Why Compound?

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

What is a compounding pharmacy?

The traditional role of compounding pharmacies is to make drugs prescribed by doctors for specific patients with needs that can't be met by commercially available drugs

Compounding: هي الأدوية التي يقوم بتركيبها الصيدلاني المصرح له قانونيًا لمريض معين للأسباب مذكورة في السلايد ١٨ لأنها مش متوفرة بالأسواق (بتكون بوصفة طبية)

1. الأطفال المرضى بكونوا بحاجة لجرعة معينة وبكون المتوافر بالسوق للبالغين
2. حالة الدوا المتواجدة بالسوق (سائلة ، حبوب ، مرهم ..الخ) ما بتناسب المريض
3. المريض عنده حساسية تجاه مكون من مكونات الدوا التجاري بالأسواق
4. بحاجة لدوا بتركيز أقل او أكتر من المتواجد بالسوق
5. أدوية للحيوانات
6. حَلّ الأدوية من شكل الباودر لشكل محلول
7. خلط أدوية او مغذيات وإعطاءها عن طريق الوريد بالمستشفى
8. إعداد وتحضير ادوية بالبيت

- **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.

بمجرد

محلول تخفيف

*** ليه بكون الدوا ع شكل powder عشان ال stability تبعه يكون اكتر، يعني مثلا الدوا وهو باودر بكون صالح ل٥ سنوات وبمجرد ما خليته بصير صالح لأسبوعين

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 46285, U.S.A.

Exp. Date/Control No.

*عبارة عن
antibiotic
وبَحله بـ
Sterile water
Or
NaCL

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.

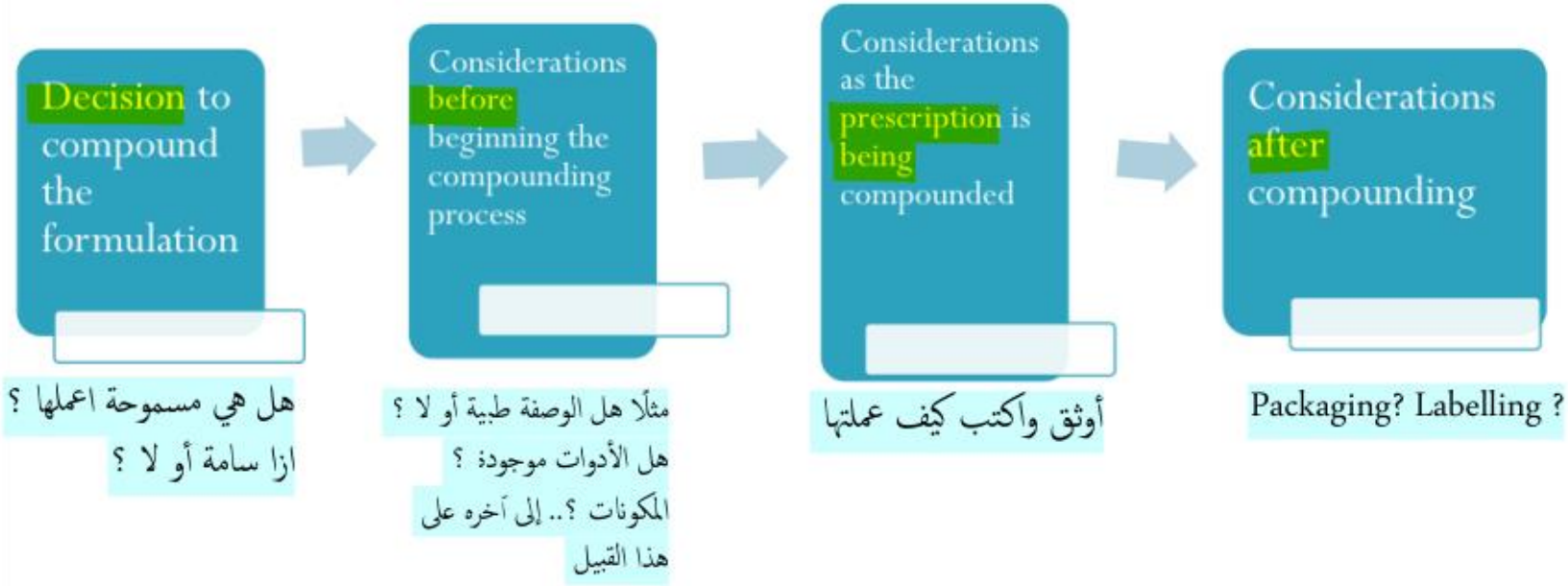
Sterile vs non-sterile

In the compound pharmacy world, the difference between sterile and non-sterile compounding is more nuanced than most people typically understand. Sterile compounded medications are intended to be used as injections, infusions, or application to the eye. Non-sterile medications include the production of solutions, suspensions, ointments, creams, powders, suppositories, capsules, and tablets.

Cream VS Ointment

General compounding considerations:

Questions to ask before, during, and after the compounding process



Compounding- Is it for every one?

مصرح له قانونيا ليعمل Compounding

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

من وين أجيب معلومات وشو المصادر للـ Compounding?

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

Compounding Regulations Applies

- Personnel
- Facilities and Equipment
- Ingredient Standards (raw material)
- Quality Assurance and Quality Control ضمان وضبط الجودة
- Packaging and Storage
- Documentation and Record Keeping

توثيق وحفظ كيف عملت الدوا، واشرح للمريض عنه
(كيف يستخدمه؟ متى؟ لحتى؟ —)

Ingredient Standards

- **USP/NF**
  - Meets standards set by the USP/NF.
- **ACS reagent (American chemical society)**
  - High purity
  - Meets specifications of the Reagent Chemicals Committee of the American Chemical Society.
- **AR (analytical reagent)**
  - Very high purity.
- **HPLC (High pressure liquid chromatography)**
  - 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.
3. **Standard Operating Procedures (SOPs)**
   - Equipment maintenance, equipment calibration, handling and disposal of supplies, etc.
4. **Material Safety Data Sheets MSDSs**
   - Ingredients records with certificates of purity.

← المادة سامة أو لا ؟ ولو بالغلط اجى ع ايدي أو بلعت أو ---
شو ممكن أعمل أو اتصرف كإجراء أمان ؟

ممكن اكتب نوت حينة شفتها وأنا بشتغل ←
(تغيير لون ، رائحة ، ترسبات ---)

اعمل محاية مثلاً للميزان حيث ما يطلع ←
عبارات خاطئة ويكون الـ error ضمن الـ range.

Major areas within the chapter

Compounding records and documents

Purpose: why?

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

المعلومات الي المفروض تكون موجودة بال Record:

2. ليقدر compounder تاني يعمل الدوا غيري.

تعليمات السلامة لكل مادة

- Material Safety Data Sheets (MSDSs):

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

NATURAL SOURCING

341 Christian Street, Oxford, CT 06478 USA
Tel: (203) 267-6061 Fax: (203) 267-6065
www.naturalsourcing.com info@naturalsourcing.com

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

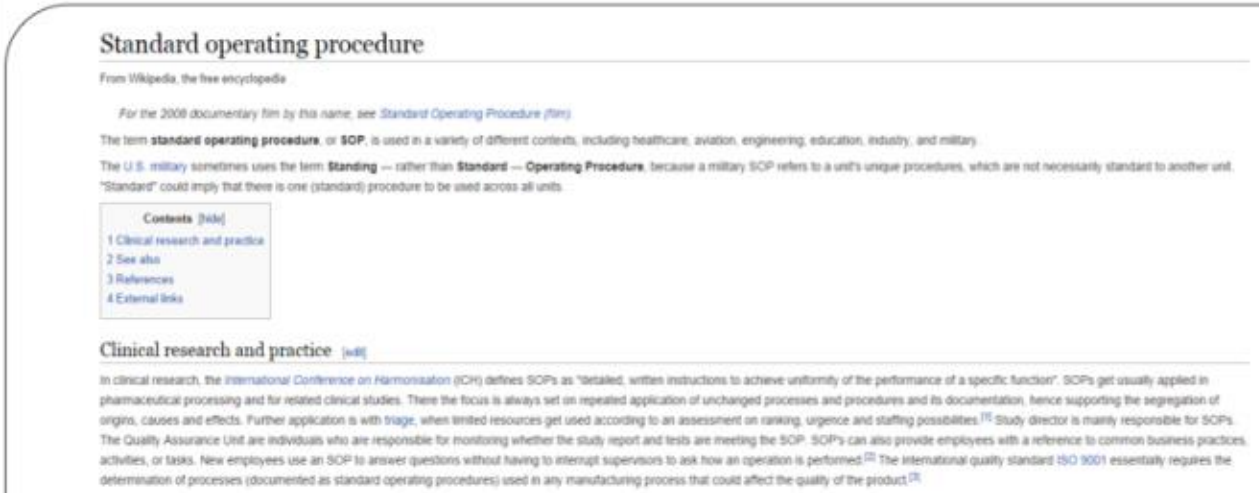
Quality control

- All the paperwork from the first step through the final preparation should be reviewed, along with observing the final finished preparation

إجراءات التشغيل المعيارية

- 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

* انه QA يشوف الريكورد الي عملته ويدققه ويوقع عليه.



Standard operating procedure

From Wikipedia, the free encyclopedia

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

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

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

Contents [hide]
1 Clinical research and practice
2 See also
3 References
4 External links

Clinical research and practice [edit]

In clinical research, the International Conference on Harmonisation (ICH) defines SOPs as "detailed, written instructions to achieve uniformity of the performance of a specific function". SOPs get usually applied in pharmaceutical processing and for related clinical studies. There the focus is always set on repeated application of unchanged processes and procedures and its documentation, hence supporting the segregation of origins, causes and effects. Further application is with triage, when limited resources get used according to an assessment on ranking, 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

مراقبة

- 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

تحقق

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

التأكد انه كل عملية الـ Compounding تمت بدقة

Patient counseling

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

تلف

افهم المريض كيف يستخدم الدوا وكيف يخزنه وشو ممكن العلامات اللي تظهر لو الدوا خلصت صلاحيته .

Storage Temperature Definitions

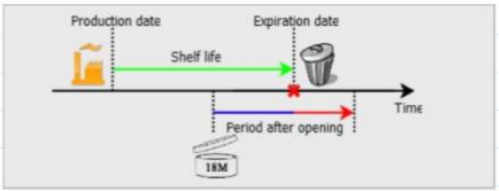
Freezer =	-20° C to -10° C
Protect from Freezing =	Store above 0° C
Cold =	Any temperature not exceeding 8° C
Refrigerator =	Between 2° C and 8° C
Cool =	Between 8° C and 15° C
Room Temperature =	Temperature in the work area
Controlled Room Temperature =	Thermostatically controlled at 20° C to 25 ^{0}C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

Stability

- **Stability** انه الdrug يحافظ على خصائصه متل ما صنّعته
  - The extent to which a dosage form retains the same properties and characteristics that it possessed at the time of its manufacture.
- **Expiration date** اخر تاريخ بتضمنلك فيه الشركة انه الدوا يضل فيه فعّال وآمن (الدواء المصنع من قبل شركات)
  - 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** آخر تاريخ بيضل الدوا آمن (الدوا الي الصيدلاني بيعمله compoundingيعني)
  - Used for compounded preparations only and are generally in the order of "days" or "months."
- **Shelf life** هي الفترة الي بيضل الدوا فيها سليم وهو ع الرف يعني مو مستخدم
  - Length of time a packaged drug will last without deteriorating

34

- A beyond-use date is the last date you can safely use a compounded medication. It's determined based on several factors by the pharmacy making the medication.
- An expiration date is the last date a manufacturer can guarantee the potency ضمان فعالية الدواء and safety of a medication. It's determined by stability testing data from the manufacturer.
- Using a medication after its beyond-use date or expiration date can be risky. Talk to your pharmacist if you have questions about your particular medication.



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.

35

Beyond use date

- **Non-aqueous liquid and solid formulation** التركيبات الصلبة
  - مثلًا بدي اعمل compounding لمرهم من كبسولة فحسب الـ E.D انه ضايل الها سنة وبتنتهي ، والكبسولة تعتبر (صلبة) ، فكيف راح احدد الـ BUD للمرهم ؟ بحكي أنه ال٢٥٪ للسنة هي ٤ أشهر ، فـ بعد ال٤ اشهر المرهم ببطل قابل للاستخدام ، لكن بحط بعين الاعتبار انه ال BUDماكسيم بكون ٦ أشهر مش أكتر ، يعني لو طلع معي أكتر من ٦ أشهر فبعتبر انه ال BUD اله ٦ اشهر فقط .
    - ال ٢٥٪
    - أقل من ٦ أشهر فبعتمدها
    - أكتر أو بتساوي ٦ أشهر فبعتمد أنها ٦ أشهر
- **Water containing formulation** التركيبات السائلة او التي تحتوي على مياه
  - طول ما المادة بودرة (مش سائلة) فبتبع بتاريخ انتهاء الصلاحية لـEDL ، أما لما أحولها لـ سائلة متل لما أحل مضاد بودرة وبصير سائل فبتبع الـBUD الها الي هو ١٤ يوم فقط من تاريخ فتحها مع حفظها في مكان بارد .
- **All other formulation**
  - بستخدمها حسب المدة التي حددها الطبيب مثلًا أسبوعين (مدة العلاج) أو إنها تضل أكتر اشي ٣٠ يوم .
  - ما تتعدى الـ ٣٠ يوم (ماكسيم)

Major areas within the chapter

The compounding process

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?
2. Perform necessary calculations (see <1160> Pharmaceutical calculations in prescription compounding>)
3. Identify equipment needed
4. Wear the proper attire (الملابس) and wash hand
5. Clean the compounding area and needed equipment

Prescription :
وصفة طبية

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. Assess 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

متل الادوية الي بتسبب ادمان (بتكون المعلومة موجودة عليها)

Major areas within the chapter

The compounding process

مؤكدًا

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

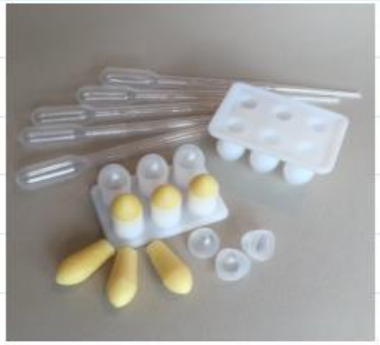
13. Clean all equipment thoroughly and promptly, and store properly

Types of Equipment

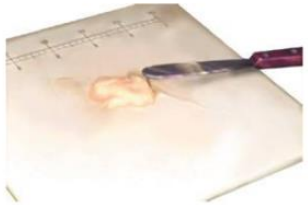
- **Measuring**
  - Balance, weights, weighing containers, volumetric glassware (graduates, pipets, flasks, syringes).
- **Mixing**
  - Beakers, Erlenmeyer flasks, spatulas, funnels, sieves, mortar and pestle.

الصّب

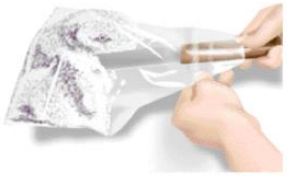
- **Molding**
  - Hot plates, suppository molds, capsule shells, ointment slabs.
- **Packaging**
  - Prescription bottles, capsule vials, suppository boxes, ointment jars.



Suppository mold



ointment slabs



mortar and pestle

41

Small Volumetric Equipment

Calibrated pipette

Single volume pipettes

Syringe

42

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. مستعجل

Label