لجان التدفعات

DOPAMINE ACADEMY

Dispensing

Subject: Introduction

31-7-2024

بسم الله الرحمن الرحيم

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)

Compounding

- **Extemporaneous compounding**
  - On-demand preparation of a drug product.
  - According to a physician's prescription.
  - Meets the unique needs of an individual patient.
- **Manufacturing**
  - The production or processing of a drug in a LARGE quantity by various mechanisms.

وهذا التشابتر يعرف تركيب الأدوية على أنه:

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"

ملاحظة: ممكن بالإمتحان يضيفو كلمة physician وهي مذكورة فإنتبه

[تحضير الدواء من خلال تعليمات شخص ممارس وخبير ومرخص] بالعربي وبشكل مختصر

Compounding is NOT manufacturing in the legal sense

- 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.
- Manufacturing is defined in USP/NF as:

" 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……."

الجهات المسؤولة عن تركيب العقاقير (compounding)

Regulatory Aspects of Compounding

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.
- These books are referred to collectively as drug compendia.
- These books are revised from time to time to introduce the latest information available.

Pharmacopoeias and Formularies

Common drug compendia

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

pharmacopeia: دستور الأدوية

USP

أصل الإسم

- 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.

موجود فيه المتطلبات والأشكال والأشياء المطلوبة لتصنيع الأدوية

USP الدستور الأمريكي

- The **United States Pharmacopeia** (**USP**) is the official pharmacopeia of the United States, 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.
- Prescription and over–the–counter medicines and other health care products sold in the United States are required to follow the standards in the USP-NF. USP also sets standards for food ingredients and dietary supplements.

USP

- The USP and NF adopt standards for:
  - drug substances,
  - pharmaceutical ingredients,
  - and dosage forms

  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.

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**
  - Published in 2000
  - Enforceable
- **Chapter <797>** - called **Pharmaceutical Compounding - Sterile Preparations,**
  - Became official in 2004.
- **Other Chapters**
  - Containers <661>
  - Good Compounding Practices <1075>
  - Pharmaceutical Stability <1150>
  - Pharmaceutical Dosage Forms <1151>

USP-NF

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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.

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 Commentary (25–Jul–2014)

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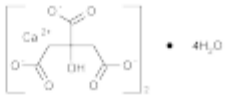
- Regulators


British Pharmacopoeia
2008
British Pharmacopoeia
2008
British Pharmacopoeia
2008

A sample of USP-NF monograph

Calcium Citrate



$C_{12}H_{10}Ca_3O_{14} \cdot 4H_2O$ 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 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

- 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.
- 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

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 to set uniform standards for the medications prescribed by physicians and to publish compendia of these standards
- NF was first published in 1888 by APA listing standardized formulas including the ingredients and their quantities required for compounding
- In 1975 the USP purchased the NF
- Today the USP/NF is an independent organization

Official compounded formulations

- USP contains monograph of most commonly compounded preparations used in pharmacy practice that has the advantage of:
  - USP testing
  - Quality assurance
  - "beyond use date" assignment

Elixir sulfanilamide

From Wikipedia, the free encyclopedia

Elixir sulfanilamide was an improperly prepared sulfanilamide medicine that caused mass poisoning in the United State 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, t 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".[2] 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 journ its toxicity was not widely known prior to the incident.)[1][4] Watkins simply added raspberry flavoring to the sulfa drug whi marketed the product. Although animal testing should have been routine in most drug company operations, Massengill p premarket safety testing of new drugs.

The company started selling and distributing the medication in September 1937. By October 11, the American Medical A by the medication. The Food and Drug Administration was notified and an extensive search was conducted to recover t 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 s results. I do not feel that there was any responsibility on our part."[6] Watkins, the chemist, committed suicide while awaiti

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 a

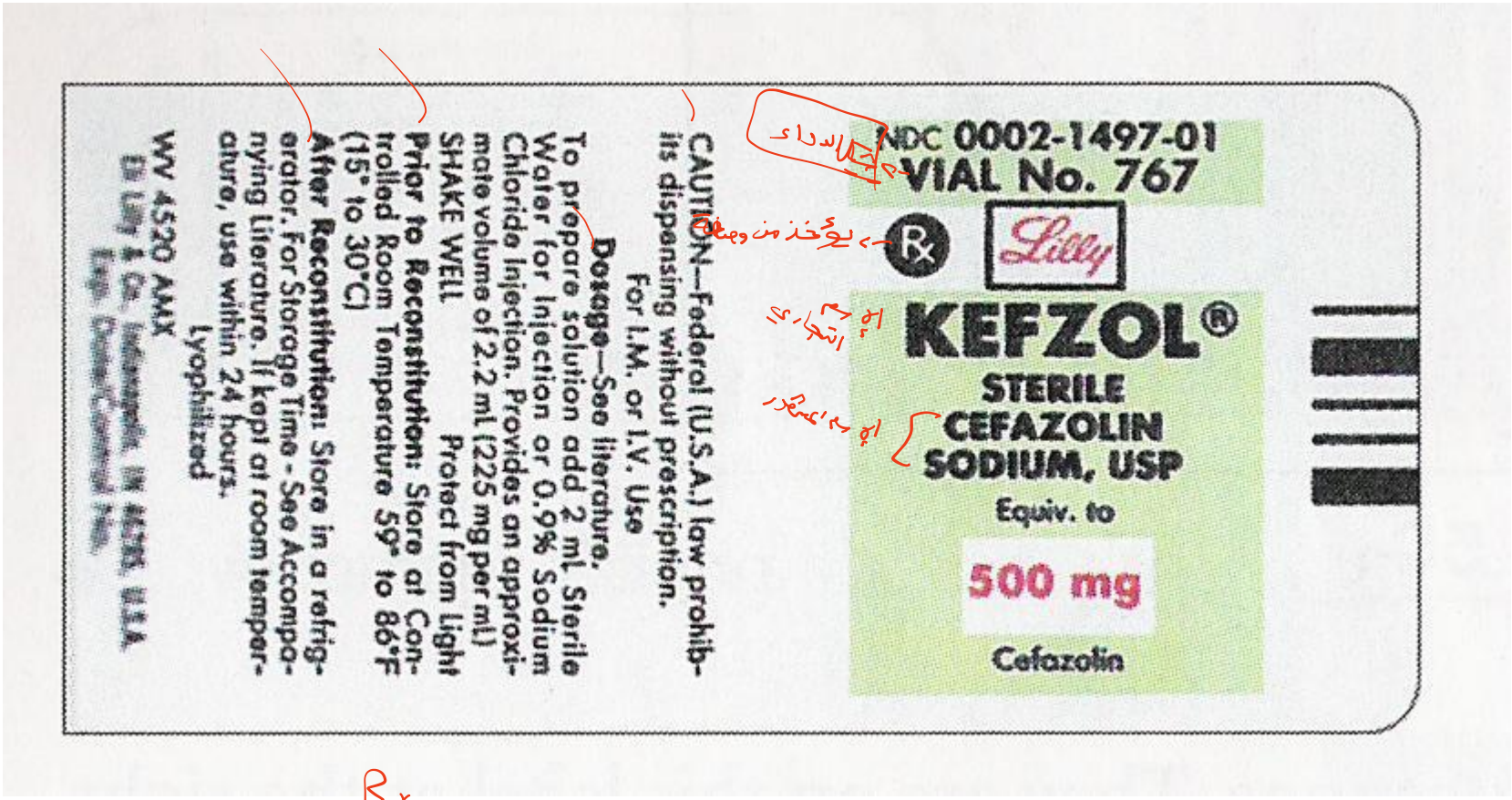
FDA

- 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.
- 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
- 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.

Why Compound?

- **Pediatric patients** requiring diluted adult strengths of drugs.
- Patients needing an oral **solution or suspension** of a product that is only available in another form.
- Patients with **sensitivity** to dyes, preservatives, or flavoring agents found in commercial formulations.
- Dermatological formulations with fortified (strengthened) or diluted concentrations of commercially available products.
- Compounding for **animals**.
- Reconstitution of a lyophilized powder to form a simple solution
- In hospital compounding involves the preparation of IV admixtures, parenteral nutrition solutions, and radiopharmaceuticals
- In home health care compounding requires the preparation of syringes and other devices for home-infusion administration

- **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.


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

Rx

R

Auxiliary label

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)

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Lyophilized

WV 4520 AMX

Eli Lilly & Co., Indianapolis, IN 46285, U.S.A.

Exp. Date/Control No.

Categories of compounding

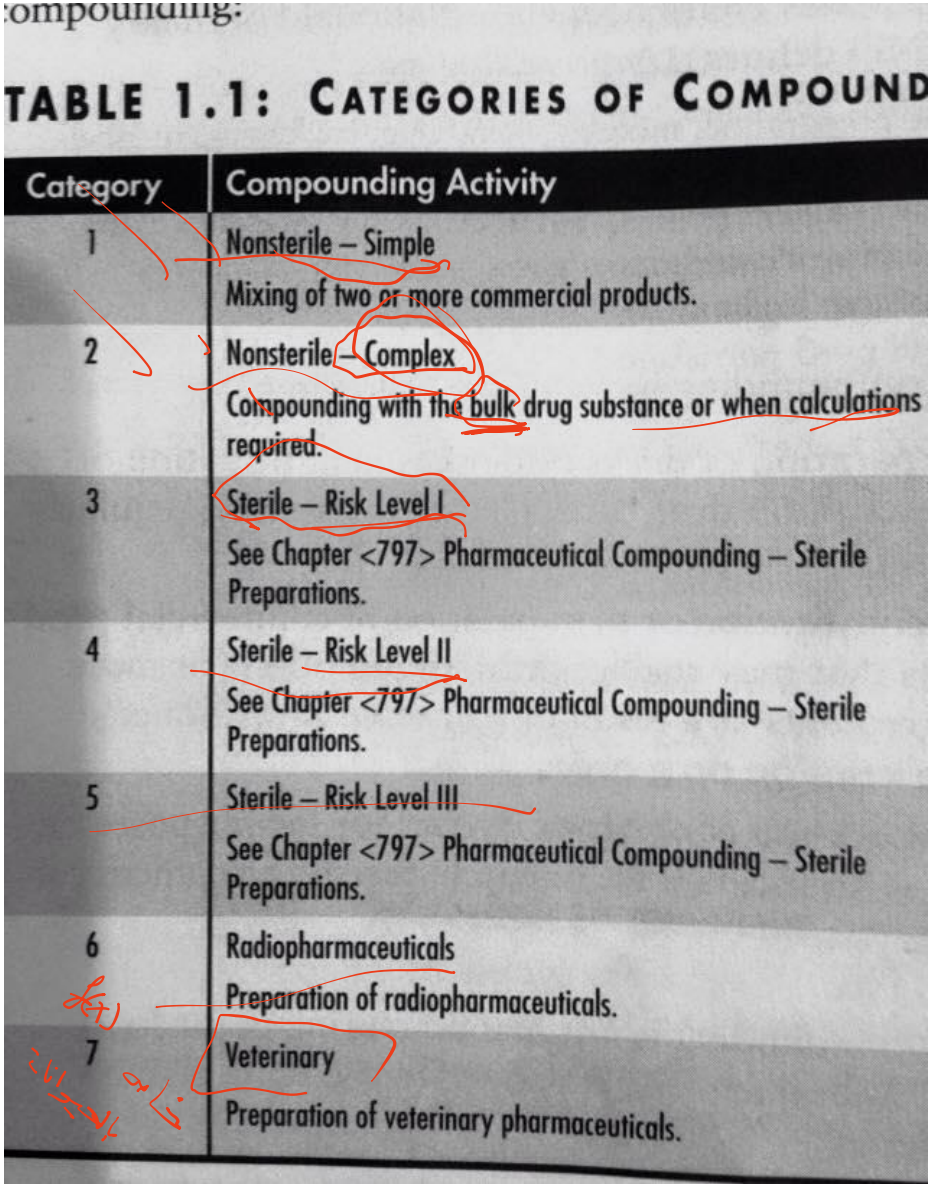
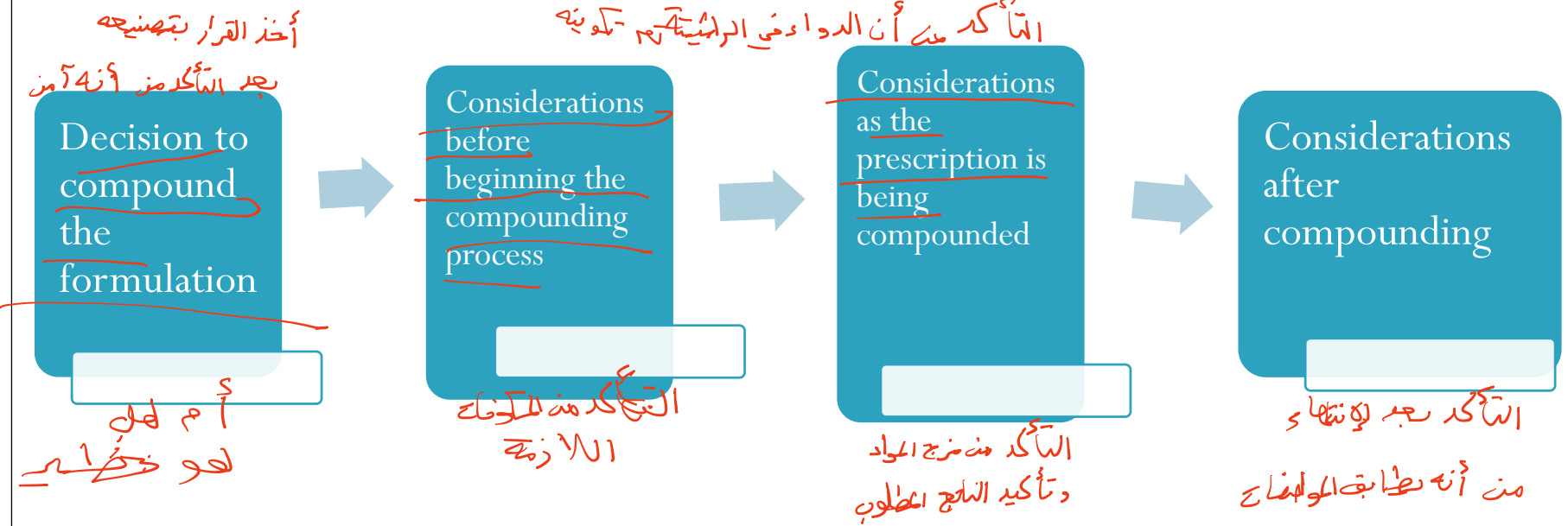


TABLE 1.1: CATEGORIES OF COMPOUND

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.

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

بعض الأسئلة التي نطرحها على أنفسنا قبل وأثناء وبعد صنع الدواء



Compounding- Is it for every one?

- A pharmacist is legally licensed to compound, but is the pharmacist technically qualified to compound?
- Compounding resources:-
  - American Pharmacist Association (APhA)
  - American College of Apothecaries (ACA)
  - National Community Pharmacists Association (NCPA)
  - ……etc

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COMPOUNDING
- FREQUENTLY ASKED QUESTIONS

SPECIALTY PHARMACY

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Bernhardt treats pedes oncology patients

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Symbicort
(budesonide/formoterol fumarate

Compounding Regulations Applies

- Personnel
- Facilities and Equipment
- Ingredient Standards
- Quality Assurance and Quality Control
- Packaging and Storage
- Documentation and Record Keeping

Ingredient Standards

- **USP/NF**
  - Meets standards set by the USP/NF.
- **ACS reagent**
  - High purity
  - Meets specifications of the Reagent Chemicals Committee of the American Chemical Society.
- **AR (analytical reagent)**
  - Very high purity.
- **HPLC**
  - Very high purity.
  - Used in high pressure chromatography.

Record Keeping

- **Formulation Record**
  - Formulas and procedures (i.e., recipes) for what should happen when a formulation is compounded.
- **Compounding Record**
  - A record of what actually happened when the formulation was compounded.
- **Standard Operating Procedures (SOPs)**
  - Equipment maintenance, equipment calibration, handling and disposal of supplies, etc.
- **Material Safety Data Sheets MSDSs**
  - Ingredients records with certificates of purity.

Major areas within the chapter

Compounding records and documents

Purpose:

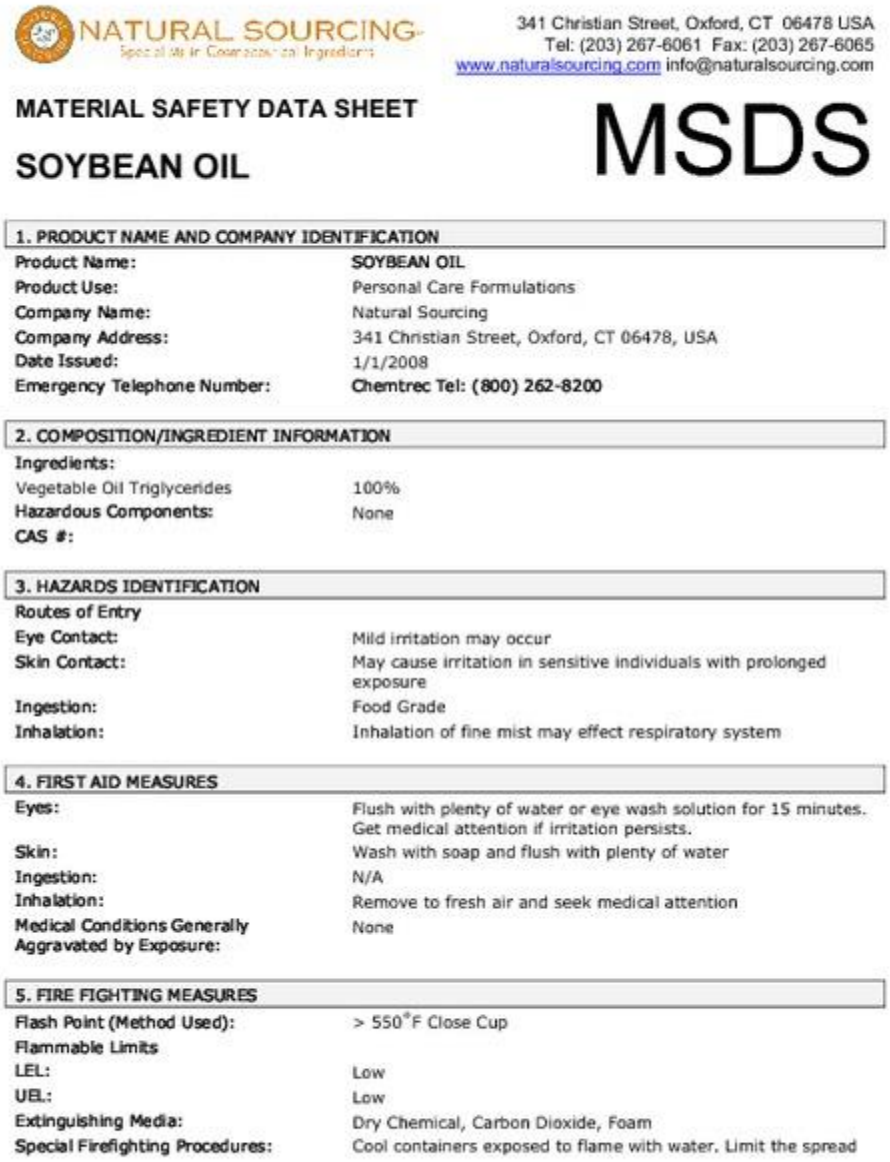
1. To meet record keeping requirements
2. To enable another compounder to duplicate the preparation

- Compounding record contains:
  - Sources and lot numbers of the ingredients
  - Calculations
  - Processes used
  - Results of any testing done
  - An assigned beyond used date
  - Identification numbers
  - Name of the compounder
  - Quantity of the preparation compounded

طرق الاستخدام الامن للمادة

- Material Safety Data Sheets (MSDSs):

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



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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:	**Chemtrec 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

Page 1 of 3

Major areas within the chapter

Quality control

- 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

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]

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, urgence 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. 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.[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]

- "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

Major areas within the chapter

Verification التوثيق

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

التأكد من أن كل العمليات
تمت بدقة

Patient counseling

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

يجب أن يعرف المريض عن التخزين
أو عن التغيرات التي تحدث في الدواء

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**
  - The extent to which a dosage form retains the same properties and characteristics that it possessed at the time of its manufacture.
- **Expiration date**
  - The date until which the manufacturer can guarantee of the safety and full potency of a drug- usually determined after extensive study of the product's stability.
- **Beyond-use dates**
  - Used for compounded preparations only and are generally in the order of "days" or "months."
- **Shelf life**
  - Length of time a packaged drug will last without deteriorating

Assigning a Beyond-Use Date

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

Major areas within the chapter

The compounding process

كيف أقلل الأخطاء المحتملة

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?

تأكد من أن الدواء آمن و يمكن تصنيعه

2. Perform necessary calculations (see <1160> Pharmaceutical calculations in prescription compounding>)

قم بالحسابات اللازمة

3. Identify equipment needed

جهز المكونات المطلوبة

4. Wear the proper attire and wash hand

البس الملابس المناسبة

اغسل يديك

5. Clean the compounding area and needed equipment

نظف مكان الخلط والمعدات اللازمة

Major areas within the chapter

The compounding process

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

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

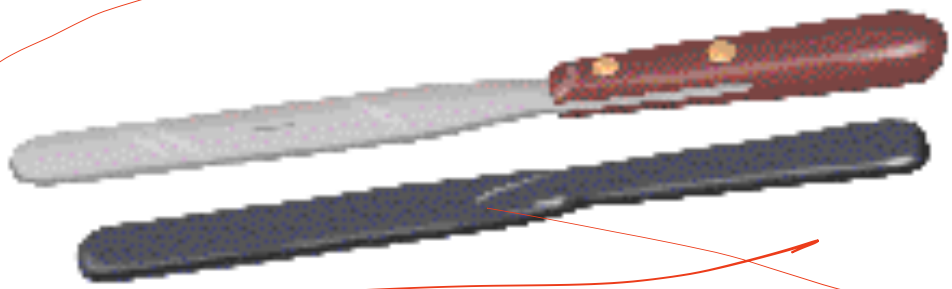
The compounding process

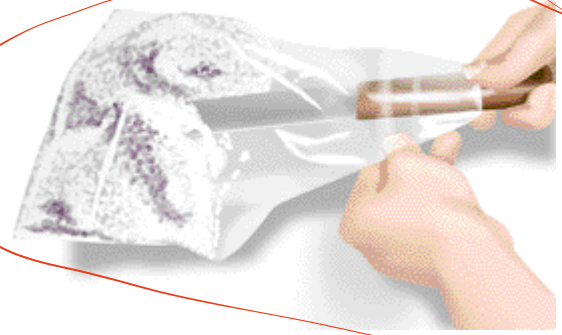
12. Sign and date the prescription, affirming that all procedures were carried out to ensure uniformity, identity, strength, quantity and purity

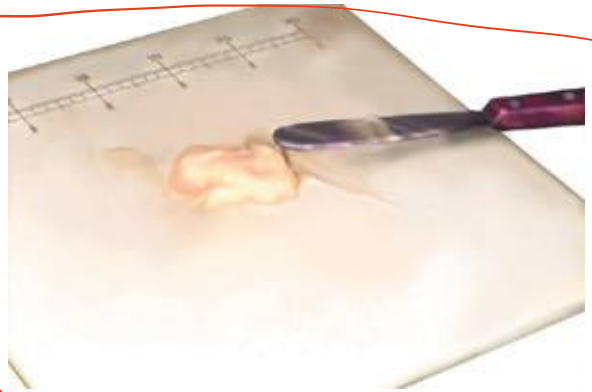
13. Clean all equipment thoroughly and promptly, and store properly

Types of Equipment

- **Measuring**
  - Balance, weights, weighing containers, volumetric glassware (graduates, pipets, flasks, syringes).
- **Mixing**
  - Beakers, Erlenmeyer flasks, spatulas, funnels, sieves, mortar and pestle.
- **Molding**
  - Hot plates, suppository molds, capsule shells, ointment slabs.
- **Packaging**
  - Prescription bottles, capsule vials, suppository boxes, ointment jars.







فارما

فارما

صيدلة

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.

Prescription vs. medication orders vs. medication administration records

هنا تميز بين انواع الوصفات الطبية

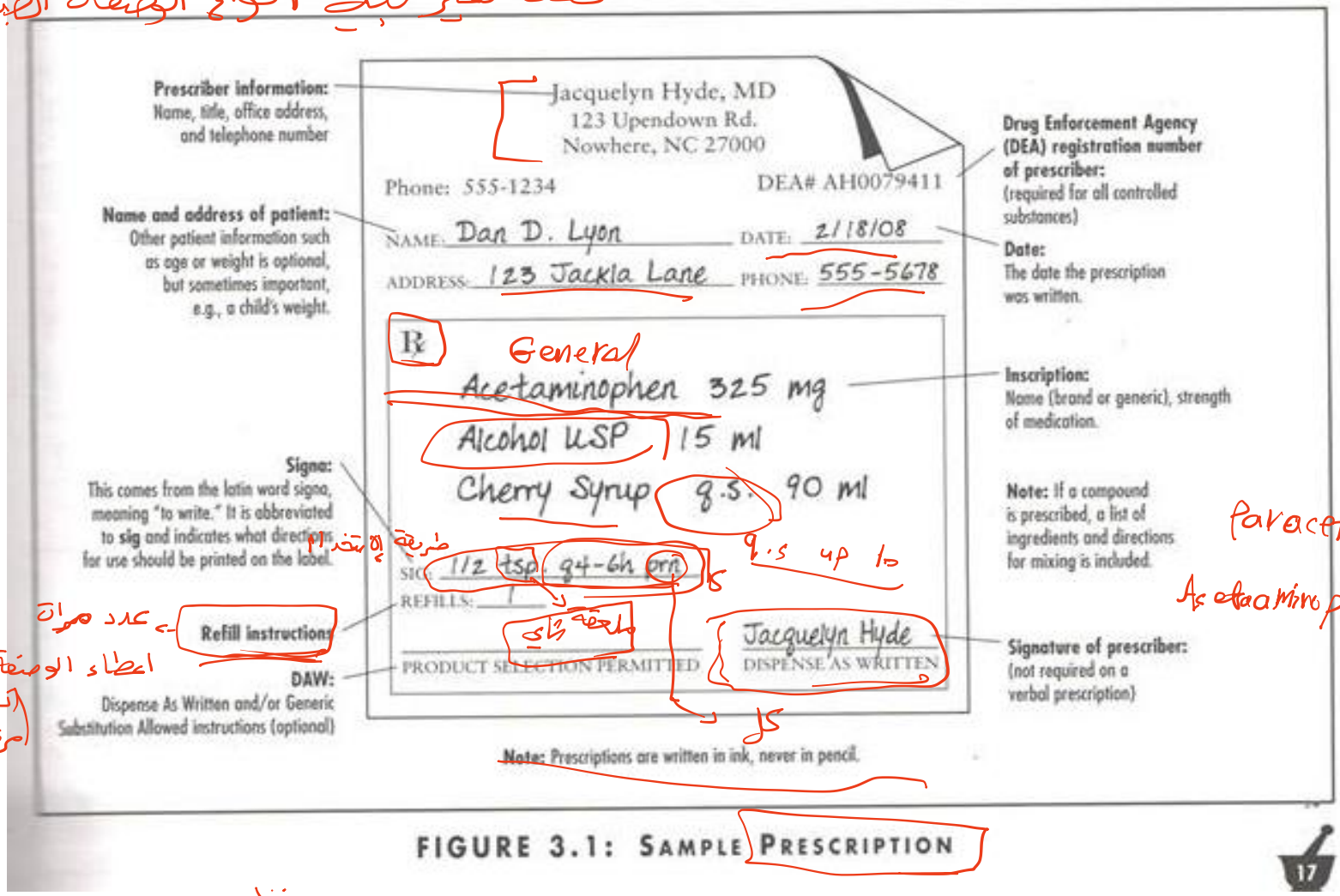


FIGURE 3.1: SAMPLE PRESCRIPTION

paracetamol

Acetaaminophen

يعني هون احفظ النموذج

Prescription Sample

TUFTS UNIVERSITY SCHOOL OF DENTAL MEDICINE
One Kneeland Street
Boston, MA 02111
555-999-9999

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

Drug: Amoxocillin 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

medication order

في صيدلية المستشفى

فيه كل اللي انعطى للمريض وكل الأدوية اللي تُعزها ويوجد هنا فحوصات

DOCTOR'S ORDERS

PATIENT IDENTIFICATION
099999999 675-01
SMITH, JOHN
12/06/1950
DR. P JOHNSON

DATE	TIME	DOCTOR'S ORDERS 1	DATE/TIME INITIALS	DATE/TIME INITIALS
1/31/08	2300	Admit patient to 4th floor	–	
		Pneumonia, Dehydration		
		All: Sulfa-Hives		
	—	Order CBC, chem-7, blood cultures stat		
	—	Start LR @ 125 ml/hr IV q8°		
		Dr Johnson x2222		
		DOCTOR'S ORDERS 2	DATE/TIME INITIALS	DATE/TIME INITIALS
2/01/08	500	Tylenol 650mg po q4-6hrs	—	
		PRN for Temp>38		
		Percocet 5/325 PO q 4 hrs prn	—	
		break through pain		
		Verbal order Dr Johnson/		
		P. Smith, RN		
		DOCTOR'S ORDERS 3	DATE/TIME INITIALS	DATE/TIME INITIALS
2/01/08	600	Start ciprofloxacin 500 mg po bid		
		multivitamin po qd		
		Phenergan 12.5 mg IV q 6 hrs prn nausea		
		Order CXR for this a.m.		
		Dr Johnson x2222		

FIGURE 3.2: SAMPLE MEDICATION ORDER

medical admistration record

COMMUNITY HOSPITAL
Medication Administration Record

Room/Bed: 675-01
Patient: SMITH, JOHN
Account #: 099999999
Sex: M
Age: 51Y
Doctor: JOHNSON, P.

From 0730 on 02/01/08 to 0700 on 02/02/08
Diagnosis: PNEUMONIA; DEHYDRATION
Height: 5'11" weight: 75KG
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 / Signature	Init / Signature
SS / Susie Smith, RN	___ / ___
JD / Jane Doe, RN	___ / ___
___ / ___	___ / ___

FIGURE 3.3: SAMPLE MEDICATION ADMINISTRATION RECORD (MAR)

نقطة الأدوية وفترات استخدامها

Prescription vs. medication orders vs. medication administration records

- Both convey necessary information to the pharmacists but are used in different patient care settings
- Prescriptions are used for outpatient care
- Medication orders:
  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

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:
  - Latin abbreviations
  - Drug name abbreviations
  - 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

في حال حدث خطأ

وكيف تقرأ في حال كان هناك خطأ

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

و يتم التبليغ على هذا الخطأ

Institute for Safe Medication Practices

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

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 S Best Practices for Hosp

REVIEW DOCUMENTS

NEW ISSUE AVAILA

QuarterWatc

Monitoring FDA MedWatch Reports

Join our mailing list

get news, announcem and event notificatio

JOIN NOW

MEDICATION SAFETY JOBS

View Job Postings

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: Main and Auxiliary
- Label on the dispensed medicine has two main functions:
  - to uniquely identify the contents of the container.
  - 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.

Main Label

- 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.
- 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,
- 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.

main label

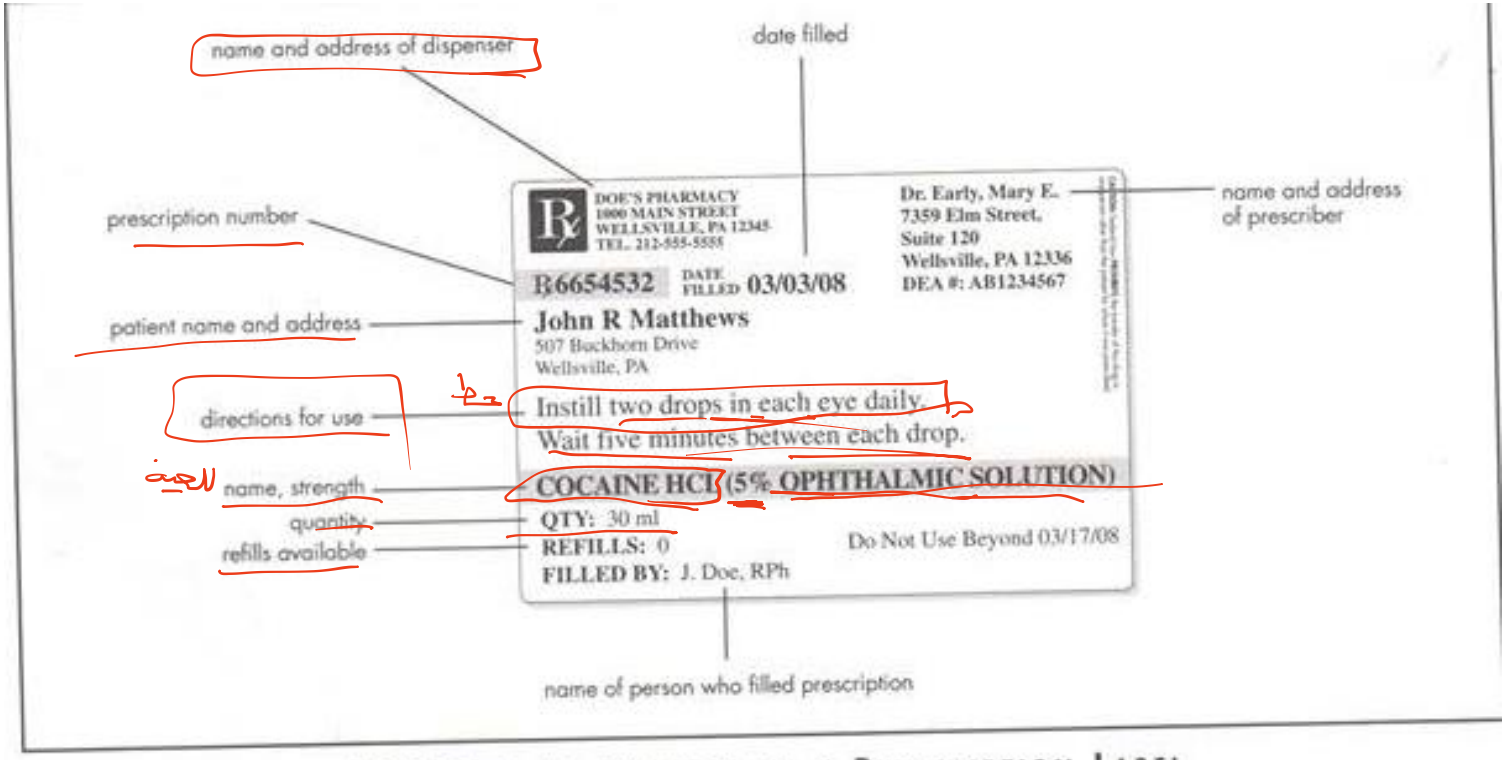


FIGURE 3.5: EXAMPLE OF A PRESCRIPTION LABEL

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:

- 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

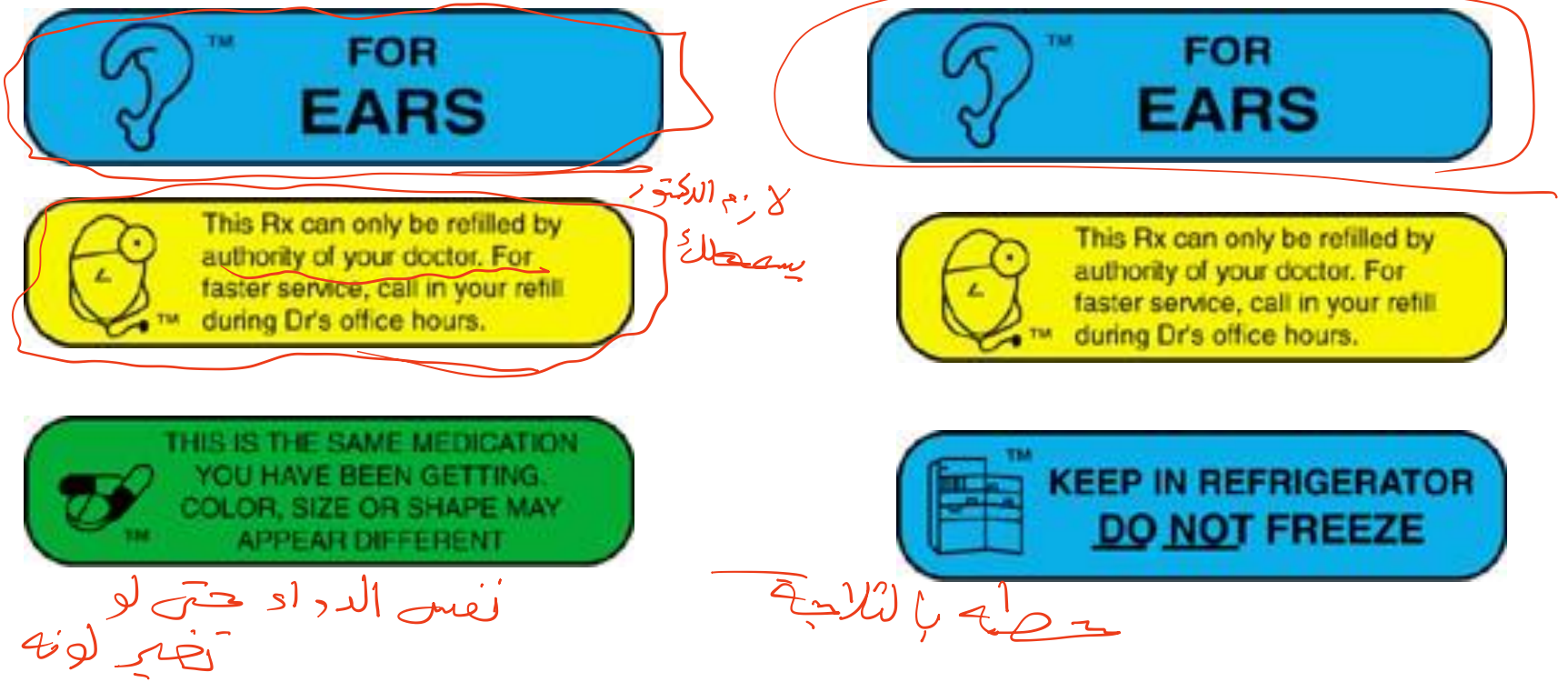
- **START WITH A VERB**
  - Take, instill, inhale, insert, or apply
- Indicate **ROUTE of ADMINISTRATION**
  - Apply to *affected area.*
  - Take one tablet *by mouth.*
  - Insert *rectally.*
  - Place one tablet *under the tongue.*
- **NO ABBREVIATIONS**
- **Use familiar words**
  - Teaspoonfuls or 10 ml

Auxiliary Labels

- The auxiliary labels: arranged on the other side of the container, these labels are cautionary or advisory depending on the type of dosage form.
- 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*
- Refer to examples in pg 25

Auxiliary Labels

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

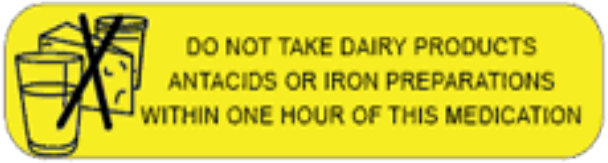


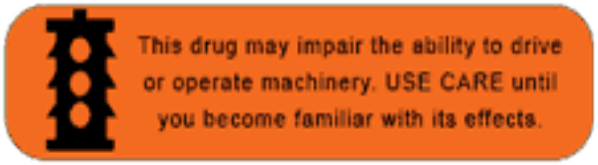
Type of preparation	Color of print	container	Auxiliary labels
Oral solutions(ORS,Elixir,syrups)	Black	Plain bottle(glass, plastic)	For oral use
Ear drops	Red	Fluted hexagonal glass dropper bottle or plastic squeeze bottle	Not to be taken orally, for ear use only
Eye drops	black	Fluted hexagonal glass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

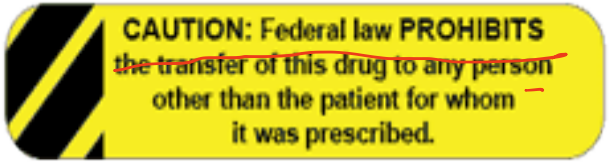
oral Eye nose Black

External Ear Red

Some Auxiliary Labels







الأنف

نفس الوصفة لكن تعود أكثر

- 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"

يجب أن تكون الصيدليات خاضعة للرقابة

Prescriptions

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

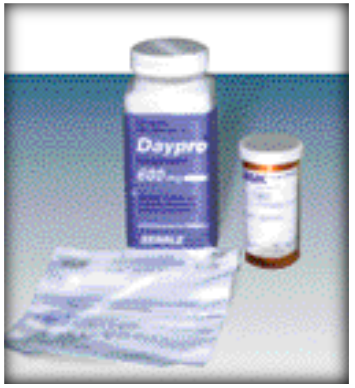
- **Community Pharmacists**
  - Dispense directly to the patient.
  - The patient is expected to administer the medication according to the pharmacist direction.
- **Institutional Pharmacy**
  - Nursing staff generally get the medications mostly from the pharmacists and administers to patients.

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

Most common abbreviations:

- Route
- Form
- Time
- Measurement

طريقة اعطاء الدواء

dosage form

وقت استخدامه

كميات القياس

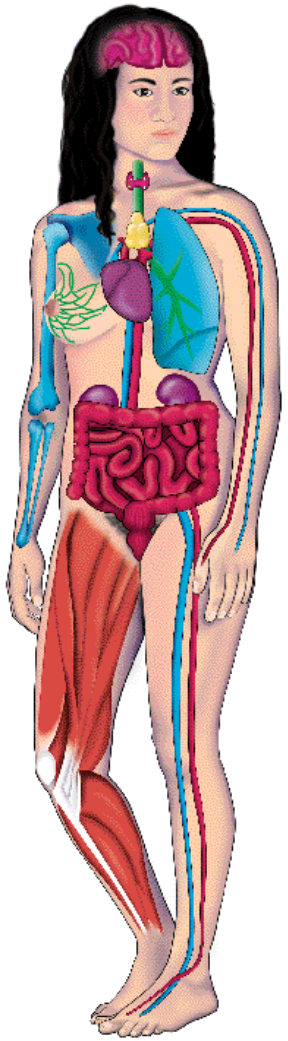
Route طريقة إعطاء
form الشكل
time
measurement

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

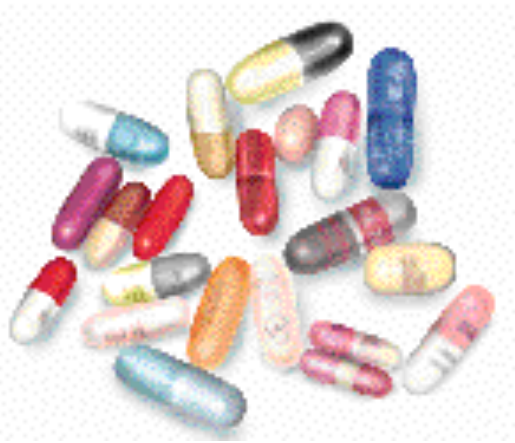
qd = every day

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

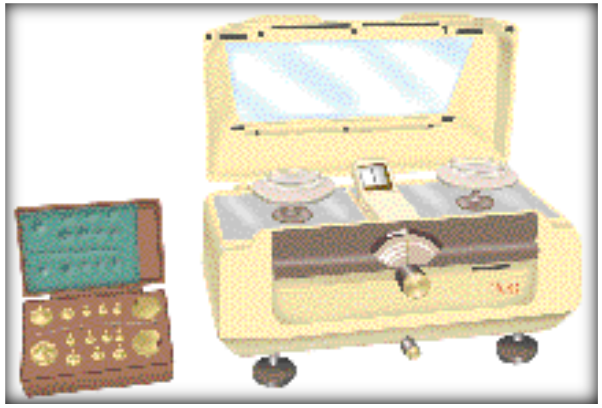
SR, XR, XL = slow/extended release

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

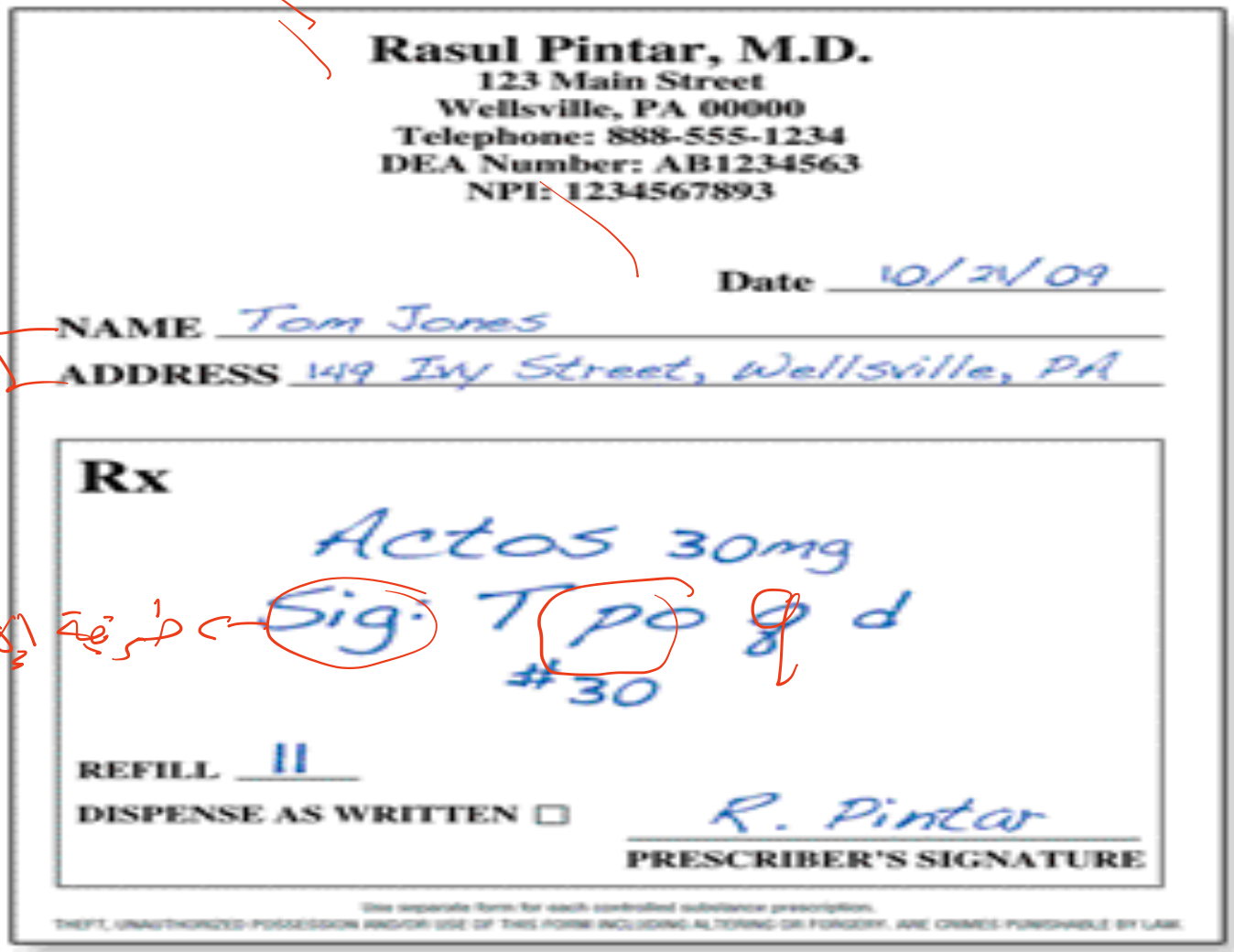
Stat = now

NR = no refill

UD = as directed

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 10/21/09
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

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

رقم الوصفة

- **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®?

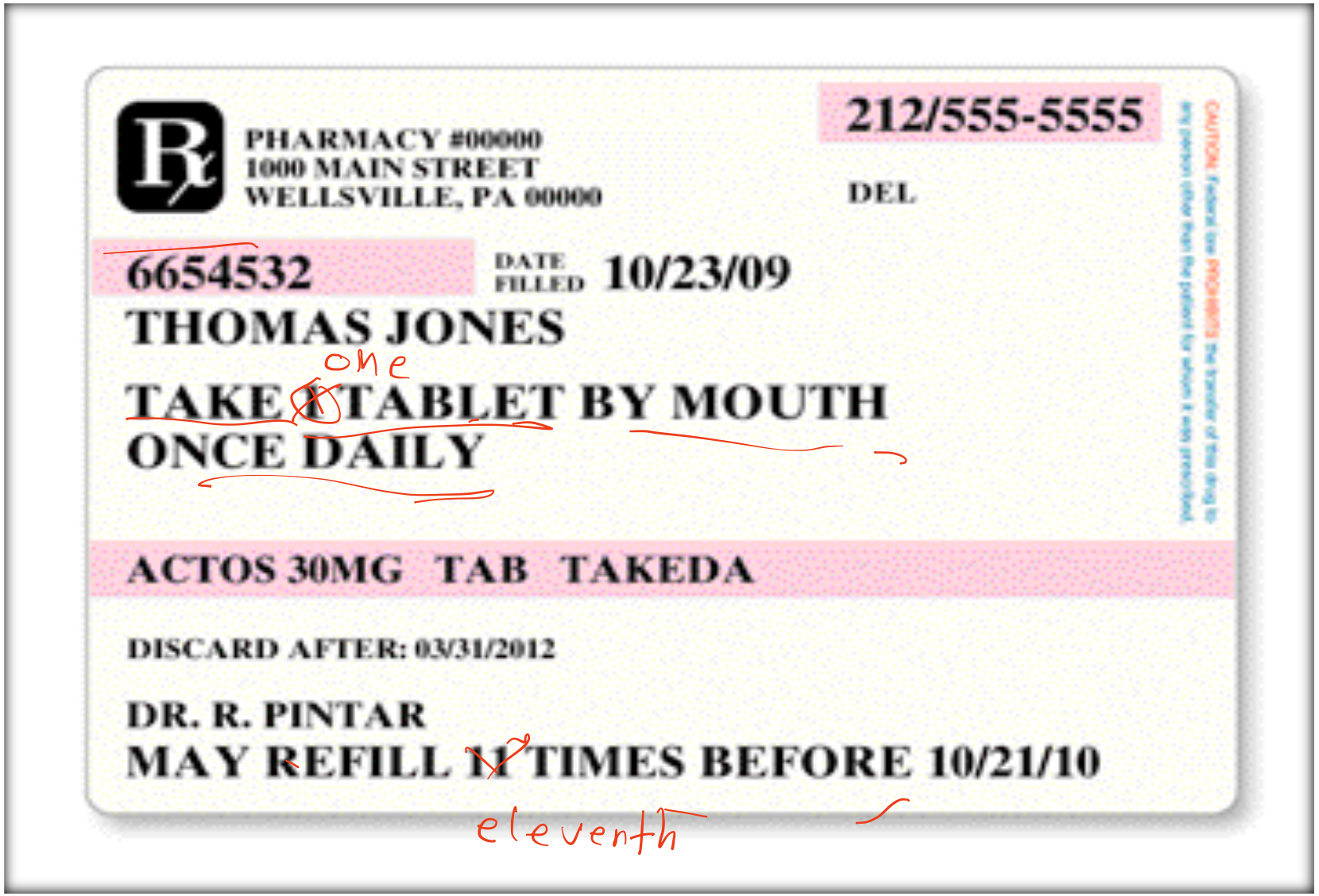
Caution!

- **Don't add information!** لا تضيف من عندك
  - 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.

تأكد من الدواء نفس الوصفة

Labels


PHARMACY #00000
1000 MAIN STREET
WELLSVILLE, PA 00000
212/555-5555
DEL
6654532
DATE FILLED 10/23/09
THOMAS JONES
TAKE X TABLET BY MOUTH
one
ONCE DAILY
ACTOS 30MG TAB TAKEDA
DISCARD AFTER: 03/31/2012
DR. R. PINTAR
MAY REFILL 11 TIMES BEFORE 10/21/10
eleventh

Prescription Label Examples

Alice Chan, M.D.
123 Main Street
Wellsville, PA 00000
Telephone: 888/555-1234
DEA number AB1234563
NPI: 1234567895

Date June 13, 2010

NAME Jane Smith

ADDRESS 108 Ivy Street, Wellsville, PA

Rx Keflex 500 mg

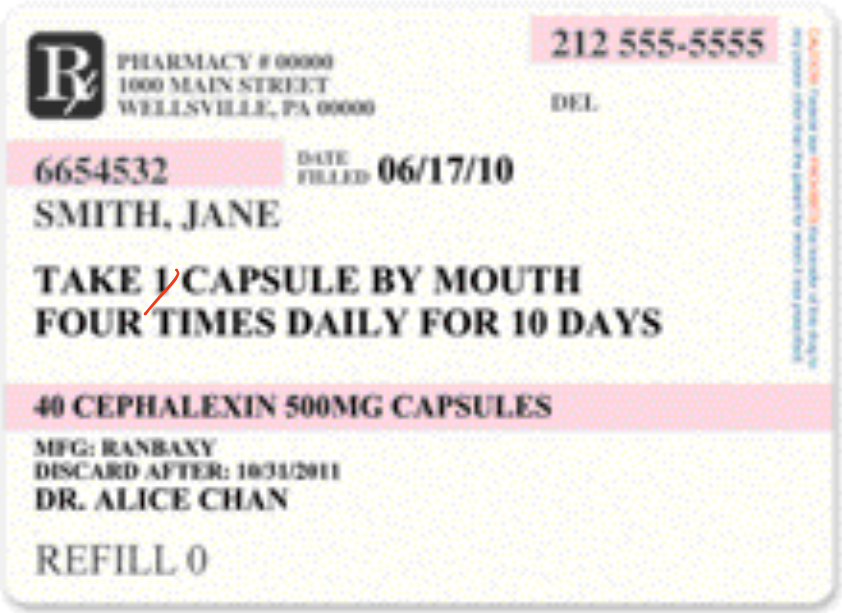
Sig: 1 cap po QID x 10d

#40

REFILL 0

DISPENSE AS WRITTEN ☐

Alice Chan
PRESCRIBER'S SIGNATURE



PHARMACY # 00000
1000 MAIN STREET
WELLSVILLE, PA 00000

212 555-5555

DEL

6654532

DATE FILLED 06/17/10

SMITH, JANE

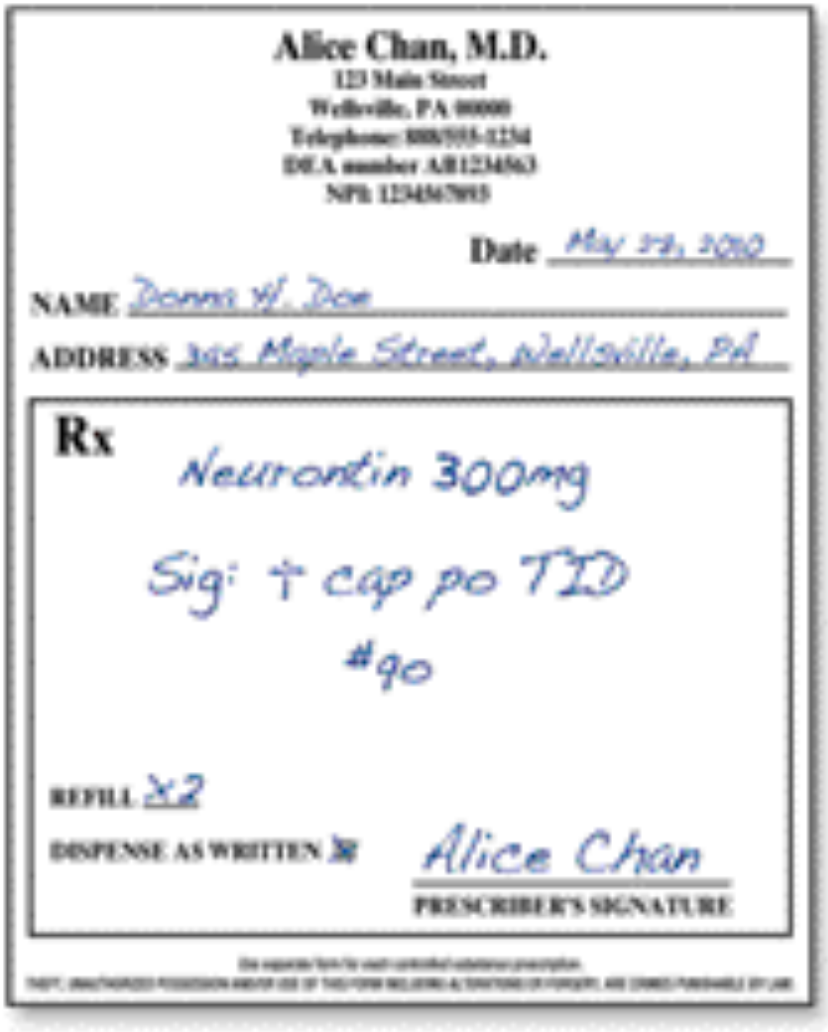
TAKE 1 CAPSULE BY MOUTH
FOUR TIMES DAILY FOR 10 DAYS

40 CEPHALEXIN 500MG CAPSULES

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

REFILL 0

Prescription Label Examples



Alice Chan, M.D.
123 Main Street
Wellsville, PA 00000
Telephone: 888/555-1234
DEA number AB1234563
NPI: 1234567893

Date May 28, 2010

NAME Donna H. Doe

ADDRESS 345 Maple Street, Wellsville, PA

Rx

Neurontin 300mg

Sig: 1 cap po TID

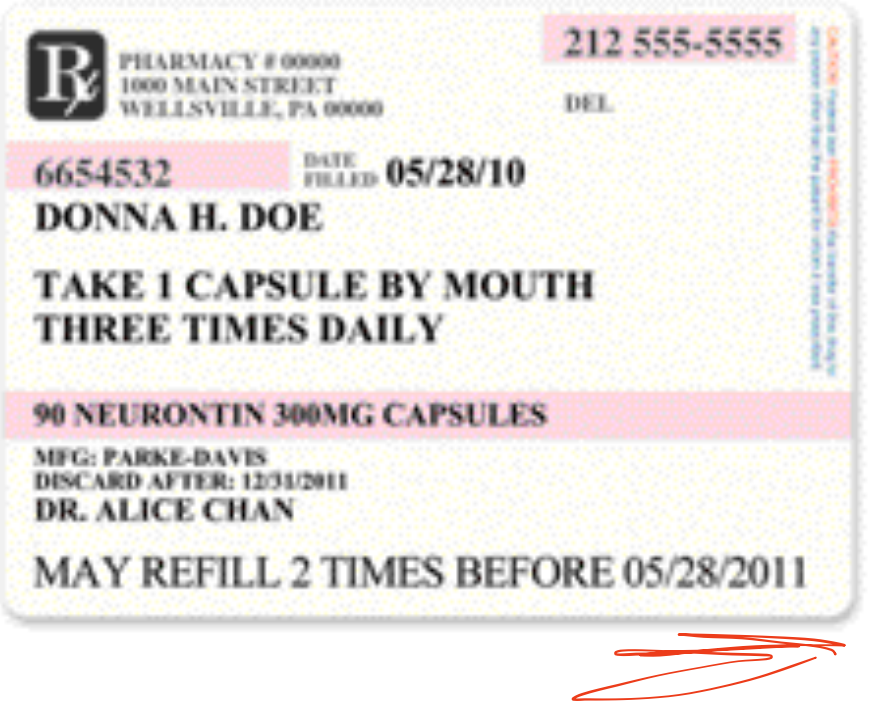
#90

REFILL x2

DISPENSE AS WRITTEN ☒

Alice Chan

PRESCRIBER'S SIGNATURE



212 555-5555

PHARMACY # 00000
1000 MAIN STREET
WELLSVILLE, PA 00000

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

suspension: معلق

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.