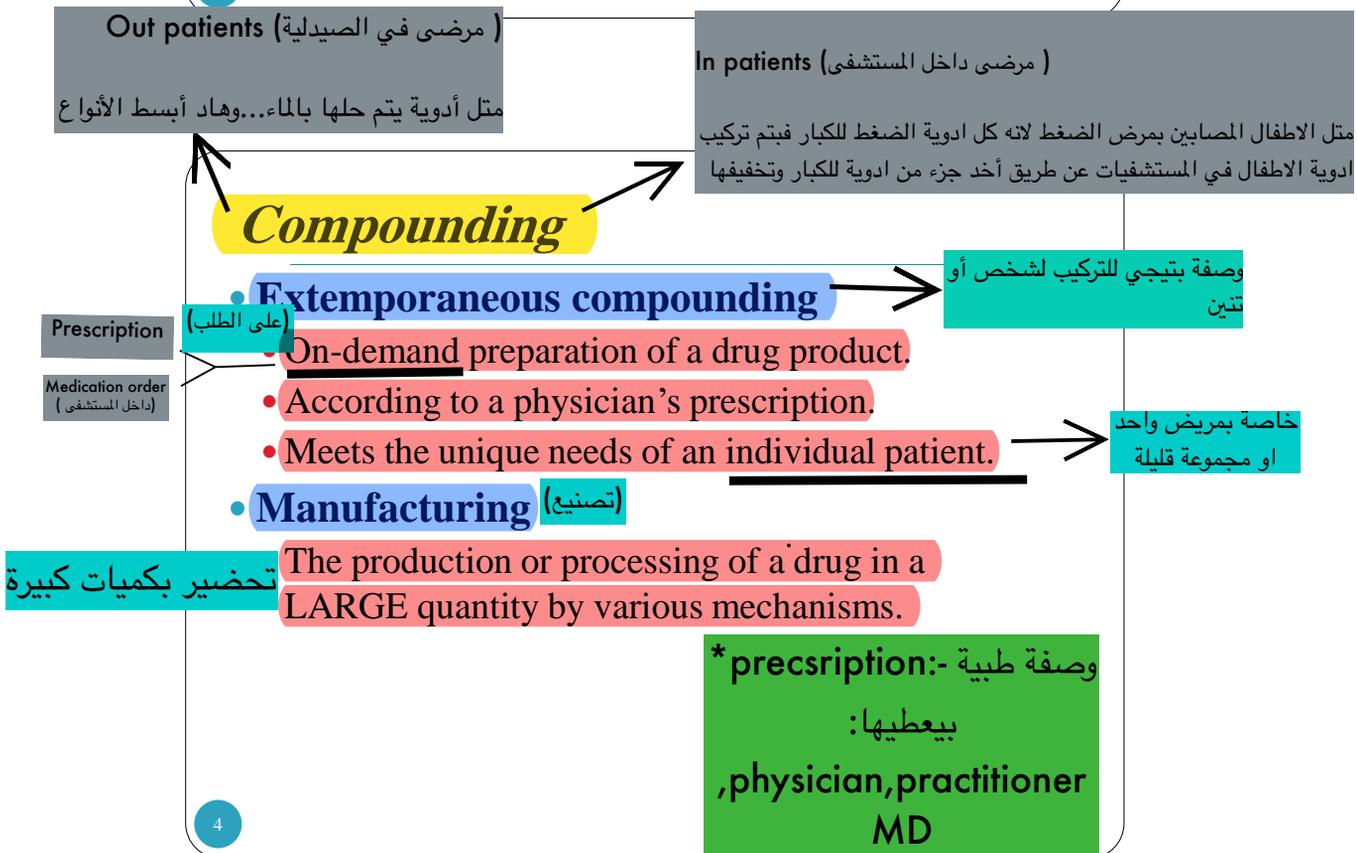


The origin of the pharmacy profession

- 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)

3

2/23/2022



4

* extraction of natural origin 2-chemical synthesis 3-biological synthesis
 ويكون الاستخلاص ل Active ingredients (مادة فعالة) بنضيف عليها مادة inactive ingredients عشان يصير product
 (دواء قابل للإستعمال)
 مثل: flavor,color,etc

Compounding is NOT manufacturing in the legal sense

بكميات كبيرة

Manufacturing is the mass production of drug products that have been approved by the Food and Drug Administration (FDA).**

من المصانع

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 (regeneration or formation), 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.....”

مشان ينزل دوا على السوق لازم يكون اول اشي مر بعملية التسجيل (registration) بعدين يتوافق عليه (approval)

اعادة تشكيل الادوية

عنا بالأردن الجهة المسؤولة JFDA

من الشجر،الصخور،الحيوانات

5

Device: drug + mechanical system

2/23/2022

في المختبر

5

Definitions



أسس الممارسة الجيدة

الارقام مش حفظ

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”



دوا للربو

مرخص:Licensed

تركيب الأشياء مع بعض : Assembling

6

ال device ما يكون بالصيدلية

2/23/2022

6
 USP-NF: United States Pharmacopoeia-National Formulary

دستور الدواء

Pharmacopeia

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

7

2/23/2022

7

- 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 (authorities) 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

9

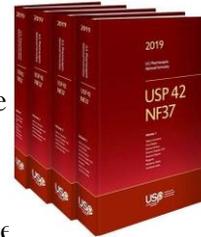
2/23/2022

9

ال USP أقدم

United States Pharmacopeia (USP)

- The 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.
- Non precipitation Prescription and over-the-counter (OTC) medicine 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.



معاييرها أقل من الأدوية مال الفيتامينات والأمنو أسيد وإلخ..

2/23/2022

10

10

Leaflet: نشرة مرفقة بالدواء

USP

- The USP and NF adopt standards for:**
 - drug substances, active ingredient بتحكي عن ال
 - pharmaceutical ingredients, Other ingredients: coloring,flavoring...
 - dosage forms الشكل الصيدلاني سواء شراب او حبوب إلخ...
 - 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.

عيار الدواء

11

2/23/2022

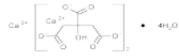
11

1-Definition

يكون فيه الشكل الكيميائي
(اسمه والوصف)

صفحة الدواء فيها تفصيل

A sample of USP-NF monograph

Calcium Citrate

$C_{12}H_{14}CaO_{14} \cdot 4H_2O$ 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 tempera-
ture 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, previ-
ously 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 naph-
thol 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

12

PURITIES

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 solu-
tion* 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 solu-
tion* 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 so-
dium hydroxide or 1 N hydrochloric acid to a pH of 5.5.
Transfer this solution to a 100-mL volumetric flask, and di-
lute with water to volume.

Electrode system: Use a fluoride-specific, ion-indicating
electrode and a silver-silver chloride reference electrode con-
nected 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 beak-
ers, and measure the potential of each solution with the
Electrode system. Between each reading wash the elec-
trodes with water, and absorb any residual water by blot-
ting 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 sys-
tem*. From the measured potential and the Standard re-
sponse line determine the concentration, *C*, in µg/mL, of
fluoride ion in the *Sample solution*. Calculate the percent-
age 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

12

2-Identification

بنتعرف على الدواء والـ standard معين

من ضمنه كمان ال Assay بحدد كم عندي مادة فعالة وازا رح نقبلها او لا
وكما ال acceptance criteria (معيار قبول الدواء)

فصل بال USP

Chapters

• Chapters <795> - called Pharmaceutical Compounding

- **Nonsterile Preparations** للتركيبات غير المعقمة مثل أدوية الشراب

- Published in 2000
- Enforceable

• Chapter <797> - called Pharmaceutical Compounding -
Sterile Preparations,

• Became official in 2004 للتركيبات المعقمة مثل قطرات العين، الإبر، بعض المراهم يلي

• Other Chapters

بتنحي على الجرح المفتوح

Containers <661> ال USP الها معايير خاصة بالعبوات

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

شابتت خاص بتعريف الأشكال الصيدلانية

13

2/23/2022

13

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

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)

Find information for...

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

14

بدنا نعرف انه ال USP صدر أول مشان هيك رقمه أكبر

USP/NF

- The point of origin for many regulations
- Its guidelines can be legally enforced by the Food and Drug Administration (**FDA**) الجهة يلي بتخص الدواء
- 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 American Pharmaceutical Association (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

ال history مش مهم

15

2/23/2022

15

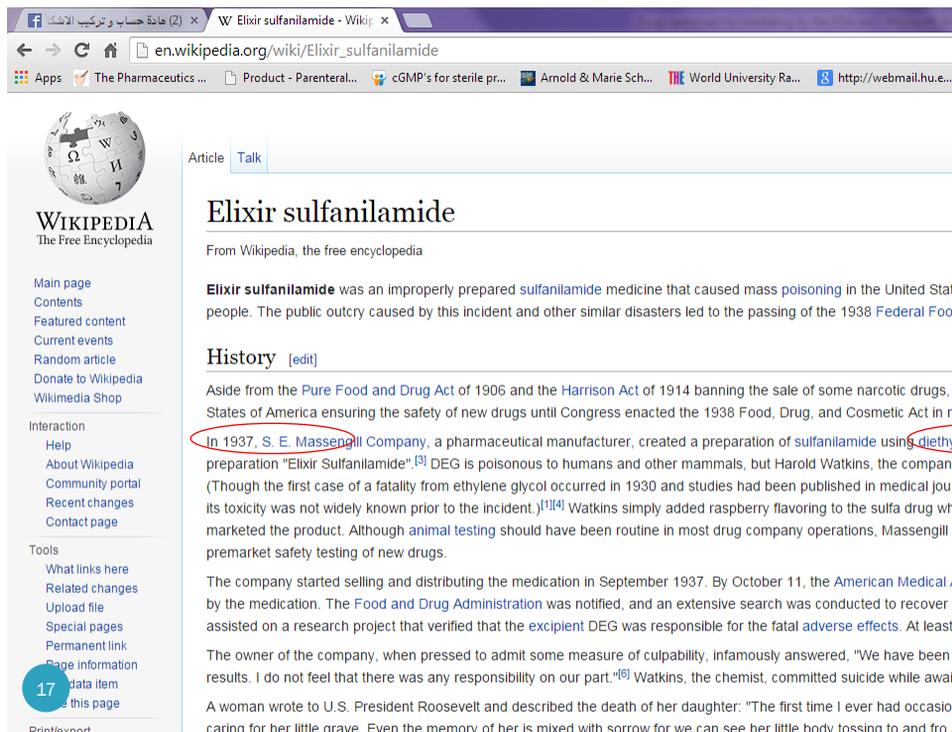
Official compounded formulations

- USP contains monograph of most commonly **Official compounded** preparations used in pharmacy practice that has the advantage of:
 - USP testing
 - Quality assurance
 - **“beyond use date” (BUD) assignment**
Expired date

16

2/23/2022

16



The screenshot shows a web browser window displaying the Wikipedia article for "Elixir sulfanilamide". The browser's address bar shows the URL "en.wikipedia.org/wiki/Elixir_sulfanilamide". The article content includes a description of the medicine, its history, and a section on animal testing. The text in the history section is circled in red, highlighting the sentence: "In 1937, S. E. Massengill Company, a pharmaceutical manufacturer, created a preparation of sulfanilamide using diethyl preparation 'Elixir Sulfanilamide'." The text in the animal testing section is also circled in red, highlighting the sentence: "Although animal testing should have been routine in most drug company operations, Massengill p premarket safety testing of new drugs."

Wikipedia, the free encyclopedia

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".^[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 jourr its toxicity was not widely known prior to the incident.)^[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 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 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

17

بصير تشريب بالقوانين بعد حادثة معينة
لازم نعمل أول animal testing

Originator: بال بنهتم **active, inactive ingredient**

أول دوا بتسجل كمادة فعالة (دواء أصيل)

General: (بديل عن دواء أصيل)

Food and Drug Administration(FDA)

NDA: New Drug Application

- 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

18

18

* product: active, inactive خلال

عملية التسجيل

active, : بعد عملية التسجيل

inactive, container , leaflet,
label outer back

حساب جرعات الأطفال على الوزن

Why Compound?

أطفال بسن المدرسة

- **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 **الوان حافظة**
- 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** **بالوريد** **admixture**s, parenteral nutrition solutions, and radiopharmaceuticals
- In home health care compounding requires the preparation of syringes and other devices for **home-infusion** administration

2/23/2022

الإبر الوريدية يلي بتطول بإيد المريض

19

19

كبار السن Geriatric:

عملية الخلط تعتبر
compounding

parenteral (injection) أو Oral: إما لل:

وينحل بشي معقم

كمان لازم نخض الدوا الباودر قبل حله بالماء ولنضيف المي بالتدريج وبنحرك

حل الدواء

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.



Vial

* بنحط بعد الحل بالتلاجة
* أي تفاعلات بالتبريد بتزيد

20

2/23/2022

20



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.



21

2/23/2022

21

sterile ممكن نحل الدواء بال
water او حسب ما مكتوب على
الدوا

22

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).
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Lyophilized

WV 4520 AMX
Eli Lilly & Co., Indianapolis, IN 46205, U.S.A.
Exp. Date/Control No.

2/23/2022

22

من 3-1 عملية التعقيم أدق

Categories of compounding

23

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.

Non sterile
زي ال
oral
المريمات
يلي بتتحت
على جروح
مفتوحة

Sterile

23

كل ما زاد ال risk بتكون تعليمات ال contamination أعلى

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



```

graph LR
    A[Decision to compound the formulation] --> B[Considerations before beginning the compounding process]
    B --> C[Considerations as the prescription is being compounded]
    C --> D[Considerations after compounding]
  
```

24

2/23/2022

24

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) **مش حفظ**
<https://www.pharmacist.com/>
 - American College of Apothecaries (ACA)
<https://acainfo.org/>
 - National Community Pharmacists Association (NCPA)
<https://ncpa.org/>
 -etc

25

2/23/2022

25

American Pharmacists Association
Improving medication use. Advancing patient care.

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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

Symbicort
Triamcinolone/Formoterol Formate
Sulfate/Respiratory Aerosol

26 2/23/2022

26

Compounding Regulations Applies

- A. Personnel
- B. Facilities and Equipment
- C. Ingredient Standards
- D. Quality Assurance and Quality Control
- E. Packaging and Storage
- F. Documentation and Record Keeping

ورقة فارغة

لما نعيها



27

27

Ingredient Standards

من ناحية ال purity

- 1
 - **USP/NF** الأغلى وما عليها تاريخ صلاحية
- 2
 - Meets standards set by the USP/NF.
- **(American Chemical Society) ACS reagent**
 - High purity
 - Meets specifications of the Reagent Chemicals Committee of the American Chemical Society.
- 4
 - **AR (analytical reagent)**
- 3
 - Very high purity.
- **HPLC** High Pressure Liquid Chromatography
 - Very high purity.
 - Used in high pressure chromatography.

28

2/23/2022

28

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, معايرة الأجهزة, handling and disposal of supplies, etc.
- **Material Safety Data Sheets MSDSs**
 - Ingredients records with certificates of purity.



29

2/23/2022

29

• Material Safety Data Sheets (MSDSs):

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

1. PRODUCT NAME AND COMPANY IDENTIFICATION	
Product Name:	SOYBEAN OIL
Product Use:	Personal Care Formulations
Company Name:	Natural Sourcing
Company Address:	341 Christian Street, Oxford, CT 06478, USA
Date Issued:	1/1/2008
Emergency Telephone Number:	Chemtec Tel: (800) 262-8200
2. COMPOSITION/INGREDIENT INFORMATION	
Ingredients:	
Vegetable Oil Triglycerides	100%
Hazardous Components:	None
CAS #:	
3. HAZARDS IDENTIFICATION	
Routes of Entry	
Eye Contact:	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

30

30

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 **التركيبه**
- Quantity of the preparation compounded **20g,30g,...**

Note number

للمواد يلي دخلت بالتركيبه

31

2/23/2022

31

Major areas within the chapter

Quality control (QC)

- 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



QA

بشوف الريبكورد يلي عمله ال QC و يدققه ويوقعه

32

2/23/2022

32

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

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

Clinical research and practice

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 of origins, causes and effects. Further application is with triage, when limited resources get used according to an assessment on ranking, urgency and staffing possibilities.^[1] Study director is mainly responsible for SOPs. The Quality Assurance Unit are individuals who are responsible for monitoring whether the study report and tests are meeting the SOP. SOPs can also provide employees with a reference to common business practices, activities, or tasks. New employees use an SOP to answer questions without having to interrupt supervisors to ask how an operation is performed.^[2] The international quality standard (ISO 9001) essentially requires the determination of processes (documented as standard operating procedures) used in any manufacturing process that could affect the quality of the product.^[3]

- **SOPs:** "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

33

2/23/2022

33

SOPs

Standard Operating Procedure		
Company Name and Address: 18 KM, RAWIND ROAD, LAHORE		Page No: 1 of 5
TITLE: STANDARD OPERATING PROCEDURE OF RO PLANT		SOP No: Revision No: 1 Review Period: 11/09-06/10
Prepared By	Reviewed By	Approved By
		SIR MASOOD AHMAD
OBJECTIVE		
It is used to de-mineralize and desalt the water to make it a pharmaceutical grade water, and free from any pyrogen and viable microbes. used for injection preparation.		
SCOPE:-		
It is applicable in • pharmaceutical		
Procedure:		
<ol style="list-style-type: none"> 1. Before starting up an RO system, it should be verified that all pretreatment systems are working according to their specifications. 2. It may be necessary to take water samples for analysis. In the case of polyamide (thin film composite) membranes free chlorine must be 0.0 ppm. The Silt Density Index (SDI) should be according to the RO design guidelines (typically < 5.0). If the water analysis (ions, temperature, pH) has changed significantly, it is recommended to run a new scale projection analysis. 3. On startup, the inlet valve should open prior to the initiation of the high-pressure pump, to completely fill the system with low pressure water (<100 psi [< 7 Bars]). 		
Standard Operating Procedure		
Company Name and Address:		Page No: 1 of 5

34

2/23/2022

34

Major areas within the chapter (USP)

تحقق Verification

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



Patient counseling

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

دليل تلف

35

2/23/2022

35

حفظ

Storage Temperature Definitions

ما بنخزن فيه

- **Freezer** = -20° C to -10° C
- Protect from Freezing = Store above 0° C
- Cold = Any temperature above 0 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 °C
- **Warm** = Between 30° and 40° C
- **Excessive Heat** = Any temperature above 40° C

36

2/23/2022

36

Stability

استقرار (ثباتية)

- **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

37

2/23/2022

37

بنشوف صلاحية التركيبة يلي
تحضرت من الدوا بنحسب كم شهر
صلاحيته وبتقسم على 4
او بتكون 6 أشهر لما نقسم وتكون
الصلاحية أعلى من 6 شهور

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.

38

2/23/2022

38

Major areas within the chapter

The compounding process

13 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 and wash hand
5. Clean the compounding area and needed equipment

39

2/23/2022

39