



لجان الرفعات

DISPENSING



MORPHINE ACADEMY

MORPHINE
ACADEMY

Pharmaceutical Compounding- Introduction

Dr. Saja Hamed

The origin of the pharmacy profession

- ^{التحضير} Compounding of medicinal preparations from material of animal, vegetable and mineral sources has been practiced Ancient Egypt, Greece, Rome and the Arabian culture
- ^{أخيون} ^{العقاقير الطبيعية} Opium, ^{عرف الموم} myrrh, and liquorice
- History of Pharmacy Profession (wikipedia)

بعض المواد
إلى كانت تستخدم
بالتحضير الدوائية

Regulatory Aspects of Compounding

Pharmacopoeias and Formularies

Common (drug compendia)

← الاسم العام

- The United States pharmacopoeia (USP)
- British pharmacopoeia (BP)
- European pharmacopoeia (Ph. Eur.)
- The pharmacopoeia of Japan
- International pharmacopoeia (Available online)
- The Indian pharmacopoeia

هناك المعاجم تحت المراجع الأساسية
التي تحدد كيفية تحضير الأدوية، مكوناتها
جودتها، طرق احتياؤها

مصنوع من ايجتة كلمة Pharmacopeia

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.

Pharmacopeia → Pharmakon meaning drug
الكلمة مشتقة من
اللغة اليونانية → Poiein meaning make

Chapters

بِسَاوِلِ عَضْرِ الْأَدْوِيَةِ عِنْدَ الْمُعْتَمَةِ

ليس

- **Chapters <795>** - called **Pharmaceutical Compounding - Nonsterile Preparations** → يعني للاستخدام في الحقن أو العين مشد

- Published in 2000

- Enforceable → فصل ملزم وقابل للتطبيق قبل الجهات الرقابية

- **Chapter <797>** - called **Pharmaceutical Compounding - Sterile Preparations**, → مثل الحقن للمعتمة

- Became official in 2004. → أصبح رسمي وملزم ب.ع.س.

- **Other Chapters**

- Containers <661>

- Good Compounding Practices <1075>

- Pharmaceutical Stability <1150>

- Pharmaceutical Dosage Forms <1151>

بِسَاوِلِ عَضْرِ الْأَدْوِيَةِ الْمُعْتَمَةِ

هو الفصول <795> و <797> هما

الضوابط الرئيسية التي تصدر من إدارة
لصحة الإنسان لإدارة تصنيع الأدوية والمعتمة

وهناك فصول إضافية تخص مواضيع
مهمة أخرى زي الحيوانات، الاستقرار، الشكالات
البرعات

بمفردته على USP بجارتين، ① الموقع الإلكتروني
② الكتاب

English Español 简体中文 Português

Log-in: Select an Account Go Cart

USP U.S. Pharmacopeial Convention

Search Entire Site

Calendar Support A to Z Reference Standards Index

- About USP
- USP-NF
- Dietary Supplements
- Food Ingredients
- Reference Standards
- Global
- Meetings & Courses
- News
- Store

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

CONVENTION 2015

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)

Find information for...

- ▶ Healthcare Professionals
- ▶ Manufacturers
- ▶ Delegates/Experts/Trustees
- ▶ Patients/Consumers
- ▶ Regulators



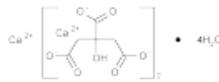
A sample of USP-NF monograph

هذه هي وصف تفصيلي للمادة
وهي شوية للمادة ذواتها
معدنية زي Calcium citrate
ويعتوي على

معلومات
التعريف
التركيب
الطرق
التحاليل
المعايير التي يرضى
أن تستعملها
المادة

شرح صفي
بقدر ادري
دو باها من الحيات

Calcium Citrate



$C_{12}H_{18}Ca_3O_{14} \cdot 4H_2O$ 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 NL T 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 mer curic 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

انتشار المعاجم الدوائية حول العالم

عبر السنوات، نشرت عدة دول معاجم دوائية خاصة بها

- Over the years, a number of countries have published their own pharmacopeias,
- Including the ^① United Kingdom, ^② France, ³ Italy, ⁴ Japan, ⁵ India, ⁶ Mexico, ⁷ Norway, and ⁸ the former Union of Soviet Socialist Republics.
- 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.
- 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

الدول التي لا تمتلك معجم دوائي وطني غالباً يتخذ على معجم دول أخرى

ما تمتلكه من معجم خاص بها

تستخدمه حالياً



WIKIPEDIA The Free Encyclopedia

- Main page
- Contents
- Featured content
- Current events
- Random article
- Donate to Wikipedia
- Wikimedia Shop

- Interaction
 - Help
 - About Wikipedia
 - Community portal
 - Recent changes
 - Contact page

- Tools
 - What links here
 - Related changes
 - Upload file
 - Special pages
 - Permanent link
 - Page information
 - Wikidata item
 - Cite this page

Article Talk

Elixir sulfanilamide

From Wikipedia, the free encyclopedia

دواء طمان مُسكّن
 بشكل غير صحيح
 وتسبب في تسمم جماعي
 في الولايات المتحدة

وهذه الحادثة كانت من الأسباب التي دفعت الولايات
 المتحدة لتشريع قوانين صارمة للدواء منها FDA

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 **diethylene glycol** 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 product. It 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 satisfied with the 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 to be 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

Why Compound?

لعمري بلجاء للدخيس لانه احياناً الشدوية ما تناسب كل الناس فتقبل بحملها بطريقة خاصة تناسب الحالة

أمثلة على أسباب

المرضى الأطفال

- **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. → الناس الي ما يقدروا يشربوا صيغون ليكملهم دواء سائل
- **Patients** with sensitivity to dyes, preservatives, or flavoring agents found in commercial formulations. حساسية
- Dermatological formulations with fortified (strengthened) or diluted concentrations of commercially available products. مركز
- Compounding for **animals**.
- Reconstitution of a lyophilized powder to form a simple solution → كل
يكتفون المرطبي لاحتاجوا أدوية/تغذية عن طريق الوريد
- 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 الرعاية الصحية المنزلية

لَيْسَ لِذَوَاءِ صَحِيحِن (مُسْتَوْق)

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.
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.

الاسم التجاري

Generic Name / الاسم الشائع

الدواء بقدر أن تعرف عليه ب ٣ أسماء :

الاسم العلمي (chemical), التجاري (Generic), الشائع ()

NDC 0002-1497-01
VIAL No. 767



Lilly

KEFZOL®

**STERILE
CEFAZOLIN
SODIUM, USP**

Equiv. to

500 mg

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 46205, U.S.A.
Exp. Date/Control No.

Categories of compounding

compounding:

TABLE 1.1: CATEGORIES OF COMPOUNDING

Category	Compounding Activity
1 غير معقم	Nonsterile – Simple بسيط منتجات جاهزة Mixing of two or more <u>commercial products</u> .
2 غير معقم	Nonsterile – Complex معقد Compounding with the <u>bulk drug substance</u> or when calculations required. المعقود مادة دوائية خام
3 معقم	Sterile – Risk Level I مستوى خطورة 1 See Chapter <797> Pharmaceutical Compounding – Sterile Preparations.
4	Sterile – Risk Level II مستوى خطورة 2 See Chapter <797> Pharmaceutical Compounding – Sterile Preparations.
5	Sterile – Risk Level III مستوى خطورة 3 See Chapter <797> Pharmaceutical Compounding – Sterile Preparations.
6	Radiopharmaceuticals أدوية مشعة Preparation of radiopharmaceuticals.
7	Veterinary أدوية بيطرية مخصصة للحيوانات Preparation of veterinary pharmaceuticals.

Compounding- Is it for every one?

بالرغم من انه الصيدلي مرخص قانونياً

- A pharmacist is legally licensed to compound, but is the pharmacist technically qualified to compound?
هل هو مؤهل تقنياً للقيام بذلك؟

- Compounding resources:- *هاي مصار compounding*

سلسلة اذاعات

- ① American Pharmacist Association (APhA)
 - ② American College of Apothecaries (ACA)
 - ③ National Community Pharmacists Association (NCPA)
-etc



American Pharmacists Association
Improving medication use. Advancing patient care.



Connect

Login/Register Contact Us

Search

Join APhA

LEARN

PRACTICE

GET INVOLVED

SHOP

ABOUT

NEWS

MTM CENTRAL

IMPLEMENTING MTM IN YOUR PRACTICE
ADVANCING THE VALUE OF MTM
MTM RESOURCE LIBRARY

IMMUNIZATION CENTER

APhA IMMUNIZATION GUIDELINES
ADMINISTRATION TECHNIQUE
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

Advertisement



Compounding Regulations Applies

- ① • Personnel (يشمل التدريب) ^{الإعزاز} والتأهيل والمعرفة والمهارة والالتزام
- ② • Facilities and Equipment (المرافق والمعدات) ^{المرفق والمعدات} تكون مجهزة ونظيفة ويتم صيانتها بشكل دوري
- ③ • Ingredient Standards (معايير المكونات) ^{الاستخدام} مكونات ذات جودة عالية
- ④ • Quality Assurance and Quality Control (الجودة) ^{وجود نظام لمراقبة الجودة خلال وبعد التركيب}
- ⑤ • Packaging and Storage (التعبئة والتخزين) ^{تخزين الدواء بطريقة تحافظ على جودته وسلامته وتخزين المنتج بطرق مناسبة}
- ⑥ • Documentation and Record Keeping (التوثيق) ^{التوثيق أول بأول وحفظ السجلات تسجيل كل خطوة بدقة}

عند تركيب الأدوية دورية ، في قواعد وتنظيمات صارمة يجب الالتزام فيها لضمان سلامة وفعالية الدواء المركب .
هذه التنظيمات تشمل جوانب مهمة ، منها :

Ingredient Standards

- **USP/NF**

- Meets standards set by the USP/NF.

يعني إذا كان مكتوب به عالمي
USP/NF تعني أن المنتج/المكونة
يعني بمعايير الجودة والصفاء المحدد
من قبل USP/NF .

- **ACS reagent**

- High purity

نقاء عالي

- Meets specifications of the Reagent Chemicals Committee of the American Chemical Society.

تلبية/تتبع

مواصفات

- **AR (analytical reagent)**

- Very high purity.

- **HPLC**

- Very high purity.

- Used in high pressure chromatography.

Record Keeping

① • Formulation Record

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

② • Compounding Record

- A record of what actually happened when the formulation was compounded. هو سجل ما تم فعليًا أثناء التركيب

③ • Standard Operating Procedures (SOPs)

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

④ • Material Safety Data Sheets MSDSs

- Ingredients records with certificates of purity.

بتحليل هاي المادة شو بتصوي
على مواد عشان أعرف أتحامل
مع الموقف لو تعرضت لشيء من المماره
← شهادات نقاوة
(معرفة طبيعة التعامل لأن من مع المواد الكيميائية)

تعليمات السكان

- Material Safety Data Sheet:
(MSDSs):

They are needed for all drug substances or bulk chemicals located in the compounding pharmacy.

MATERIAL SAFETY DATA SHEET

SOYBEAN OIL

MSDS

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:	Chemtrek 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:	Mild irritation may occur
Skin Contact:	May cause irritation in sensitive individuals with prolonged exposure
Ingestion:	Food Grade
Inhalation:	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

قابليتها للاشتعال

Major areas within the chapter

② Quality control ^{مراجعة} _{الجودة}

- 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

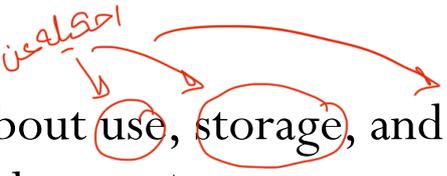
Major areas within the chapter

③ Verification ^{التحقق}

- Involves checking to ensure that all the process were appropriate and performed accurately ^{جميع العمليات}  ^{يتضمن التحقق أن جميع العمليات التي تمت كانت مناسبة ولم تنفيذها بدقة وصحة}

(إرشاده) الاستشارة إلى مقدمها للمريض

Patient counseling

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

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

ما اقله 1

ما يتخى 8 ولا 1

Assigning a Beyond-Use Date

مادة سائلة ما في صيغتها
زيت الزينة / الكحوليات

السائلة غير المائية

الصلبة

1 • **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.

عنا حاليين

لا يتجاوز

لا يتجاوز

الجميع التي يوصف على ما

2 • **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.

أني غير
التوعية
الى صحتي

* ما يخص لكل نوع مع مدة :-

النوع	الوصف	المدة المحددة لتاريخ ما بعد الاستخدام Beyond-Use Date
1) Nonaqueous liquids and solid Formulations	<p>a) مصدر المادة الفعالة دواء مصنع (manufactured drug Product)</p> <p>b) مادة USP/NF</p>	<p>a) لا تتجاوز 25% من الوقت المتبقي حتى انتهاء الصلاحية</p> <p>b) لا تتجاوز 6 أشهر</p>
2) Water containing Formulations	من مكونات مهيأة مخزنة في درجة حرارة باردة	لا تتجاوز 14 Days
3) All other Formulations	جميع الصيغ الأخرى	30 Days

Major areas within the chapter

The compounding process

6. Compound only one prescription at one time in a specified compounding area وصفة
7. Assemble all necessary material to compound the prescription المواد
8. Compound the preparation following the formulation record or prescription, according to the art and science of pharmacy
9. Assess weight variation, adequacy of mixing, clarity, odor, color, consistency, and pH as appropriate. تقسيم اختلاف الوزن رائحة
10. Annotate the compounding log and describe the appearance of the formulation توثيق

Major areas within the chapter

The compounding process

11 Label the prescription containers to include the following items:

- Name of the preparation
- Internal identification number
- Beyond used date
- Initials of the compounder who prepared the label
- Any storage requirements
- Any other statements required by law

Major areas within the chapter

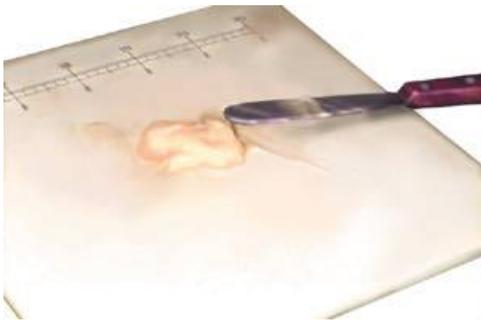
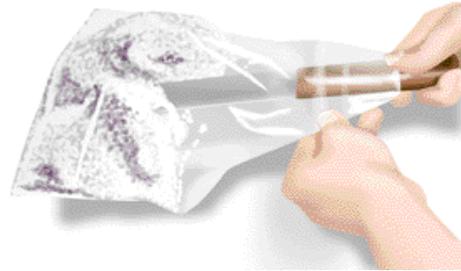
The compounding process

12. Sign and date the prescription, affirming that all procedures were carried out to ensure uniformity, identity, strength, quantity and purity

13. Clean all equipment thoroughly and promptly, and store properly

Types of Equipment

- **Measuring** معدات تستخدم لقياس الأوزان والأحجام
 - Balance, weights, weighing containers, volumetric glassware (graduates, pipets, flasks, syringes).
- **Molding** معدات تستخدم لتشكيل الأدوية في أشكال معينة
 - Hot plates, suppository molds, capsule shells, ointment slabs. قوالب التحاميل الواح تمخّن الكبسولات الواح المرهم
- **Mixing** معدات تستخدم لخلط المكونات مع بعضها
 - Beakers, Erlenmeyer flasks, spatulas, funnels, sieves, mortar and pestle. ملاعق مضممة قمع مناخل
- **Packaging** تعبئة
 - Prescription bottles, capsule vials, suppository boxes, ointment jars.



Small Volumetric Equipment



Calibrated pipette



Single volume pipettes

Syringe



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.

ملاحظه
مهم
!!!

Prescription vs. medication orders vs. medication administration records

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

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.

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

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

عدد مراتب صرف الوصفة
Refill instructions

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

يجب الوصفة بالرمز ليتم صرفها
الصيرلاني او لخط مادة بديلة

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

Drug Enforcement Agency (DEA) registration number of prescriber:
 (required for all controlled substances)

Date:
 The date the prescription was written.

Signature of prescriber:
 Jacquelyn Hyde
 DISPENSE AS WRITTEN

PRODUCT SELECTION PERMITTED

REFILLS: 1

SIG: 1/2 tsp. q4-6h prn

Acetaminophen 325 mg
Alcohol USP 15 ml
Cherry Syrup q.s. 90 ml

Ⓡ

NAME: Dan D. Lyon **DATE:** 2/18/08

ADDRESS: 123 Jackla Lane **PHONE:** 555-5678

Phone: 555-1234 **DEA#** AH0079411

Jacquelyn Hyde, MD
 123 Upendown Rd.
 Nowhere, NC 27000

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

FIGURE 3.1: SAMPLE PRESCRIPTION

Prescription Sample

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

هفوفك لجهوا
المستشفيات

تكون عند
المرضى عالسير
هو بنكتب
الطبيب
تج المريض بشكل
يوحي

DOCTOR'S ORDERS		PATIENT IDENTIFICATION	
		09999999 675-01 SMITH, JOHN 12/06/1950 DR. P JOHNSON	
DATE	TIME	DOCTOR'S ORDERS	DATE/TIME INITIALS
1/5/108	2300	Admit patient to 4th floor Pneumonia, Dehydration All: Sufa-Hives	
		Order CBC, chem-7, blood cultures stat Start LR @ 125 ml/hr IV q8*	
		Dr Johnson x2222	
DOCTOR'S ORDERS		DATE/TIME INITIALS	DATE/TIME INITIALS
2/10/108	2300	Tiabend 650mg po q4-6hrs PRN for Temp > 38 Peracet 5/525 PO q 4 hrs prn break through pain Verbal order Dr Johnson/ P. Smith, RN	
DOCTOR'S ORDERS		DATE/TIME INITIALS	DATE/TIME INITIALS
2/10/108	2300	Start ciprofloxacin 500 mg po bid Multivitamin po qd Penzon 12.5 mg IV q 6 hrs prn nausea Order CXR for this a.m.	
		Dr Johnson x2222	

FIGURE 3.2: SAMPLE MEDICATION ORDER

هون كل
الوقت
التي
مفضلة
زي ما

COMMUNITY HOSPITAL Medication Administration Record			
Room/Bed: 675-01	From 0730 on 02/01/08 to 0700 on 02/02/08	Patient: SMITH, JOHN	Diagnosis: PNEUMONIA; DEHYDRATION
Account #: 099999999	Sex: M	Height: 5'11"	Weight: 75KG
Age: 51Y	Doctor: JOHNSON, P	Verified by: Susie Smith, RN	
Allergies: PENICILLIN->RASH			
	0730-1530	1600-2300	2330-0700
LACTATED RINGERS 1 LITER BAG DOSE 125 ML/HR IV Q 8HRS ORDER #2	800 JD	1600 SS	2400
MULTIVITAMIN TABLET DOSE: 1 TABLET PO QD ORDER #4	1000 GIVEN @ 9AM JD		
CIPROFLOXACIN 500 MG TABLET DOSE: 500MG PO BID ORDER #5	1000 JD	2200 SS	
ACETAMINOPHEN 325 MG TABLET DOSE: 650 MG PO Q 4-6 HRS PRN FOR TEMP>38°C ORDER #7	1200 JD		
Init / Signatures	SS, Susie Smith, RN	Init / Signatures	/
	JD, Jane Doe, RN		/
	/		/

FIGURE 3.3: SAMPLE MEDICATION ADMINISTRATION RECORD (MAR)

Review and interpretation

أوضح / أترجم
أضخم شئ مكتوب

← لما يستلم الصيدلي

- Once the pharmacist has received an order **he must**:

الوصفة

1. Review and interpret (translate) the prescription

← يعني ضخم

و تحليل تعليمات
الوصفة بدقة .

2. Accurately weigh and measure all components

← هون بتأكد من

القياسات الدقيقة لكل

مكون من مكونات الدواء

3. Use appropriate compounding techniques to convert

استخدام تقنيات التجهيز

لتحويل

individual components into a finished formulation

المكونات الفردية

4. Properly package and label the formulation

← تعبئة (الدواء في

العبوة المناسبة ووضع

ملصق يحتوي على

المعلومات اللازمة

5. Deliver the formulation to the correct patient with adequate

تسليم / إعطاء

instructions for administration and storage

← شرح كيفية الاستخدام

الدواء وصي وأن يتم تناوله

وحيث يتم تخزينه بشكل

صحيح

Review and interpretation

- Reviewing, interpreting, and labeling the prescription involves a “language” that must be learned and utilized

- Abbreviations: اختصارات

- Latin abbreviations لَاتِينِيَّة

- Drug name abbreviations الدوا

- Medical abbreviations طبية

تتضمن استخدام الاختصار
يجب تعلمها واستخدامها
بشكل صحيح.

أنواع الـ
Abbrevia...

Please refer to tables 3.1-3.2 and 3.3 for examples

Common misinterpreted abbreviations

- Care must be taken when interpreting any abbreviation ^{أي، اختصار}
- Some abbreviations are prone to mis-interpretation so their use is not encouraged ^{تفسير}

← عُرْضَةُ لِسَوْدِي
النظير يعني
مَنْ كَانَ الْبَيْتُ
مَعَهُمْ فِيهَا
فَمَا بَيْتُهُمْ

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

بخطی



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](#)



Google™ Custom Search

Search

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

Comment on Draft Best Practices for IV Push Medications

[Click here to learn more](#)

Learn More and Apply for **ISMP Fellowships**

[LEARN MORE & APPLY](#) [Deadline 3/31/2015](#)

ISMP ANNUAL FUND

Looking forward to next 20 years of advancing medication safety

[FIND OUT MORE](#)

2015
Medication Safety Intensive

Education & Awareness

- [Newsletters](#)
- [Consulting Services](#)
- [Educational Programs](#)
- [Let ISMP be your PSO](#)
- [Professional Development](#)
- [Self Assessments](#)
- [ISMP Guidelines](#)
- [QuarterWatch](#)

Medication Safety Tools & Resources

Featured Tools

- [New standards for healthcare connectors – the "Stay Connected" program](#)
- [The Root Cause Analysis Workbook for Community/ Ambulatory Pharmacy](#)
- [Special Error Alerts](#)
- [2014-15 Targeted Medication Safety Best Practices for Hospitals](#)
- [ISMP Guidelines](#)
- [High-Alert Medications](#)

2014-15

Targeted Medication Safety Best Practices for Hospitals

[REVIEW DOCUMENTS](#)

NEW ISSUE AVAILABLE

QuarterWatch

Monitoring FDA MedWatch Reports



Join our mailing list to get news, announcements and event notifications

[JOIN NOW](#)

MEDICATION SAFETY JOBS

[View Job Postings](#)

Labeling

- **Extemporaneous preparations:** preparations done by the pharmacist in his own small lab. *التحضيرات المختبر الخاص*
- Pharmaceutical formulations must be suitably contained, protected and labeled.
- There are two types of labels: Main and Auxiliary *① رئيسية ② ثانوية*
- Label on the dispensed medicine has two main functions:
 - ① *لماذا بسوي* to uniquely identify the contents of the container. *محتويات*
 - ② *لماذا بسوي؟* to ensure that patients have clear and concise information *مفاتيح* which enable them to take or to use their medication in the most effective and appropriate way.

← ضمان أن المريض لديه معلومات واضحة ومختصرة
تتمكنهم من تناول الدواء
أو استخدامه بطريقته المثالية

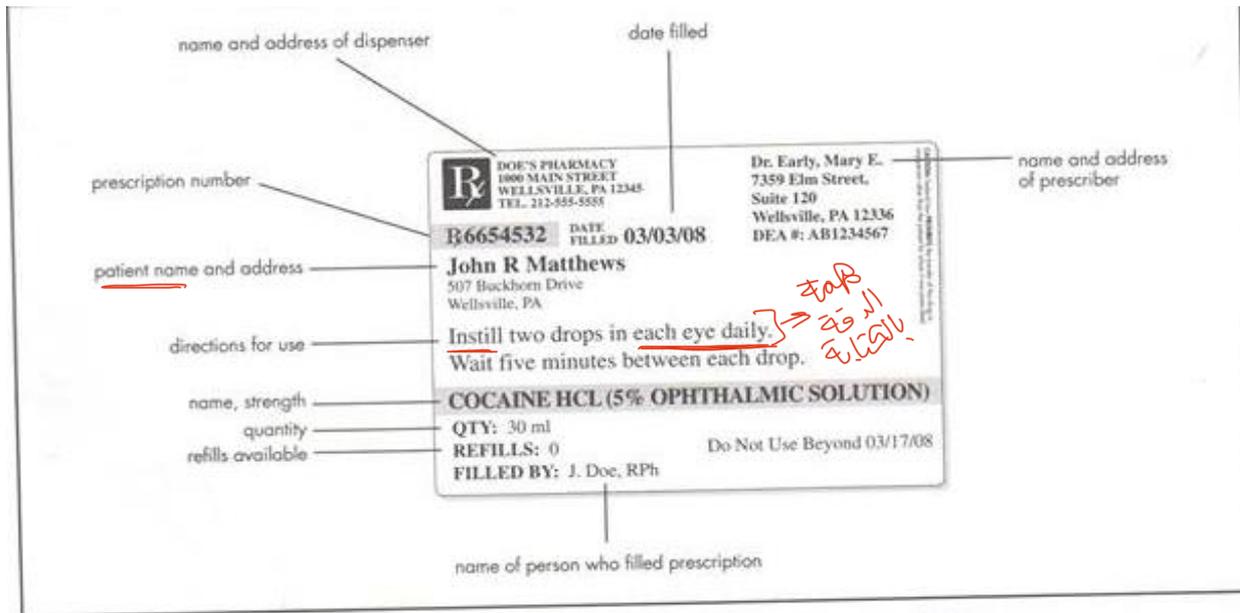


FIGURE 3.5: EXAMPLE OF A PRESCRIPTION LABEL

Some guidelines about wording patient instructions:

- Indicate the dosage form to be administered: →

يجب ذكر
شكل الدواء
مثل بين القوس

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

- Use words instead of numbers: →

استخدم
كلمات بدل
أرقام

“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: →

يعني احد طرق
اعطاء الدواء انما كان
فموي

“Insert one suppository vaginally every night at bed time”

- Specify which side is to receive the medication if more than one organ is present: →

حدد الجانب الذي يجب
اعطاء الدواء اليه ان كان هناك
اكثر من عضو

“Instill two drops in left eye daily” instead of “instill ~~two drops~~ daily”

- Do not use abbreviations: →

ما استخدم
الاختصارات

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

Some guidelines about wording patient instructions:

- In general, specify the amount of active ingredient ^{كمية} per dosage ^{لعل} 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:
^{بكميات كبيرة}
^{المحاليل}
^{مراهم} ^{الكريمات}

Hydrocortisone cream 1%

Betadine solution 2%

يجب عند صرف الأدوية بالجملة تأثيلها
المذكورة لئلا يُعترض عن مقدار المادة الفعالة
كنسبة مئوية

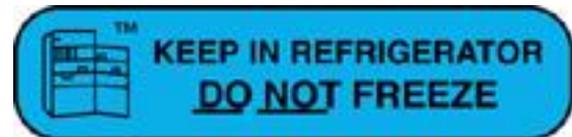
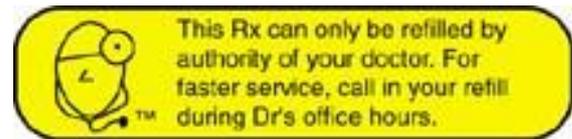
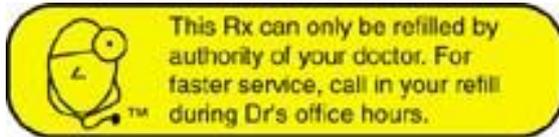
2 غرام
لعل 100ml

Rule When Writing Directions For Use

- **START WITH A VERB** → ابدأ بفعل
تناول قطره استنشاق أدخل ضع / طبق
- Take, instill, inhale, insert, or apply
- Indicate **ROUTE of ADMINISTRATION**
المنطقة المصابة حدد طريقة الإعطاء
- Apply to affected area.
ضع
- Take one tablet by mouth.
قرص واحد
- Insert *rectally*.
- Place one tablet *under the tongue*.
- **NO ABBREVIATIONS**
- Use familiar words
-  or 10 ml
← لسقطت سميكا

Auxiliary Labels

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



بیمه
تفصیلاً
از پزشک

بكونوا مهتمين

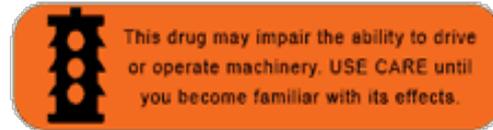
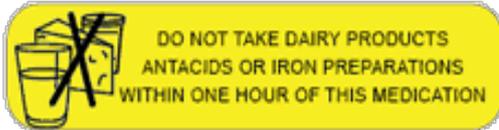
نوع العبوة (التسمية)
(المميز)

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

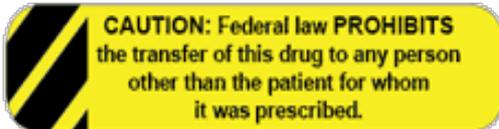
Some Auxiliary Labels



ببسيب
نحاشي



بالشعلى قدرق
تركيزك بالسوانفة



المواد الخاضعة للرقابة
الى هيبة الادوية الى
باعتبارها على مواد ق
تسمى الادمان او تستخدم
في غير حادها

- Controlled substances from schedules II, III, and IV must carry an auxiliary label stating “Caution: Federal Law ^{القانون} ^{الفيدرالي} prohibits the transfer of this drug to any person other than the patient for whom it was prescribed”
^{يمنع} ^{نقل}

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.

ويستلمها الممرضين

The Prescription Process

الوصفة الطبية
عليه

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

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

مرات
بوقع عليها

مراجعة
كامل

Pharmacists provide counseling.

تقديم الاستشارة
للمريض



Pharmacy Abbreviations

الاحتمالات

Most common abbreviations:

- Route طريقته اعطاء
PO/IV/IM
ممكن ان تكون
- Form الشكل
Tab/Cap/Sol
- Time التوقيت
QD/BID
- Measurement وحدة القياس
mg/mL

Dosage Form Abbreviations

elix = elixir

رَحْمِيلَة

(اختصارات الجرعات)

supp = suppository

ung = ointment

مَرَسْم

tab = tablet

cap = capsule

كَبْسُولَة

SR, XR, XL = slow/extended release

sol = solution

مَحْلُول

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

رج نوزدها طر
بالكمية الطوية



Others Abbreviations

Stat = now

NR = no refill

UD = as directed

Examples

الأمثلة

Drug	Rx	Label Directions
Diovan® 80 mg tablet	i po qd ٥٥ طريق الفم يوم	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

٥٥
٩

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

اسم الدواء

Actos 30mg
Sig: T po q d
#30

REFILL II

DISPENSE AS WRITTEN

R. Pintar
PRESCRIBER'S SIGNATURE

Use separate form for each controlled substance prescription.
THEFT, UNAUTHORIZED POSSESSION AND/OR USE OF THIS FORM INCLUDING ALTERING OR FORGERY, ARE CRIMES PUNISHABLE 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.”
- **Are there look-alike names?**
 - Is it Metadate[®] 10 mg or Methadone 10 mg; Lamictal[®] or Lamisil[®]?

Caution!



- **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.

- **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~~^١ 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

CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

Prescription Label Examples

Alice Chan, M.D.
123 Main Street
Wellsville, PA 00000
Telephone: 800/555-1234
DEA number AB1234563
NPI: 1234567893

Date May 28, 2010

NAME Donna H. Doe

ADDRESS 305 Maple Street, Wellsville, PA

Rx Neurontin 300mg
Sig: † cap po TID
#90

REFILL x2

DISPENSE AS WRITTEN Alice Chan
PRESCRIBER'S SIGNATURE

This space is for each individual patient's prescription.
NOFT, UNAUTHORIZED REPRODUCTION AND/OR USE OF THIS FORM WILL BE PROSECUTED TO THE FULL EXTENT OF THE LAW.

R_x PHARMACY # 00000
1000 MAIN STREET
WELLSVILLE, PA 00000

212 555-5555
DEL.

6654532 DATE FILLED **05/28/10**

DONNA H. DOE

**TAKE 1 CAPSULE BY MOUTH
THREE TIMES DAILY**

90 NEURONTIN 300MG CAPSULES

MFG: PARKE-DAVIS
DISCARD AFTER: 12/31/2011
DR. ALICE CHAN

MAY REFILL 2 TIMES BEFORE 05/28/2011

PHARMACY # 00000
1000 MAIN STREET
WELLSVILLE, PA 00000
212 555-5555
DEL.

**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)

New Slides

Definitions

- **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**.

Definitions

- **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*.

Definitions

- **COMPONENT**—Any ingredient used in the compounding of a drug preparation, including any **active ingredient or added substance** that is used in its preparation.
- **COMPOUNDER**—A professional authorized by the appropriate jurisdiction to perform compounding pursuant to a prescription or medication order by a licensed prescriber.