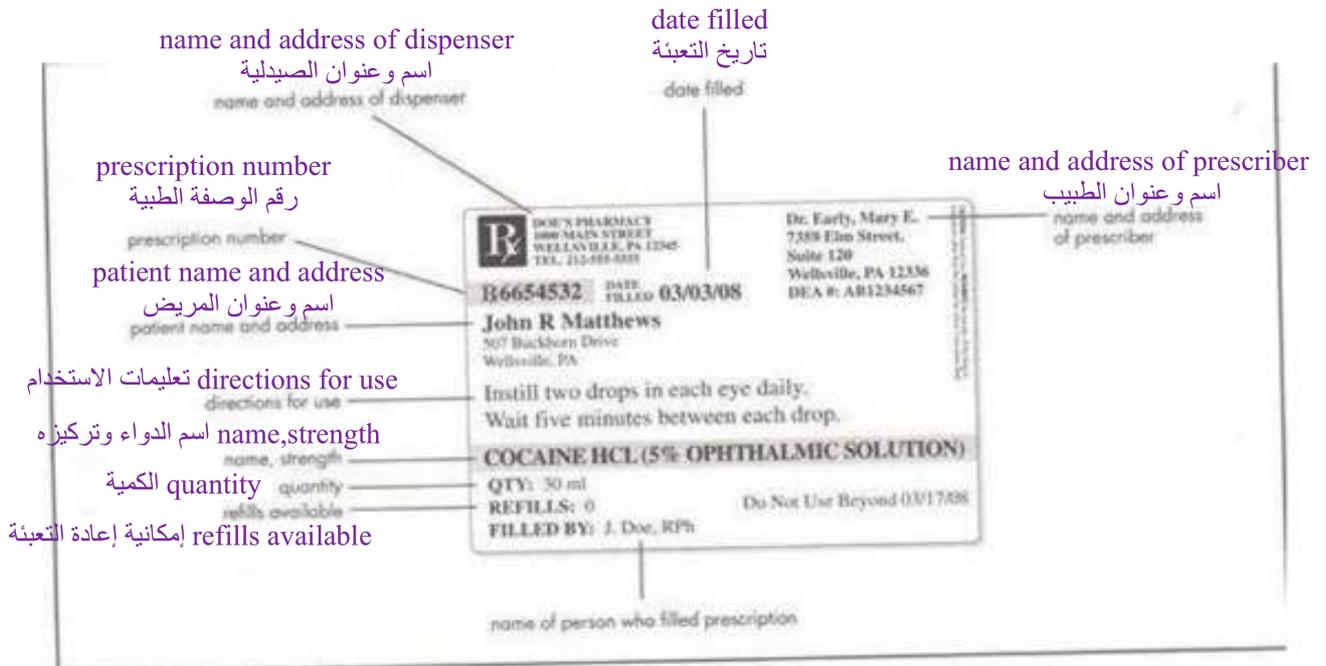


FIGURE 3.5: EXAMPLE OF A PRESCRIPTION LABEL

Some guidelines about wording patient instructions:

- Indicate the dosage form to be administered:

“Take one capsule every day” instead of “Take one every day”.

- Use words instead of numbers:

“Take one capsule every day” instead of “Take 1 capsule every day”

- Specify the route of administration if the medication is not intended for oral use:

“Insert one suppository vaginally every night at bed time”

- 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”

- Do not use abbreviations:

“Take two capsules twice a day” and not “Take two caps twice a day”

Some guidelines about wording patient instructions:

بالمختصر انك تكتب كل التفاصيل على الدواء عشان المريض يكون متأكد
وفاهم كل شيء عشان يدعيلك مش يدعي عليك 😊

- In general, specify the amount of active ingredient per dosage unit:

Amoxicillin 250mg/ 5ml

Phenergan 25mg/ suppository

- When dispensing medications in bulk, such as solutions, suspensions, emulsions, ointments, or creams, express the amount of active ingredients as a percentage strength:

Hydrocortisone cream 1%

Betadine solution 2%

Rule When Writing Directions For Use

- **START WITH A VERB**

- Take, instill, inhale, insert, or apply

- Indicate **ROUTE** of **ADMINISTRATION**

- Apply to *affected area*.
- Take one tablet *by mouth*.
- Insert *rectally*.
- Place one tablet *under the tongue*.

- **NO ABBREVIATIONS**

- Use familiar words

- 10 ml

Auxiliary Labels

مكونات الملصق المساعدة

بتكون عبارة عن اضافات بالجهة الثانية للدواء

- The auxiliary labels: arranged on the other side of the container, these labels are **cautionary** or **advisory** depending on the type of dosage form.
تحذيرية استشارية
- Needed to provide supplementary information regarding proper and safe administration, use, or storage of the formulation
- '*keep out of reach of children*' *for oral use* "**for external use**" "*not to be taken orally*" "**flammable**" "*not to be swallowed*" "**shake the bottle before use**"
للاستخدام الخارجي
قابل للاشتعال مش للبلع يعني زي الحبة تحت اللسان او الي يتمضغها رجهها قبل الاستخدام
- Refer to examples in pg 25

<i>Type of preparation</i>	<i>Color of print</i>	<i>container</i>	<i>Auxiliary labels</i>
<i>Oral solutions(ORS,Elixir,syrups)</i>	<i>Black</i>	<i>Plain bottle(glass, plastic)</i>	<i>For oral use</i>
<i>Ear drops</i>	<i>Red</i>	<i>Fluted hexagonal glass dropper bottle or plastic squeeze bottle</i>	<i>Not to be taken orally, for ear use only</i>
<i>Eye drops</i>	<i>black</i>	<i>Fluted hexagonal glass dropper bottle or plastic squeeze bottle</i>	<i>Not to be taken orally, for eye use only, sterile till open</i>
<i>Nasal drops</i>	<i>black</i>	<i>Fluted hexagonal glass dropper bottle or plastic squeeze bottle</i>	<i>Not to be taken orally, for nasal use only</i>
<i>External solutions(antiseptic, lotions)</i>	<i>red</i>	<i>Fluted bottle (glass, plastic)</i>	<i>For external use only</i>

Some Auxiliary Labels



للاستخدام الشرجي فقط



رجها قبل الاستخدام



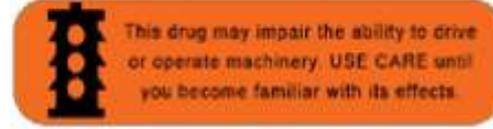
قد يسبب النعاس



للاستخدام الخارجي



لا تتناول منتجات الألبان



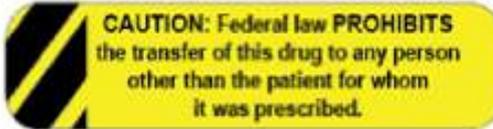
يشوش عليك خلال القيادة



لازم تأخذه مع ماء



خذه مع الاكل



للاذوية المرصدة



للأنف

- Controlled substances 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”

Prescriptions

Prescriptions are a written order from a practitioner for the preparation and administration of a medicine or a device.

- **Community Pharmacists**

- Dispense directly to the patient.
- The patient is expected to administer the medication according to the pharmacist direction.

- **Institutional Pharmacy**

- Nursing staff generally get the medications mostly from the pharmacists and administers to patients.

The Prescription Process

The pharmacy technician prepares the filled prescription for the pharmacist to check.

- **THE PHARMACIST CHECKS** the prescription(s) and may **initial it.**

Pharmacists provide counseling.



Pharmacy Abbreviations

طبعًا لازم تكون حافظ كل الاختصارات او على الاقل بتعرفهم



Most common abbreviations:

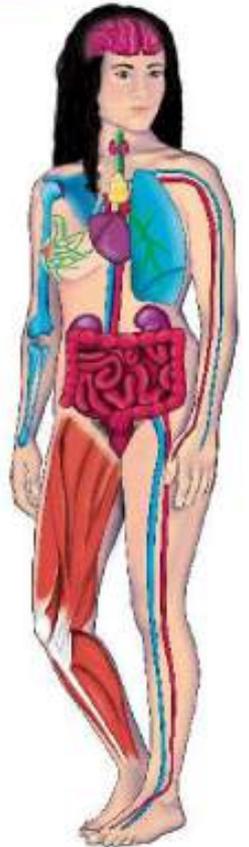
- Route
- Form
- Time
- Measurement

Route of Administration Abbreviations

ad = right ear
as., al – left ear
au = each ear

IM - intramuscular
IV = intravenous
od = right eye
os = left eye

ou = each eye
po = by mouth
sl = sublingually



Time of Administration Abbreviations

ac = before meals

pc = after meals

hs = at bedtime

qd = every day

prn = as needed

qid = four times a day

tid = three times a day

bid = two times a day



Dosage Form Abbreviations

elix = elixir

supp = suppository

ung = ointment

tab = tablet

cap = capsule

SR, XR, XL = slow/extended release

sol = solution

susp = suspension

Measurement Abbreviations

i, ii	=	one, two
gtt	=	drop
gm	=	gram
gr	=	grain
l	=	liter
mcg	=	microgram
mg	=	milligram
meq	=	milliequivalent
ml	=	milliliter
qs	=	a sufficient quantity
disp	=	dispense



Others Abbreviations

Stat = now

NR = no refill

UD = as directed

qs = a sufficient quantity

disp

Examples

Drug	Rx	Label Directions
Diovan® 80 mg tablet	i po qd	Take one tablet by mouth once daily
Cephalexin 250 mg capsules	ii stat, i po QID x 10 d	Take two capsules by mouth now, then take one capsule four times daily for ten days
Alphagan-P® 0.1% eye drops	i q 8h ou	Instill one drop into each eye every 8 hours
Strettera® 25 mg capsules	i q a.m	Take one capsule by mouth every morning
Enbrel® 50 mg SC injection	i q week	Inject the contents of one syringe, subcutaneously, once weekly

Rasul Pintar, M.D.
123 Main Street
Wellsville, PA 00000
Telephone: 888-555-1234
DEA Number: AB1234563
NPI: 1234567893

Date 10/24/09

NAME Tom Jones

ADDRESS 149 Ivy Street, Wellsville, PA

Rx

Actos 30mg
Sig: T po q d
#30

REFILL 11

DISPENSE AS WRITTEN

R. Pintar
PRESCRIBER'S SIGNATURE

This template form is for each controlled substance presentation.
STATE'S UNAUTHORIZED PRACTITIONER VIOLATION OF THIS FORM INCLUDING ALTERING OR FALSIFYING ANY SPACES PURCHASED BY LAW.

Elements Of The Prescription Information

- **Prescriber information** - Name, title, office address, and telephone number.
- **Date:** The date the prescription is written.
- **Inscription:** Name (brand or generic), strength of medication and quantity.
- **Name and address of patient**
- **Signa:** Sig or S and indicate the **directions for use and the administration route** (e.g., p.o., p.r., sc).
- **Refill instructions**

Elements Of The Prescription Information

- **DAW/PSC:** Dispense As Written/Product Select Code—generic substitution instructions (optional).
- **Signature of prescriber:** Required on written prescriptions.
- **National Provider Identifier (NPI):** Prescriber's unique national identification number.
- **Drug Enforcement Agency (DEA) registration number of prescriber:** Required for all controlled substances).

Caution!

- **Are the fill instructions clear and reasonable?**

- Is it q.i.d. or q.d; 4 ml or .4 ml.

- **Are the administration directions clear?**

- Are these the same? “Take two tablets daily” vs. “Take one tablet twice daily” vs. “Take two tablets once daily.”

يعني خذ حبة كل 12 ساعة

يعني خذ حبتين مع بعض في اليوم

- **Are there look-alike names?**

- Is it Metadate[®] 10 mg or Methadone 10 mg; Lamictal[®] or Lamisil[®]?

Caution!

- **Don't add information!** لا تجتهد وتحط معلومات من عقلك انت استنتجتها
 - Never add information based on what you assume the prescriber meant. The prescriber has knowledge of the patient's condition that you don't.
- **Check against the original!**
 - During the fill process, always refer to the original prescription first and then refer to the label.

Labels



PHARMACY #00000
1000 MAIN STREET
WELLSVILLE, PA 00000

212/555-5555

DEL.

6654532

DATE
FILLED 10/23/09

THOMAS JONES

TAKE 1 TABLET BY MOUTH
ONCE DAILY

ACTOS 30MG TAB TAKEDA

DISCARD AFTER: 03/31/2012

DR. R. PINTAR

MAY REFILL 11 TIMES BEFORE 10/21/10

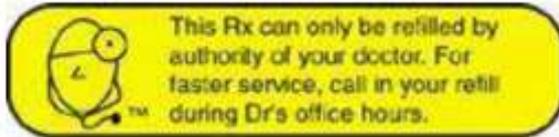
Pharmacist: [unreadable] Pharmacist: [unreadable]
in this pharmacy. [unreadable]

Auxiliary Labels

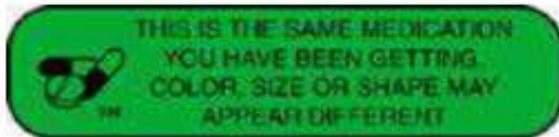
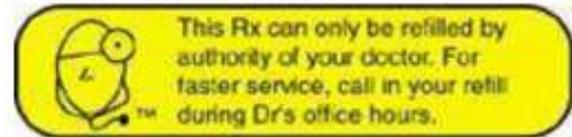
Provide additional information to the patient and applied to the prescription container



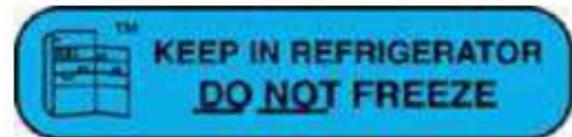
للأذن



لا يمكن إعادة صرف الدواء الا بموافقة الطبيب



هذا نفس الدواء بس غيروا شكل او لون الحبة



خليها بالثلاجة بس لا اتجمدها

Prescription Label Examples

Alice Chan, M.D.
113 Main Street
Wellsville, PA 16899
Telephone: 814/533-1234
DEA number AB1234567
NPI 123456789

Date June 17, 2010

NAME Jane Smith

ADDRESS 200 Ivy Street, Wellsville, Pa

Rx Keflex 500 mg

Sig: 1 cap po QID x 10d

#40

REFILL 0

DISPENSE AS WRITTEN

Alice Chan
PRESCRIBER'S SIGNATURE

DO NOT WRITE IN THESE SPACES
THIS INFORMATION IS FOR THE USE OF THE PHARMACEUTICAL MANUFACTURER AND IS NOT TO BE REPRODUCED OR TRANSMITTED IN ANY FORM OR BY ANY MEANS, ELECTRONIC OR MECHANICAL, INCLUDING PHOTOCOPYING, RECORDING, OR BY ANY INFORMATION STORAGE AND RETRIEVAL SYSTEM.

R PHARMACY # 00000 212 555-5555
1000 MAIN STREET
WELLSVILLE, PA 16899 DTL

6654532 DATE FILLED **06/17/10**

SMITH, JANE

**TAKE 1 CAPSULE BY MOUTH
FOUR TIMES DAILY FOR 10 DAYS**

40 CEPHALEXIN 500MG CAPSULES

MFG: RANBAXY
DISCARD AFTER: 10/31/2011
DR. ALICE CHAN

REFILL 0

Pharmacist: [Signature] Pharmacist License No. [Number] State of Pennsylvania

Label Examples

Sample Rx	Comments
<p data-bbox="284 468 641 562">UNC School of Pharmacy Chapel Hill, NC 27511 962-0057</p> <hr data-bbox="277 578 647 580"/> <p data-bbox="220 609 427 738">Rx #123456 Dr.Upendown Baby Stan Dupp 9/1/00</p> <p data-bbox="220 743 660 802">Empty contents of capsule into formula and give every four hours.</p> <p data-bbox="220 809 612 872">Hydrochlorothiazide capsules 5 mg/cap (#30)</p> <p data-bbox="220 879 628 943">2 refills; expires 9/31/00 Dispensed by Y. Ourname, R.Ph.</p>	<p data-bbox="753 444 1235 707">This prescription is for an infant, so the pharmacist has provided instructions for suitably administering the capsule. Always consider the possibility that a patient will be unable to swallow a solid dosage form especially if the patient is a child or an older adult.</p>

**UNC School of Pharmacy
Chapel Hill, NC 27511
962-0057**

Rx #123456

Dr.Upendown

Luce Morals

9/1/00

Take one teaspoonful every eight hours.

**Amoxicillin suspension 250 mg/5ml
(150 ml)**

No refill; expires 9/15/00

Dispensed by Y. Ourname, R.Ph.

Amoxicillin is an antibiotic and thus requires that the patient be instructed to complete the full course of therapy. It is also a suspension, and thus should be well shaken before administration. Finally, since it has poor chemical stability and a limited shelf-life, it should be kept refrigerated and any unused portion discarded after 14 days.
(Attach Finish All...)

**UNC School of Pharmacy
Chapel Hill, NC 27511
962-0057**

Rx #123456

Dr. Upendown

Mel Batost

9/1/00

Insert one suppository rectally every
six hours

for nausea and vomiting.

Phenergan 25 mg/supp. (#10)

No refill; expires 9/31/00

Dispensed by Y. Ourname, R.Ph.

Auxiliary labels are used here to instruct the patient on proper medication storage and route of administration. Additionally, the patient should be verbally instructed to warm the suppository in his hand and remove the foil from the suppository prior to insertion. (Attach Rectal..., Drowsiness, Do Not Freeze)