LEARN FILES

Pharmacy Technician Training Program

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SECTION: ORIENTATION

Orientation Sub-Section 2: Exams and Re-Certification

Two Nationally Known Certifying Organizations

1) The National Healthcareer Association (NHA) offers the Exam for Certifying Pharmacy Technicians (ExCPT)
2) The Pharmacy Technician Certification Board (PTCB) offers the Pharmacy Technician Certification Exam (PTCE)

Make sure to visit your state's board of pharmacy website to find out which exam is a requirement.

Many states will accept either exam.

NHA

Organizations endorsing the ExCPT include:

- American Association of Pharmacy Technicians
- National Alliance of State Pharmacy Associations
- National Organization for Competency Assurance
- National Pharmacy Technician Association
- Northwest Career Colleges Federation
- Pharmacy Technician Educators Council

Mission Statement

The mission of ExCPT is to recognize pharmacy technicians who are proficient in the knowledge and skills needed to assist pharmacist to safely, accurately and efficiently prepare and dispense prescriptions, and to promote high standards of practice for pharmacy technicians.

Requirements to sit for this exam:

- Be at least 18 years of age
- Have a high school diploma or the equivalent
- Have successfully completed a training program OR have a minimum of 12 months of pharmacy-related work experience within the last 36 months.

*Please Note: PassAssured is an NHA accepted program and meets the requirements for a training program.

PTCB

Established in January 1995

Four Founding Organizations:

- American Pharmacists Association (APhA)
- American Society of Health-System Pharmacists (ASHP)
- Illinois Council of Health-System Pharmacists (ICHP)

- Michigan Pharmacists Association (MPA)

Mission Statement
PTCB develops, maintains, promotes, and administers a nationally accredited certification and recertification program for pharmacy technicians to enable the most effective support of pharmacists to advance patient safety.

Goals
The PTCB was founded to create one consolidated voluntary national certification program for pharmacy technicians. It is responsible for the development and implementation of policies related to voluntary national certification for pharmacy technicians.

Requirements to sit for this exam:
- High school diploma or equivalent education diploma (e.g. a GED or foreign diploma)
- Full disclosure of all criminal and state board of pharmacy registration or licensure actions

*Please Note: PassAssured is a PTCB approved program and meets the requirements for a training program.

Both national exams are accredited by the National Commission for Certifying Agencies also known as the NCCA. The NCCA was created in 1987 by the Institute for Credentialing Excellence. Its main goal was to help ensure the health, welfare, and safety of the public through the accreditation of a variety of certification programs that assess professional competence.

For purposes of the national certifications, pharmacy technicians are defined as individuals working in a pharmacy, who under the supervision of a licensed pharmacist, assist in pharmacy activities not requiring the professional judgment of the pharmacist.

Both exams sample the candidates' knowledge and skill base for activities performed in the work of pharmacy technicians. Functions and responsibilities of pharmacy technicians may be specifically defined by state rules and regulations as well as job-center policies and procedures.

The pharmacy technician is accountable to the supervising pharmacist, who is legally responsible by virtue of state licensure for the care and safety of patients served by the pharmacy. The pharmacy technician performs activities as the result of having certain knowledge and skills.

Not every state requires national certification; pharmacy technicians who receive certification are more marketable. Individuals can work as a pharmacy technician part or full-time, allowing for experience and income while studying to become a pharmacist, Emergency Medical Technician, nurse, doctor, or a variety of other fields in the medical profession. Pharmacy technicians can also move on to become a pharmaceutical representative.

Pharmacy technicians who further their training with nuclear or IV certifications can find work in more advanced pharmacies or hospitals, potentially with better pay. Pharmacists can become specialized in nuclear pharmacy, become a consulting or clinical pharmacist, be a diabetic specialist, or have credentials with medication therapy management (MTM). There are a myriad of career paths that have the ability to stem from becoming a pharmacy technician.

The Re-Certification Process

- Renewal of certification is required every two years.
- Re-certification fees are set by the NHA and the PTCB.
- Continuing Education (CE) must be pharmacy technician specific.

To recertify for ExCPT through NHA:

The technician must complete 20 hours of continuing education. To view what the 20 hours must include, please view NHA's website at www.nhanow.com.
Additional CE credits will not carry over to the next two year period. You must complete the 20 hours required within that time period.

All technicians have a 90 day grace period after their certification expires to recertify.

If a technician fails to recertify past the 90 day grace period, the technician will lose their certification status.

Again, visit NHA's website for the forms to fill out and the proper procedure to recertify.

To recertify for PTCE through PTCB:

CPhTs can apply for recertification 100 days prior to the expiration date.

Application should be submitted at least 30 days prior to certification expiration date and must be online unless otherwise requested in writing.

Failure to recertify: certified pharmacy technicians that fail to recertify by midnight EST on the date of the certification expiration are no longer certified by the PTCB. They must immediately stop using the title CPhT.

Reinstatement: to apply for reinstatement, visit the NHA or PTCB website for instructions - whomever your certification is through.

Continuing Education (CE) Guidelines

- Twenty (20) contact hours of continuing education required for re-certification.
- Please refer to NHA website and PTCB website for a list of all accepted topics.
- Hours must be earned within the two-year period.
- Requirements must be completed on or before the certification expiration date.

- No continuing education hours earned before passing the ExCPT exam or PTCB exam may be used for recertification.

Extra hours earned during any two-year certification period may not be carried over and applied to the next certification period requirements.

Audits

A certain number of CPhTs will be chosen at random for an audit of continuing education by the Pharmacy Technician Certification Board (PTCB) and National Healthcareer Association (NHA).

If chosen for an audit, the CPhT must observe all requirements and upload or submit copies of the continuing education documentation as instructed. If you choose to not comply with the audit instructions, your certification will not be renewed and you will no longer be able to use the title certified pharmacy technician.

All continuing education documentation should be kept for at least one year beyond the expiration date of each certification period.

There are different sources where you can obtain continuing education credits. For a list of where to obtain continuing education credits, visit the PTCB's or NHA's websites.

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SECTION: FEDERAL LAW

Federal Law Sub-Section 3: Rules of Controlled Substances

Recordkeeping Requirements

Every pharmacy must maintain complete and accurate records on a current basis for each controlled substance

- purchased
- received
- stored
- distributed
- dispensed
- or otherwise disposed of

These records are required to provide accountability of all controlled substances starting with the manufacturing process, to the dispensing pharmacy and to the patient. The potential for diversion of controlled substances is reduced using this closed system.

- All required records concerning controlled substances must be maintained for at least two years for inspection and copying by duly authorized DEA officials.
- Records and inventories of schedule II controlled substances must be maintained separately from all other records of the registrant.
- All records and inventories of schedules III, IV, and V controlled substances must be maintained either separately from all other records or in such a form that the information required is readily retrievable from the ordinary business records.

Required Records

1. The records which must be maintained by a pharmacy are:
2. Executed and unexecuted official order forms (DEA Form 222) or the electronic equivalent
3. Power of Attorney authorization to sign order forms
4. Receipts and/or invoices for schedules III, IV, and V controlled substances
5. All inventory records of controlled substances, including the initial and biennial inventories, dated as of beginning or close of business
6. Records of controlled substances distributed (i.e., sales to other registrants, returns to vendors, distributions to reverse distributors)
7. Records of controlled substances dispensed (i.e., prescriptions, schedule V logbook)
8. Reports of Theft or Significant Loss (DEA Form 106), if applicable
9. Inventory of Drugs Surrendered for Disposal (DEA Form 41), if applicable
10. Records of transfers of controlled substances between pharmacies
11. DEA registration certificate
12. Self-certification certificate and logbook (or electronic equivalent) as required under the Combat Methamphetamine Epidemic Act of 2005

Prescription Records

Pharmacies have two options for filing paper prescription records under the Code of Federal Regulations (C.F.R.). All prescription records must be readily retrievable for DEA inspection. Controlled substance prescriptions must be filed in one of the following ways:

Paper Prescriptions Records Option 1 (Three separate files):

- A file for schedule II controlled substances dispensed.
- A file for schedules III, IV and V controlled substances dispensed.
- A file for all non-controlled (Legend) drugs dispensed.

Paper Prescriptions Records Option 2 (Two separate files):

- A file for all schedule II controlled substances dispensed.
- A file for all other drugs dispensed non-controlled (Legend) and those in schedules III, IV and V). If this method is used, a prescription for a schedule III, IV or V drug must be made readily retrievable by use of a red "C" stamp not less than one inch high. If a pharmacy has an electronic recordkeeping system for prescriptions which permits identification by prescription number and retrieval of original documents by prescriber's name, patient's name, drug dispensed, and date filled, the requirement to mark the hard copy with a red "C" is waived.

If there is a conflict between federal and state requirements for filing prescriptions, DEA recognizes that the pharmacy must choose a filing system that would comply with both federal and state law (you should use the stricter of the two).

Electronic Prescription Records

- If a prescription is created, signed, transmitted, and received electronically, all records related to that prescription must be retained electronically.
- Electronic records must be maintained electronically for two years from the date of their creation or receipt. However, this record retention requirement shall not pre-empt any longer period of retention which may be required now or in the future, by any other Federal or State law or regulation, applicable to pharmacists or pharmacies.
- Records regarding controlled substances must be readily retrievable from all other records. Electronic records must be easily readable or easily rendered into a format that a person can read.

Records of electronic prescriptions for controlled substances shall be maintained in an application that meets the requirements of **21 C.F.R. §1311**. The computers on which the records are maintained may be located at another location, but the records must be readily retrievable at the registered location if requested by the DEA or other law enforcement agent. The electronic application must be capable of printing out or transferring the records in a format that is readily understandable to an Administration or other law enforcement agent at the registered location. Electronic copies of prescription records must be sort able by prescriber name, patient name, drug dispensed, and date filled.

Federal law mandates a log of controlled substances dispensed be documented and signed daily by the pharmacist.

Transfer or Disposal of Controlled Substances

- Return to supplier must issue an official order form (DEA Form 222)
- Send to "Reverse Distributor" must issue an official order form (DEA Form 222)
- Receive permission from DEA to destroy onsite use DEA Form 41 (Inventory of Drugs Surrendered)
- Two witnesses are required to oversee the disposal of controlled substances onsite
- CIII thru CIV prescriptions can be transferred to another pharmacy only once

Required records must be maintained for two years.

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SECTION: MEDICAL REVIEW

Medical Review Sub-Section 6: Cardiovascular Drugs

Cardiovascular System

- Composed of the heart, arteries, capillaries, and veins
- Transports nutrients to tissues and removes wastes from tissues

Arrhythmia

Abnormal heart rhythm or heartbeats occur and vary from the normal order sequence. This can reduce the heart's ability to pump blood.

Angina

Chest pain is caused by an insufficient amount of oxygenated blood reaching the heart muscle.

Endocarditis

An infection involving the heart

Cardiomyopathy

Disease of the heart muscle that makes it harder for your heart to pump blood to the rest of your body

Congenital Heart Disease

Term for birth defects that affect the normal workings of the heart. The defects can involve the walls of the heart, the valves of the heart, and the arteries and veins near the heart.

Coronary Artery Disease

Develops when the major blood vessels that supply the heart with blood, oxygen and nutrients become damaged or diseased. Cholesterol-containing deposits (plaque) in the arteries and inflammation are usually to blame for coronary artery disease.

Cardiac Glycosides

Are obtained from the digitalis plant and exert powerful action on the heart, they also increase the muscle's contraction and improve irregular heartbeats.

Use

- Congestive heart failure (CHF)
- Some arrhythmias

Mechanism of Action

- Unknown, but cardiac glycosides increase the contraction of the heart

Side Effects

- Nausea/vomiting
- Confusion
- Arrhythmias
- Yellow/green halos

- Low therapeutic index

Examples:

- Digoxin (Lanoxicaps, Lanoxin® Digitek) - Legend Drug

Antiarrhythmics

Uses

- Help to restore and maintain normal heart rhythms

Mechanism of Action

- Multiple classes have different effects on the heart to affect its rhythm.

Side Effects

- Nausea/vomiting
- Confusion
- Arrhythmias

Examples:

- Lidocaine (Xylocaine®) - Legend Drug
- Procainamide (Procan®) - Legend Drug
- Quinidine (Quinidex®) - Legend Drug
- Amiodarone (Cordarone®) - Legend Drug
- Disopyramide (Norpace®) - Legend Drug
- Mexiletine (Mexitil®) - Legend Drug
- Flecainide (Tambocor®) - Legend Drug
- Propafenone (Rythmol®) - Legend Drug
- Adenosine (Adenocard®) - Legend Drug
- Dofetilide (Tikosyn®) - Legend Drug
- Ibutilide (Covert®) - Legend Drug
- Dronedarone (Multaq®) - Legend Drug

Antianginals

Uses

- Angina

Mechanism of Action

- Decrease the amount of blood that returns to the heart, decreasing the heart rate or decreasing the resistance to pump, and decreases the amount of work for the heart

Side Effects

- Headaches - because of dilation of blood vessels
- Dizziness
- Low blood pressure

Examples:

- Nitroglycerin (Nitrostat®) - Legend Drug
- Isosorbide Dinitrate (Isordil®) - Legend Drug
- Isosorbide Mononitrate (Imdur®, ISMO®, Monoket®) - Legend Drug
- Ranolazine (Ranexa) – Legend Drug

- Calcium channel blockers
- Nitroglycerin is also available as transdermal patches.
  *NOTE: Nitroglycerin should avoid heat and be stored with a tightly sealed lid. Nitroglycerin must be administered in a glass I.V. container because Nitroglycerin readily undergoes absorption to many soft plastics.

Vasodilators

Uses

- Peripheral vascular disease caused by arteriosclerosis and advanced diabetes

Mechanism of Action

- Dilate peripheral blood vessels
- Increase blood flow to extremities by relaxing the smooth muscles of the blood vessels

Side Effects

- Tachycardia (increased heart rate)

Examples:

- Hydralazine (Apresoline®) - Legend Drug - Use to decrease blood pressure
- Nitroprusside (Nitropress®) - Legend Drug - Used in hospitals to decrease blood pressure
- Papaverine (Pavabid®) - Legend Drug
- Isoxsuprine (Vasodilan®) - Legend Drug
- Nitrates (Nitroglycerin, Isosorbide Dinitrate) - Legend Drug
- Aspirin – Dipyridamole (Aggrenox) – Legend Drug

Endothelin Receptor Antagonists

Use

- Treat pulmonary arterial hypertension (PAH).

Mechanism of Action

- These medications reverse the effect of endothelin, a substance in the walls of blood vessels that causes them to narrow.

Side Effects

- Pale skin
- Troubled breathing with exertion
- Unusual bleeding or bruising
- Unusual tiredness or weakness

Contraindication

- *Females*: Women of childbearing potential must have a negative pregnancy test prior to starting treatment and monthly pregnancy test during treatment.

Examples:

- Macitentan (Opsumit)
- Bosentan (Tracleer)
- Ambrisentan (Letairis)

Phosphodiesterase Type 5 Inhibitor (PDE-5)

Uses

- Treat erectile dysfunction
- Treat pulmonary arterial hypertension (PAH).

Mechanism of Action

- A phosphodiesterase type-5 (PDE-5) inhibitor, works to increase blood flow in the penis through vasodilation.
- PDE-5 is also used to treat pulmonary arterial hypertension (PAH) through vasodilation.

Side Effect

- The occurrence of side effects with PDE5 inhibitors appears to be dose related.
- Headache
- Dizziness
- Flushing
- Dyspepsia
- Nasal congestion
- Rhinitis

Contraindications

- PDE5 inhibitors are contraindicated in patients taking nitrate medication. They are also contraindicated in men for whom sexual intercourse is inadvisable because of cardiovascular risk factors.

Examples:

There are six PDE5 medications taken by mouth that are approved in the United States.

- Sildenafil (Viagra) - Legend Drug - is a drug used to treat erectile dysfunction
- Sildenafil (Revatio) - Legend Drug - is used to treat pulmonary arterial hypertension (PAH)
- Tadalafil (Cialis) - Legend Drug - is a drug used to treat erectile dysfunction
- Tadalafil (Adcirca) - Legend Drug - is used to treat pulmonary arterial hypertension (PAH)
- Vardenafil (Levitra) - Legend Drug - is a drug used to treat erectile dysfunction
- Avanafil (Stendra)- Legend Drug-is a drug used to treat erectile dysfunction

**These medications reverse the effect of endothelin, a substance in the walls of blood vessels that causes them to narrow

Calcium Channel Blockers

Use

- Hypertension
- Angina

Mechanism of Action

- Dilate coronary arteries, reduce oxygen demand on the heart, and decrease heart rate
- Calcium channel blockers work by blocking voltage-gated calcium channels (VGCCs) in cardiac muscle and blood vessels.

Side Effects

- Constipation

Examples:

- Nifedipine (Procardia®) - Legend Drug
- Verapamil (Calan®, Isoptin®) - Legend Drug

- Diltiazem (Cardizem®, Cartia XT®) - Legend Drug
- Nicardipine (Cardene®) - Legend Drug
- Amlodipine (Norvasc®) - Legend Drug
- Felodipine (Plendil®) - Legend Drug
- Nisoldipine (Sular®) - Legend Drug
- Bepridil (Vascor®) - Legend Drug
- Isradipine (DynaCirc®) - Legend Drug
- Clevidipine (Cleviprex®) - Legend Drug

Angiotensin-Converting Enzyme (ACE) Inhibitors

Uses

- Hypertension
- Congestive Heart Failure (CHF)
- Cardiomyopathy
- Congenital Heart Disease

Mechanism of Action

- Prevents the conversion of Angiotensin I to Angiotensin II

NOTE: Angiotensin II causes vasoconstriction and fluid retention

Side Effects

- Cough - If the cough is persistent try another ACE Inhibitor

Examples:

- Captopril (Capoten®) - Legend Drug
- Enalapril (Vasotec®) - Legend Drug
- Lisinopril (Zestril®, Prinivil®) - Legend Drug
- Benazepril (Lotensin®) - Legend Drug
- Fosinopril (Monopril®) - Legend Drug
- Quinapril (Accupril®) - Legend Drug
- Ramipril (Altace®) - Legend Drug
- Moexipril (Univasc®) - Legend Drug
- Perindopril (Aceon®) - Legend Drug
- Trandolapril (Mavik®) - Legend Drug

ACE I and Calcium Channel Blocker

Use

- Hypertension

Mechanism of Action

- Inhibits angiotensin converting enzyme

Side Effects

- Light headed/dizziness
- Swelling or rapid weight gain
- Little or no urination

Example:

- Benazepril and Amlodipine (Lotrel) – Legend Drug

Ace Inhibitor and Diuretic

Use

- Hypertension

Mechanism of Action

- Long-acting ACE inhibitor

Side Effects

- Eye pain/vision problems
- Slow heart rate/weak pulse
- Muscle weakness
- Confusion
- Extreme thirst
- Increased urination

Example

- Lisinopril and Hydrochlorothiazide (Zestoretic) – Legend Drug

Angiotensin II Receptor Blockers (ARB)

Use

- Hypertension
- Congestive Heart Failure (CHF)
- Congenital heart disease

Mechanism of Action

- Inhibits Angiotensin II
- Reduces vasoconstriction and blood pressure

Examples:

- Losartan (Cozaar®) - Legend Drug
- Valsartan (Diovan®) - Legend Drug
- Irbesartan (Avapro®) - Legend Drug
- Irbesartan and hydrochlorothiazide (Avalide) – Legend Drug
- Candesartan (Atacand®) - Legend Drug
- Telmisartan (Micardis®) - Legend Drug
- Eprosartan (Teveten®) - Legend Drug
- Olmesartan (Benicar®) - Legend Drug
- Azilsartan (Edarbi®) - Legend Drug

Angiotensin II Receptor Blocker and Calcium Channel Blocker

Use

- Hypertension

Mechanism of Action

- Relaxes heart muscles
- Reduces vasoconstriction and blood pressure

Examples:

- Amlodipine / Olmesartan (Azor®) - Legend Drug
- Amlodipine / Valsartan (Exforge, Exforge HCT) – Legend Drug

Renin Inhibitors

Use

- Hypertension

Mechanism of Action

- Inhibit the renin-angiotensin-aldosterone system (RAAS), namely the conversion of angiotensinogen to angiotensin I

Side Effects

- Fatigue
- Headache
- Dizziness
- Diarrhea

Examples

- Aliskiren (Tekturna) – Legend Drug
- Aliskiren Hydrochlorothiazide (Tekturna HCT) – Legend Drug

Beta-Adrenergic Blockers

Uses

- Hypertension
- Angina
- Cardiomyopathy
- Congenital heart disease

Mechanism of Action

- Inhibits the action at the beta receptors on the heart
- Some are selective for the beta cells only on the heart, while others are non-selective and can act in other places within the body, e.g. lungs.

Side Effects

- Hypotension
- Bronchoconstriction - not used with asthma patient- If used, must be with caution.
- Dizziness

Examples:

- Atenolol (Tenormin®) - Legend Drug
- Metoprolol (Lopressor®) - Legend Drug
- Propranolol (Inderal®) - Legend Drug
- Nadolol (Corgard®) - Legend Drug
- Pindolol (Visken®) - Legend Drug
- Sotalol (Betapace®) - Legend Drug
- Acebutolol (Sectral®) - Legend Drug
- Timolol (Blocadren®, Timoptic®) - Legend Drug

    - Ophthalmic: for the management of glaucoma
- Bisoprolol (Zebeta®) - Legend Drug
- Betaxolol (Kerlone®) - Legend Drug
- (Note: Betoptic®) - Legend Drug
    - Ophthalmic: for the management of glaucoma
- Nebivolol (Bystolic®) - Legend Drug
- Penbutolol (Levatol®) - Legend Drug
- Atenolol / Chlorthalidone (Tenoretic) – Legend
- Metoprolol XL (Toprol XL) – Legend Drug

Selective Alpha-2 Adrenergic Agonist

Use

- Treatment of glaucoma or ocular hypertension

Example

- Brimonidine Tartrate (Alphagan P Opth)

Alpha-Adrenergic Blockers

Uses

- Hypertension
- Severe Congestive Heart Failure (CHF)
- Benign prostatic hyperplasia (BPH)

Mechanism of Action

- Inhibits the action at the alpha receptors in the blood vessels

Side Effects

- Orthostatic hypotension
- Dizziness

Examples:

- Prazosin (Minipress®) - Legend Drug - Hypertension
- Terazosin (Hytrin®) - Legend Drug - Hypertension and BPH
- Doxazosin (Cardura®) - Legend Drug - Hypertension and benign prostatic hyperplasia (BPH)
- Tamsulosin (Flomax) - Legend Drug - Benign prostatic hyperplasia
- Alfuzosin (Uroxatral) - Legend Drug - Benign prostatic hyperplasia (BPH)
- Silodosin (Rapaflo) – Legend Drug - Benign prostatic hyperplasia (BPH)

Alpha/Beta-Adrenergic Blocking Agents

Use

- Management of hypertension

Mechanism of Action

- Combines alpha-1-adrenergic blocking and beta-adrenergic blocking activity in a single substance.

Side Effect

- Dizziness and tiredness may occur

Examples

- Labetalol (Normodyne®, Trandate®) - Legend Drug
- Carvedilol (Coreg®) Legend Drug

5-alpha Reductase Inhibitor

Use

- Treat Benign Prostatic Hyperplasia (BPH)

Mechanism of Action

- Prevents the conversion of testosterone to dihydrotestosterone (DHT) in the body

Side Effect

- Dizziness and chills may occur

Examples

- Finasteride (Proscar) - Legend Drug
- Dutasteride (Avodart) - Legend Drug

Antilipidemic Agents

Uses

- Heart disease (Cardiomyopathy)
- High cholesterol
- Helps reduce risk of Coronary Artery Disease

Mechanism of Action

- Reduces serum lipids and minimizes the rate of new fat deposition.
- Decreases LDL, decreases Triglycerides

Side Effects

- Diarrhea
- Constipation
- Flushing

Examples:

- Lovastatin (Mevacor®) - Legend Drug
- Gemfibrozil (Lopid®) - Legend Drug
- Nicotinic acid/Niacin - B3 vitamin, plus increases HDL
- Cholestyramine (Questran®) - Legend Drug
- Pravastatin (Pravachol®) - Legend Drug
- Simvastatin (Zocor®) - Legend Drug
- Atorvastatin (Lipitor®) - Legend Drug
- Fluvastatin (Lescol®) - Legend Drug
- Colestipol (Colestid®) - Legend Drug
- Colesevelam (WelChol®) - Legend Drug
- Rosuvastatin (Crestor®) - Legend Drug
- Fenofibrate (Tricor®) - Legend Drug
- Ezetimibe (Zetia®) - Legend Drug
- Pitavastin (Livalo®) - Legend Drug
- Lomitapide (Juxtapid®) - Legend Drug

- Omega 3 Fish Oil- (Lovaza)- Legend Drug
- Lovastatin and Niacin (Advicor) – Legend Drug
- Simvastatin and Ezetimibe (Vytorin) – Legend Drug
- Fenofibric Acid (Trilipix) – Legend Drug

HMG – CoA Reductase Inhibitor – Calcium Channel Blocker

- Amlodipine and Atorvastatin (Caduet) – Legend Drug

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SECTION: ASEPTIC TECNIQUE

Aseptic Technique Sub-Section 4: Techniques for Sterile Compounding

Prior to Compounding

1. Remove rings, watches, and bracelets (ideal for bacteria)
2. Wash hands and forearms to the elbows with appropriate germicidal agent. This must be done for 30 seconds.

Working in a Laminar Air Flow Hood

It is recommended by most policies and procedures that the laminar flow hood should be running for at least 30 minutes prior to use.

Disinfection

- Disinfection should be done at least at the beginning and end of each shift, hourly during operation, and after spills or known contamination.
- Use parallel sweeping motions from the back of the hood to the front, not circular motions
- Isopropyl Alcohol 70% should be used for cleaning and disinfection

Placement of Items to Prepare

- Avoid working over open containers or a preparation to prevent contaminates falling into the preparation area.

Non-Essential Items

- Do not introduce items that are not essential for the preparation process into the hood (i.e., paper, pencils, etc.).

Work Area Utilized

- Work at least six inches within the hood for maximum benefit
- Avoid working close to the outer edge of the hood as the product may be contaminated.

Waste Disposal

- Hazardous waste buckets should be accessible.
- Needles used in IV preparation should be disposed in a Sharps Container.

Prevent Shadowing

- Make sure you block areas of preparation that must remain sterile from the air flow, so that there is no contamination.
- One must be careful not to place hands, equipment, vials, etc., in front of critical areas of preparation products.
- "Dead spaces" are created behind objects in the airflow:
- Areas on products that must remain sterile should never be placed in dead spaces.

Location of Sterile Room

- Sterile product preparation room should be free of dust, especially cardboard as a source of particles.
- Should be kept away from common routes of personnel traffic.

Personnel Precautions

- While laminar air flow hoods prevent airborne contamination, they do not guarantee a sterile product.
- Use precautions to minimize contamination in the product preparation area.
- Use strict aseptic technique to avoid introduction of contaminants into the hood.

Withdrawing Liquid from a Vial

1. Remove the cover of the vial and wipe rubber surface with an alcohol swab.
2. Withdraw the same volume of air into the syringe as the volume of drug intended to be withdrawn.
3. Uncap the needle, and insert it with the bevel side up at a 45 degree angle.
   NOTE: Once the rubber surface has been penetrated, the syringe may then go into the rest of the vial straight on, prevent coring (cutting out part of the rubber stopper).
4. Inject the sterile air in the syringe into the vial
   This creates pressure inside of the vial forcing the liquid out.
5. Keeping the needle in the vial, invert the vial and hold it with one hand to control the syringe.
6. Pull back the plunger of the syringe to withdraw the liquid.
7. Needle should penetrate the rubber closure, but not go much further into the vial so that all medication can be withdrawn.
8. Once the medication has been withdrawn, tap the syringe to make all of the bubbles go to the top of the syringe.
9. Pull down on the plunger to remove the bubbles and then push the plunger back up to the desired volume.
10. Remove the bubbles for accurate measurement.
11. Remove needle from vial and recap the syringe with a Luer-tip cap.
    (Check with your institution and JCAHO requirements for the handling and disposal of needles.)

Withdrawing Liquid from an Ampule

- Ampules are containers made entirely of glass.
- They are broken at the neck, which is usually pre-weakened.

1. Hold the ampule upright and tap the top to remove any liquid trapped in this area.
2. Wipe the neck of the ampule with an alcohol swab to reduce contamination.
3. Wrap the gauze pad around the neck when breaking it open to reduce the chance of cutting fingers and preventing glass fragments.
4. Grasp the ampule using the thumb and index fingers of both hands on each side of the ampule neck.
5. Snap the ampule quickly, breaking it away from yourself, and the filter to avoid glass fragments.

6. Tilt the ampule and insert the filter needle or filter straw attached to the syringe.
7. Avoid touching the neck of the ampule with the needle.
8. A filter needle or filter straw always must be used when withdrawing liquid from ampules to prevent glass particles from being introduced into the product, and thus, the patient.
9. To remove liquid, hold the ampule in one hand and the syringe in the other.
10. Push the plunger back with the thumb of the hand holding the syringe to the desired volume.
11. Before injecting contents of the syringe into a parenteral product, be sure to remove the filter straw or filter needle, and replace it with a regular needle.
12. Removal of filter needle before injection is necessary so that the filtrate will not be injected into the product.
13. Hold the syringe upright, tap out bubbles, and push the plunger up to the desired volume.

Reconstituting a Sterile Powder in a Vial

For drugs in a vial in powder form, it is necessary to reconstitute with a suitable diluent, which will be specified in the vial or package insert.

Examples:

- Sterile Water
- D5W
- NS (normal saline 0.9% NaCl)

Follow the steps described previously for entering a vial.

Inject diluent and tilt or roll until the drug is dissolved. **Do Not Shake.**

Introduce Liquid into a Plastic IV Bag

1. Remove plastic IV bag from the outer wrap and inspect for leaks, tears, or particulates.
2. Swab the rubber port of the bag with an alcohol swab, being careful not to block the airflow from the port.

Inside of the medication port is a diaphragm. Needle must be at least ½" to penetrate the diaphragm so that liquid drug will reach IV solution.

3. Insert the needle straight on to into the diaphragm to avoid puncturing sides of the plastic bag.
4. Inject contents of the syringe, and remove the needle from the port.
5. Mix the final product by inverting the bag and squeezing the port to be sure that all of the medication is diluted in the solution and has not been retained in the diaphragm.

Introducing Liquid into a Glass IV Bottle

1. Remove protective cover from the IV bottle and swab the rubber closure with an alcohol swab.
2. Inject the contents of the syringe into the rubber entry port, using the technique described previously.

Some glass IV bottles are created with a vacuum which "pulls" the medication from the syringe into the bottle.

3. After withdrawing the syringe, place a protective covering over the injection site to prevent contamination or tampering.

Places to Avoid Touching or Blocking Air Flow during Preparation

- Portions of equipment, containment, and devices which come into contact with the sterile product:
- Needle shaft
- Inside of needle hub
- Syringe plunger
- Tip of syringe barrel that attaches to needle hub
- Surface of rubber entry on vial, bottle, or bag

Visual and Quality Control Inspection of Parenteral Products

- Check for particulate matter, crystals, and precipitation.
- Isotonicity is important because the injectable solution needs to be isotonic with the blood.
- Acid content or the pH of the solution is an important characteristic.
- Color and clarity of an IV is an important characteristic.
- Hold product in front of well illuminated light or dark background to detect particles
- TPNs that contain lipid emulsion are not clear, therefore precipitation cannot be seen.

Components of a Parenteral Product Label

- Solution name, lot number, and volume (note this may be part of the manufacture's label)
- Patient name, record number, and room number
- Bottle/bag sequence number
- Additive names, strengths, and quantities
- Date of preparation and initials of preparer
- Expiration and initials of preparer
- Expiration time and date
- Flow rate
- Administration: time, date, and by whom
- Appropriate auxiliary labels

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SECTION: CALCULATIONS

Calculations Sub-Section 2: Abbreviations

Abbreviations

Some abbreviations are from Latin:

- b.i.d. = bis in die = twice a day

Some are from the first letter of a word:

- CNS = Central Nervous System

Abbreviations Commonly Used in Prescriptions and Medication Orders

For a more complete list, consult one of the published books of medical abbreviations, such Medical Abbreviations: 12,000 Conveniences at the Expense of Communications and Safety by Neil M. Davis.

Abbreviation	Meaning
a	before
aa	of each
ABW	actual body weight
a.c.	before meals
ad	up to
ad lib	at pleasure, freely
a.m.	morning
amp.	ampule
APAP	Acetaminophen
aq.	water
aq. dist.	distilled water
a.s.	left ear
ASA	aspirin
ATC	around the clock
a.u.	each ear
b.i.d.	twice a day
BM	bowel movement
BP	blood pressure
BS	blood sugar
BSA	body surface area
BUN	blood urea nitrogen
BW	body weight
C	centigrade
c. or c	with
CA	cancer or cardiac
cap	capsule(s)

Abbreviation	Meaning
CBC	complete blood count
cc	cubic centimeter
CCT	crude coal tar
chart or chartulae	powder of powder paper
CHF	congestive heart failure
CNS	central nervous system
comp.	compound
COPD	chronic obstructive pulmonary disease
CPZ	Chlorpromazine
C&S	culture and sensitivity
d	day
disc or DC	discontinue
disp.	dispense
div.	divide
DOB	date of birth
DPT	diphtheria, pertussis, tetanus
DS	double strength
d.t.d.	give of such doses
DW	distilled water
D5W	dextrose 5% in water
DX	diagnosis
EC	enteric coated
ECG or EKG	electrocardiogram
EDTA	edetate

Abbreviation	Meaning
EENT	eyes, ears, nose, throat
EFAD	essential fatty acid deficiency
elix	elixir
e.m.p.	as directed
EPI	epinephrine
ER	emergency room
et	and
f. or ft.	make
F	Fahrenheit
FBS	fasting blood sugar
FFA	free fatty acid
fl or fld	fluid
ft.	make
g or gm or GM	gram
GI	gastrointestinal
gr	grain
gtt, gtts	drop, drops
GYN	gynecology
H	hypodermic
h or hr	hour
HA	headache
HBP	high blood pressure
HCT	hematocrit
HCTZ	hydrochlorothiazide
HEPA	high efficiency particular air
h.s.	at bedtime
HT	height or hypertension
IBW	ideal body weight
ICU	intensive care unit
ID	intradermal
IM	intramuscular
INH	isoniazid
I&O	input and output
inj.	injection
IPPB	intermittent positive pressure breathing

Abbreviation	Meaning
IU or iu	international unit
IV	intravenous
IVP	intravenous push or IV pyelogram
IVPB	intravenous piggy back
L	liter
LCD	Coal Tar Solution
M.	mix
m2 or M2	square meter
mcg	microgram
mEq	milliequivalent
mg	milligram
MI	myocardial infarction
ml or mL	milliliter
MMR	measles, mumps, rubella
MO	mineral oil
MOM	milk of magnesia
mOsm or mOsmol	millimoles
MR	may repeat
MRX	may repeat _____ times
n	nostril
N&V	nausea and vomiting
NG	nasogastric
NK	none known
no. or No.	number
noct.	night
non rep., nr	do not repeat, or no refills
NPO	nothing by mouth
NS	normal saline
1/2 NS	half-strength normal strength
NTG	nitroglycerin
NVD	nausea, vomiting & diarrhea
O.	pint
OB-GYN	obstetrics-gynecology
OC	oral contraceptive
OD	overdose
o.d.	right eye

Abbreviation	Meaning
oint.	ointment
o.l.	left eye
o.s.	left eye
OR	operating room
OT	occupational therapy
OTC	over-the-counter
o.u.	each eye
O2	both eyes
oz	ounce
p or per	by
Pb	Phenobarbital
p.c.	after meals
PCN	penicillin
p.m.	afternoon-evening
p.o.	by mouth
post	after
PPD	purified protein derivative (tuberculin)
PPI	patient package insert
PPM	parts per million
pr	rectally
pre-op	before surgery
p.r.n.	when required or as needed
PT	physical therapy
pulv.	powder
pv	vaginally
q	every
q.d.	every day
q.h.	every hour
q.i.d.	four times a day
q.o.d.	every other day
q.s.	a sufficient quantity
q.s. ad	a sufficient quantity to make
r, rec	rectal
R.L. or R/L	Ringer's Lactate
s	without
sat.	saturated
Sig.	write on label

Abbreviation	Meaning
SL	sublingually
SOB	shortness of breath
sol.	solution
s.o.s.	if there is a need
SS	saturated solution
ss	one-half
SSKI	saturated solution of potassium iodide
stat.	immediately
subc or subq or s.c.	subcutaneously
supp.	suppository
susp.	suspension
SVR	alcohol
syr.	syrup
SZ	seizure
T&C	type and crossmatch
tab	tablet(s)
TAC	Tetracaine, Adrenalin and Cocaine
tal.	such
tal. dos	such doses
tbsp.	tablespoon
TCA	tricyclic antidepressant
TCN	Tetracycline
t.i.d.	three times a day
t.i.w.	three times a week
TMP/SMX	Trimethoprim/sulfamethoxazole
top	topically
TPN	total parenteral nutrition
tr.	tincture
tsp.	teaspoon
U or u	unit(s)
UA	urinalysis
u.d., utd	as directed
ung.	ointment
URI	upper respiratory infection

Abbreviation	Meaning
USP	United States Pharmacopeia
UTI	urinary tract infection
UUN	urine area nitrogen
UV	ultraviolet
VS	vital signs
w/	with
WBC	white blood cell count
w/o	without
X	times
y.o	year old
ZnO	zinc oxide

Prefix	Definition
A-, An-	Without
Ante-	Before
Anti-	Against
Bi-	Two, Twice, Double
Brady-	Slow
Dia-	Through, across
Dys-	Bad, difficult
Ecto-	Outside
Endo-	In, within
Epi-	Upon
Homeo-	Same
Hyper-	High, excessive
Hypo-	Low, deficient
Inter-	Between
Intra-	Within
Mal-	Bad, poor
Micro-	Tiny
Neo-	New
Para-	Near, beside
Peri-	Around
Poly-	Many
Post-	After
Pre-	In front of
Pseudo-	False
Sub-	Below
Tachy-	Rapid, fast
Tri-	Three
Ulta	Beyond, excessive

Suffix	Definition
-algia	Pain, discomfort
-ism	Condition
-ectomy	Removal
-itis	Inflammation
-megaly	Enlargement
-meter	Measure
-oid	Like
-oma	Tumor
-osis	Abnormal condition
-pathy	Disease
-plasty	Surgical repair
-rrhea	Discharge, flow
-sclerosis	Hardening
-scopy	Visual examination
-tomy	Act of cutting

Root Word	Definition
Abdomin/o	Abdomen
Arthr/o	Joint
Carcin/o	Cancer
Cardi/o	Heart
Dermat/o	Skin
Gastr/o	Stomach
Gynec/o	Female
Hemat/o	Blood
Mamm/o	Breast
My/o	Muscle
Nas/o	Nose
Neur/o	Nerve
Opt/o	Eye
Oste/o	Bone
Pulmon/o	Lungs

*The degree symbol (°) can either indicate degrees of temperature - for example, 98.6°F; or it can mean "hour" or "hours" - for example "q3°" means every three hours.

Abbreviation Errors

- Some abbreviations or notations have become notorious for causing confusion either because they are commonly misinterpreted, or because their misinterpretation may have serious consequences.

Abbreviations, Symbols, or Syntax that Should be Avoided

- **u for unit:**
  - When handwritten, can be read as an O with possible resulting ten-fold overdose.
  - The word unit should always be written out.
- **mcg for microgram:**
  - The accepted abbreviation for microgram is mcg.
  - The symbol µg can easily be misread as mg.
- **q.o.d. for every other day:**
  - Has been read both as q.d. for daily or q.i.d. for four times daily.
  - To avoid confusion, every other day should be written out.
- **q.d. for every day:**
  - The period after the q can be mistaken for an I, causing the medication to be given four times a day.
- **SC or SQ for subcutaneous:**
  - Could be misinterpreted as SL, meaning sublingually
- **T.I.W. for three times a week:**
  - Has been misread as three times a day or misinterpreted as two times a week.

When the same symbols have more than one meaning, misinterpretation may result:

- **D/C**, which can mean either *discontinue* or *discharge*
- **HS** which can mean either at *bedtime* or half *strength*
- **IVP** which can mean *IV push* or *intravenous pyelogram*

The Latin abbreviations *au*, *as*, and *ad* which mean respectively *both ears*, *left ear* and *right ear*, have been misread or misinterpreted as *ou*, *os*, or *od* meaning *both eyes*, *left eye*, and *right eye*. The opposite misinterpretation may also occur.

When writing or typing the names, strengths, and units of drugs, do not omit the spaces between the words, unit abbreviations, or set of numbers:

- For **example**, write *Atenolol 100 mg*, not Atenolol 100mg or Atenolol100mg.

Avoid the symbols **/** and **&**:

- **/** can be mistaken for a number 1.
- **&** when handwritten can look like a number 4.

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SECTION: PHARMACY OPERATIONS

Pharmacy Operations Sub-Section 4: USP Chapter 795 – Nonsterile Preparations

Became official May 1, 2011.
Helped to define Good Compounding Practices
Provides general information to support a Pharmacy Technician's ability to extemporaneously compound preparations that are of acceptable strength, quality and purity.

Definitions

For consistency in implementing 795, the technician should be familiar with these eleven definitions:

1. **Active pharmaceutical ingredient (API)**: Any substance or mixture of substances intended to be used in the compounding of a drug preparation,
2. **Added substances:** Ingredients that are necessary to compound a preparation but are not intended or expected to cause a pharmacologic response.
3. **BEYOND-USE Date (BUD):** The date after which a compounded preparation should not to be used; determined from the date the preparation is compounded.
    - For **Nonaqueous Formulations** - The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier
    - Water-Containing Oral Formulations-BUD is not later than 14 days when stored at controlled cold temperatures.
    - Water-Containing Topical/Dermal and Mucosal Liquid and Semisolid Formulations the BUD is not later than 30 days
4. **Component**: Any ingredient used in the compounding of drug preparation, including any active ingredient or added substance that is used in its preparation.
5. **Compounder**: A professional authorized by the appropriate jurisdiction to perform compounding pursuant a prescription or medication order by a licensed prescriber.
6. **Compounding**: the preparation, mixing, assembling, altering packaging and labeling of a drug, drug delivery device or device in accordance with a licensed practitioner's prescription, medication order, or initiative based on the practitioner-patient-pharmacist-compounder relationship in the course of professional practice.
    - Compounding includes the following:
        - Preparation of drug dosage forms for both human and animal patients
        - Preparation of drugs or devices in anticipation of prescription drug orders, on the basis of routine, regularly observe prescribing patterns
        - Reconstitution or manipulation of commercial products that may require the addition of one or more ingredients
        - Preparation of drugs or devices for the purposes of, or as an incident to, research (clinical or academic), teaching, or chemical analysis, and
        - Preparation of drugs and devices for prescriber's office use where permitted by federal and state law.
7. **Hazardous drug**: any drug identified by at least one of the following six criteria:
    - Carcinogenicity

- Teratogenicity or developmental toxicity
- Reproductive toxicity in humans
- Organ toxicity at low doses in humans or animals
- Genotoxicity
- New drugs that mimic existing hazardous drugs in structure or toxicity

8. **Manufacturing**: the production, preparation, propagation, conversion, and/or processing of a drug or device, either directly or indirectly, through extraction from substances of natural origin or independently through means of chemical or biological synthesis; the term includes any packaging or repackaging of the substance(s) or labeling or relabeling of its container and the promotion and marketing of such drugs or devices.
9. **Preparation**: compounded drug dosage form or dietary supplement or a device to which a compounder has introduced a drug.
10. **Stability**: The extent to which a preparation retains, within specified limits and throughout its period of storage and use, the same properties and characteristics that it possessed at the time of compounding.
11. **Vehicle**: A component for internal or external use that is used as a carrier or diluent in which liquids, semisolids, or solids are dissolved or suspended.

The following are guidelines for distinguishing between compounding and manufacturing.

- Pharmacists may compound, in reasonable quantities, drug preparations that are commercially available in the marketplace if a pharmacist–patient–prescriber relationship exists and a valid prescription is presented.
- Pharmacists may compound non-prescription medications in commercially available dosage forms or in alternative dosage forms to accommodate patient needs as allowed by individual state boards of pharmacy.
- Pharmacists may compound drugs in limited quantities prior to receiving a valid prescription, on the basis of a history of receiving valid prescriptions that have been generated solely within an established pharmacist–patient–prescriber relationship, and provided that the prescriptions are maintained on file for all such preparations dispensed at the pharmacy.
- Pharmacists should not offer compounded medications to other pharmacies for resale; however, a practitioner may obtain compounded medication to administer to patients, but it should be labeled with the following: “For Office Use Only,” date compounded, use-by date, and name, strength, and quantity of active ingredients. An exception to this may be the outsourcing of some compounded preparations by hospitals to contract compounding pharmacies.
- Compounding pharmacies and pharmacists may advertise or otherwise promote the fact that they provide prescription compounding services.

Three General Categories of Non-Sterile Compounding

- **Simple compounding** is described as making a preparation from a USP monograph or that appears in a peer-reviewed journal article containing specific quantities of all components, procedures and equipment and stability data; it also involves reconstituting or manipulating

commercial products that may require the addition of one or more ingredients as directed by the manufacturer.

- **Moderate compounding** is a step up and requires special calculations or procedures to determine quantities of components for the preparation or per individualized dosage units or making a preparation for which stability data is not available and the USP default BUDs are used. This even includes the mixing of two commercial products for which stability of the mixture is not known.
- **Complex compounding** requires special training, environment, facilities, equipment and procedures to produce an acceptable preparation. This can include transdermal dosage forms, modified- release preparations, some inserts and suppositories where a systemic effect is intended. It would also include innovative dosage forms for which little information may be currently available.

It is the compounder's responsibility for compounding preparations of acceptable:

- strength
- quality
- purity
- appropriate packaging
- labeling
- official standards
- relevant scientific data and information

Compounders engaging in compounding should have to continually expand their compounding knowledge by:

- participating in seminars
- studying appropriate literature
- consulting colleagues

Responsibility of the Compounder

The compounder is responsible for ensuring that the quality is built into the compounded preparations of products, with key factors including the following general principles.

- Personnel are capable and qualified to perform their assigned duties.
- Ingredients used in compounding have their expected identity, quality, and purity.
- Compounded preparations are of acceptable strength, quality, and purity, with appropriate packaging and labeling, and prepared in accordance with good compounding practices, official standards, and relevant scientific data and information.
- Critical processes are validated to ensure that procedures, when used, will consistently result in the expected qualities in the finished preparation.
- The compounding environment is suitable for its intended purpose.
- Appropriate stability evaluation is performed or determined from the literature for establishing reliable beyond-use dating to ensure that the finished preparations have their expected potency, purity, quality, and characteristics, at least until the labeled beyond-use date.

- There is assurance that processes are always carried out as intended or specified and are under control.
- Compounding conditions and procedures are adequate for preventing errors.
- Adequate procedures and records exist for investigating and correcting failures or problems in compounding, testing, or in the preparation itself.

Two Types of Compounding

- **Extemporaneous**: on the sport compounding for one specific patient
- **Bulk**: Preparing and packaging for more than one patient
    - Must include lot numbers and expiration dates of ingredients
    - Documentation of procedure on prescription/medication order

Remington's Pharmaceutical Sciences: reference book used to look up formulas.

Definitions:

- **Desiccation**- the process of using dehydration to remove moisture from a solid substance. This is the complete or nearly complete deprivation of moisture or of water not chemically combined.
- **Colation**- (straining) the process of separating a solid from a fluid by pouring the mixture on a cloth which will permit the fluid to pass through, but will retain the solid.
- **Distillation**- the process that involves a change of state - from liquid to vapor and back to liquid.
- **Filtration**- the process of separating liquids from solids with the purpose of obtaining optically transparent liquids.
- **Levigation**- the process of producing a smooth dispersion of a drug with a spatula.
- **Trituration**- the grinding of tablets into a fine powder in a porcelain mortar.
- **Stability**- the ability for medication to maintain chemical and physical integrity over time.
- **Sublimation**- the process of distilling volatile solids
- **Gelatin capsules-** used for extemporaneous compounding. Sizes vary from 5 (the smallest) to 000 (the largest).
- **Controlled Room Temperature**- between 15 - 30 degrees centigrade and 59 - 86 degrees Fahrenheit.
- **Refrigeration**- between 2 to 8 degrees C or 36 to 46 degrees F.
    - Temperatures must be checked and logged for refrigerators and freezers twice a day.
- **Suspending** or **thickening agents** are added to suspensions to thicken the suspending medium and the sedimentation rate.
    - ***Examples***
        - Acacia
        - Tragacanth
        - Bentonite
        - Carboxymethylcellulose
- **Weighing**- to ascertain a definite weight of a material to be used in compounding or manufacturing a dosage form.

    - Two classes of balances or scales:
        - Class A Torsion Balance
            - 6 mg sensitivity
            - Accurately weighs between 120 mg and 15 gm
        - Class B Balance
            - 30 mg sensitivity
            - Accurately weighs between 650 mg and 120 gm
- **Process**
    - Paper is placed on each pan
    - Balance or "zero"
    - Desired weight is placed on right tray (weights)
    - Substance on the left to be measured until balanced
- **Reconstitution**:
    - Liquids that are stored as powders because of stability limitations
    - Must add water
    - Label with time and date when reconstituted
    - Expiration date on label - Exp. in 14 days
    - Refrigeration is often (not always) required to increase stability
- **Aseptic Technique / IV Admixtures**- must be prepared under special circumstances to prevent the introduction of contaminants such as bacteria and other microorganisms from the environment, devices, equipment, and people.

Controlled Substances:

Require Strict Inventory Control

- Documentation of Receipt - Commercial invoice
- Documentation of Distribution – Narcotic inventory record
- DEA Form 222 must be used to purchase or transfer schedule I and II controlled substance
- DEA Form 106 is used to report theft or loss of controlled substances
- DEA strongly encourages submitting the DEA Form 106 and 222 online
- Compounded Products
    - The label of a compounded product should contain the following:
        - Name, address, and phone number of the pharmacy
        - Pharmacist and technician’s signature or initials involved in preparation
        - Prescriber’s name
        - Date prepared
        - BUD/expiration
        - Patient’s name
        - Medication name
        - Additives
        - Directions for use

When the Americans with Disabilities Act (ADA) was amended in 2010, it clarified instructions on how pharmacies must provide auxiliary aids and services to blind or low-vision customers in order to provide effective communication. This requirement may be in the form of large printed or Braille labels to talking labels.

Compounding Documentation

Can be kept electronically or in a written log book

Compounding Required Records

- **Master formulation record**
  - Name, strength, and dosage form of compounded preparation
  - Calculations required
  - Ingredients and quantities
  - Compounding formula
  - Thorough directions for preparation
  - Equipment needed
  - Compatibility and stability information
  - Beyond use date
  - Description of final product
  - Packaging
- **Compounding Record**
  - Date of preparation
  - Name, strength, and dosage form of compounded preparation
  - Ingredients used along with their expiration date, lot number, manufacturer, and amount used
  - Documentation of steps to prepare the compound
  - Beyond use date
  - Total quantity compounded
  - Signature of technician and pharmacist involved in preparation and verification

Preparation of Ointments

Ointments are semisolid preparations intended for external application.

Selection of the Appropriate Base

Selection of the base to use in the formulation of an ointment depends on assessing a few factors:

- The release rate of the medication from the ointment or cream base
- The topical or percutaneous drug absorption
- The effect of blocking the moisture from the skin
- Stability of the drug in the ointment base
- Effect of the drug on the consistency or quality of the base
- Desirability of a base that can Easley be removed by washing with water
- Surface characteristics to which medication is applied

  Examples:

- *Ointments* are generally applied to dry, scaly skin
- *Creams* are applied to weeping or oozing surfaces
- *Lotions* are applied to intertriginous areas or where friction may occur, as between the thighs or under the armpit

Methods of Ointment Preparation

Ointments are prepared by two general methods depending primarily on the nature of the ingredients

- incorporation
- fusion

Incorporation Method

- The components are mixed until a uniform preparation is attained.
- On a small scale, the Pharmacy Technician may mix the components using:
  - spatula may be used to rub the ingredients together on an ointment slab or ointment paper. (Spatulation)
  - or a mortar and pestle

Spatulation

1. When preparing an ointment by spatulation, the Pharmacy Technician works the ointment with a stainless steel spatula having a long, broad blade and periodically removes the accumulation of ointment on the large spatula with a smaller one.
2. If the components of an ointment react with metal, a hard rubber spatula may be used.
3. The ointment is prepared by thoroughly rubbing and working the components together on the hard surface until the product is smooth and uniform.
4. The ointment base is placed on one side of the working surface and the powdered components, on the other side. (Note: Powder previously reduced to fine powder and thoroughly blended in a mortar)
5. A small portion of the powder is mixed with a portion of the base until uniform.
6. Geometric dilution is continued until all portions of the powder and base are combined and thoroughly and uniformly blended.

Note: To prevent the final product from becoming gritty it is desirable to reduce the particle size of a powder or crystalline material before incorporation into the ointment base. This done by levigation.

- Levigation is the process of reducing particle size of a solid by triturating it in a mortar or spatulating it on an ointment slab or pad with a small amount of a liquid or melted base in which the solid is not soluble

If levigating agents are used they should be:

- Physically and chemically compatible with the drug and base
  - Mineral oil for bases in which oils are the external phase
  - Glycerin for bases in which water is the external phase
- About equal in volume to the solid material

Mortar and Pestle

- When preparing an ointment with a mortar and pestle The technician uses the mortar and pestle for levigation. This allows both reduction of particle size and dispersion of the substance in the vehicle.

- After levigation, the dispersion is incorporated into the ointment base with the mortar and pestle until the product is uniform.

Fusion Method

1. All or some of the components of an ointment are combined by being melted together with constant stirring and cooled until congealed.
    a. In general, the materials with the highest melting points are heated to the lowest required temperature that will produce a melt.
    b. During the cool down process, the other materials needing to be melted are added with constant stirring
2. As the congealing mixture is cooled and stirred, add the components that are not melted. (Not all of the components are subjected to the highest temperature using this method.
3. All heat-labile substances and if any volatile components are to be added last, when the temperature is low enough not to cause decomposition and volatilization of the components.
4. Solutions or insoluble powders may be added to the congealing mixture. (by levigated with a portion of the base)
5. Fusion may be conducted in a glass beaker or porcelain dish.
6. Once congealed, the ointment may be rubbed with a spatula or in a mortar to ensure a uniform texture.

Note: Medicated ointments and ointment bases containing: beeswax, paraffin, stearyl alcohol, or high-molecular-weight PEGs do not mix well by incorporation and must be prepared by infusion.

Preparation of Suppositories

Suppositories are semisolid dosage forms intended for insertion into body orifices where they melt, soften, or dissolve and exert localized or systemic effects.

Suppositories are commonly employed rectally, vaginally and occasionally urethral.

They have various shapes and weights depending upon density of the base and the medication present in it.

Suppository Bases

- Oleaginous bases: cocoa butter, also called theobroma oil and synthetic triglyceride mixtures
- Newer synthetic triglycerides consist of hydrogenated vegetable oils
- Water soluble/water miscible bases: those containing glycerinated gelatin or the polyethylene glycol (PEG) polymers. Examples: glycerinated gelatin, polyethylene glycol polymers

Methods of Suppository Preparation

Three methods can be used to prepare suppositories.

1. Hand Rolling is the oldest and simplest method of suppository preparation. Effective hand rolling requires considerable practice and skill.
2. Compression Molding is a method of preparing suppositories from a mass of grated suppository base and medication which is forced into a special compression mold.
3. Fusion Molding involves first melting the suppository base, and then dissolving the drug in the melted base. The mixture is removed from the heat and poured into a suppository mold. When the mixture has congealed, the suppositories are removed from the mold. This method can be used with all types of suppositories.

Suppository Molds and Packaging

- Aluminum metal molds come in a variety of cavity sizes and with a variety of number of cavities per mold.
- Plastic suppository shells come in long strips that can be torn into any number of cavities.
- Suppository molds made from flexible rubber.
- Hard rubber molds are similar to the metal molds they have screws to hold the mold together.

Suppository Molds

- Molds should be filled only when they are at room temperature. Each cavity should be filled slowly to ensure that no air bubbles are trapped in the cavity. The pouring process should not be stopped until all the cavities have been filled to prevent layering. Molds should be allowed to set at room temperature and not refrigerated. If the suppository has not congealed after 30 to 40 minutes then refrigerate.
- Aluminum molds and hard rubber molds usually require lubrication before use. Whatever lubricant is used, only a light coating is needed.
- When suppository mixtures and bases cool, they contract and will produce a hole in the open end of the suppository. Such a hole is undesirable. If the suppository mixture is poured just immediately before it reaches its congealing temperature, the contraction will be minimized. Pouring a small excess of the suppository mixture on top of the open end of the mold will also help.
- Start pouring the melt at one end and pour continuously without stopping. Do not go to the next cavity until the previous cavity is filled and a slight excess has been poured to overfill the cavity. The excess base can be removed with a stainless steel spatula after the suppositories have congealed.

When the suppository mixture has congealed and the excess is removed from the top surface, the mold is then separated into the two halves.

- Flexible rubber molds can be packaged with the suppository still in the mold.
- Plastic shell molds must be heat-sealed.

Preparation of Emulsions

Emulsion is a mixture of two or more liquids that are normally immiscible (unmixable or unblendable)

- Emulsions are, by nature, physically unstable; they tend to separate into two distinct phases or layers over time.
- Where oils are the dispersed phase, and water is the continuous phase, the system is called an oil-in-water (o/w) emulsion.
- Where water or aqueous solutions are dispersed in an oil medium, the system is known as a water-in-oil (w/o) emulsion.
- Creaming occurs when dispersed oil droplets merge and rise to the top of an o/w emulsion or settle to the bottom in w/o emulsions. In both cases, the emulsion can be easily be dispersed by shaking.
- Coalescence (breaking or cracking) is the complete and irreversible separation and fusion of the dispersed phase.
- Phase inversion is a change from w/o to o/w (or vice versa).

Emulsifying Agents

Emulsions are stabilized by adding an emulsifying agent. Some commonly used emulsifying agents include tragacanth, sodium lauryl sulfate, sodium dioctyl sulfosuccinate, and polymers.

Synthetic Emulsifying Agents

- Cationic, e.g., benzalkonium chloride, benzethonium chloride
- Anionic, e.g., alkali soaps (sodium or potassium oleate); amine soaps (triethanolamine stearate); detergents (sodium lauryl sulfate, sodium dioctyl sulfosuccinate, sodium docusate).
- Nonionic, e.g., sorbitan esters (Spans®), polyoxyethylene derivatives of sorbitan esters (Tweens®), or glyceryl esters

Natural Emulsifying Agents

- A variety of emulsifiers are natural products derived from plant or animal tissue. Most of the emulsifiers form hydrated lyophilic colloids (called **hydrocolloids**) that form multi-molecular layers around emulsion droplets.
    - Hydrocolloid emulsifiers may be classified as:
        - vegetable derivatives, e.g., acacia, tragacanth, agar, pectin, carrageenan, lecithin
        - animal derivatives, e.g., gelatin, lanolin, cholesterol
        - Semi-synthetic agents, e.g., methylcellulose, carboxymethylcellulose Synthetic agents, e.g., Carbopols®

Methods of Emulsion Preparation

Several methods are generally available to the Pharmacy Technicians. Each method requires that *energy* be put into the system in some form. The energy is supplied in a variety of ways: trituration, homogenization, agitation, and heat.

Continental Method, Dry Gum, or 4:2:1 method

The continental method is used to prepare the initial or primary emulsion from oil, water, and a "gum" type emulsifier (usually acacia). The primary emulsion is formed from 4 parts oil, 2 parts water, and 1-part emulsifier. (4:2:1) The 4 parts oil and 1-part emulsifier represent their total amounts for the final emulsion.

Steps

1. In a mortar, the 1 part gum is levigated with the 4 parts oil until the powder is thoroughly wetted;
2. Then the 2 parts water are added all at once, and the mixture is vigorously and continually triturated until the primary emulsion formed is creamy white and produces a "crackling" sound as it is triturated. Should take 3 to 5 minutes.
3. Additional water or aqueous solutions may be incorporated after the primary emulsion is formed.
4. Solid substances (e.g., active ingredients, preservatives, color, flavors) are generally dissolved and added as a solution to the primary emulsion.
5. Oil soluble substance, in small amounts, may be incorporated directly into the primary emulsion.
6. Any substance which might reduce the physical stability of the emulsion, such as alcohol (which may precipitate the gum) should be added as near to the end of the process as possible to avoid breaking the emulsion.
7. When all agents have been incorporated, the emulsion should be transferred to a calibrated vessel, brought to final volume with water, then homogenized or blended to ensure uniform distribution of ingredients.

Dry Gum Method

Ingredients: cod liver oil 50 ml, acacia 12.5 g, syrup 10 ml, flavor oil 0.4 ml, and purified water, qs ad 100 ml

1. Accurately weigh or measure each ingredient
2. Place cod liver oil in dry mortar
3. Add 25ml of water and immediately triturate to form the thick, white, homogenous primary emulsion
4. Add the flavor and mix
5. Add syrup and mix
6. Add sufficient water to total 100 ml

English Method or Wet Gum

In this method, the proportions of oil, water, and emulsifier are the same (4:2:1), but the order and techniques of mixing are different.

1. 1-part gum is triturated with 2 parts water to form a mucilage;
2. 4 parts oil is added slowly, in portions, while triturating.
3. After all the oil is added, the mixture is triturated for several minutes to form the primary emulsion.
4. Other ingredients may be added as in the continental method.
5. The English method is more difficult to perform successfully, but often result in a more stable emulsion.

Bottle or Forbes Method

Used to prepare emulsions of volatile oils, or oleaginous substances of very low viscosities. Not suitable for very viscous oils since they cannot be sufficiently agitated in a bottle. This method is a variation of the dry gum method.

1. One part powdered acacia (or other gum) is placed in a dry bottle
2. Four parts oil are added.
3. Cap bottle and thoroughly shake.
4. Required volume of water is added all at once, and the mixture is shaken thoroughly until the primary emulsion forms.
   Note: It is important to minimize the initial amount of time the gum and oil are mixed. The gum will tend to absorb the oil, and will become more waterproof.

The bottle method is also effective in preparing an olive oil and lime water emulsion, which is self-emulsifying.

1. Lime water and olive oil, equal parts of lime water and olive oil are added to the bottle and shaken.
2. No emulsifying agent is used, but one is formed following a chemical interaction between the components.

Beaker Method

When synthetic or non-gum emulsifiers are used, the previous methods become meaningless. The most appropriate method for preparing emulsions from surfactants or other non-gum emulsifiers is by dividing components into water soluble and oil soluble components.

1. Oil soluble components are dissolved in the oily phase in one beaker
2. Water soluble components are dissolved in the water in a separate beaker.
3. Oleaginous components are melted and both phases are heated to approximately 70°C over a water bath.
4. The internal phase is then added to the external phase with stirring until the product reaches room temperature.
   Note: The mixing of such emulsions can be carried out in a beaker, mortar, or blender.

Auxiliary Methods

Instead of, any of the preceding methods, the pharmacy technician can usually prepare an excellent emulsion using an electric mixer or blender. An emulsion prepared by other methods can also usually be improved by passing it through a hand homogenizer.

Preparation of Enemas

Enema is the injection of fluid into the lower bowel by way of the rectum and are employed for the same purposes as orally administered laxatives: To relieve constipation.

Soft Soap Enema

1. Add 6.6 ml soft soap
2. Add purified water to 133 ml

Mixing Powdered Drugs with Water:

1. Measure the total amount of liquid needed in a graduated cylinder.
2. Add half the water to dry powder and shake well.
3. Add remaining water and shake well.

Preparation of Solutions

Solutions are thermodynamically stable, system composed of 2 or more components, one of which is completely dissolved in the other. Pharmaceutical solutions are those composed of a solid, liquid, or gas dissolved in a liquid solvent.

A solution that contains the maximum amount of solute that the solvent will accommodate at room temperature and pressure is a saturated solution.

A solution that contains a larger amount of solute than the solvent can normally accommodate at that temperature and pressure is a supersaturated solution. A supersaturated solution is usually obtained by preparing it at a higher temperature and reducing the temperature. Saturated and supersaturated solutions are unstable and tend to precipitate the excess solute.

Solutions are widely used in the pharmaceutical industry as vehicles for oral, parenteral, topical, otic, ophthalmic, and nasal products. They may also be used as flavorings, buffers, preservatives, and suspending agents.

Classification of Solutions

Aqueous solutions are the most common of the oral solutions. Drugs, flavorings, preservatives and buffering salts are dissolved in water. In preparing pharmaceutical solutions *Distilled or purified water* should always be used.

Examples of aqueous pharmaceutical solutions:

- Syrups contain less than 10% alcohol and are concentrated, viscous, sweetened, aqueous solutions, Examples: Syrup USP, Wild Cherry Syrup USP.
- Aromatic waters are used to provide a pleasant flavor or aroma and consist of saturated solutions of volatile oils in water. Example: Peppermint Water, USP.
- Mucilages are thick, viscous macromolecular solutions produced by dispersing vegetable gums in water. They are commonly used as suspending or thickening agents, Examples: Acacia; Tragacanth.
- Aqueous acids are dilute aqueous solutions of acids (usually < 10%), e.g. Diluted HCl, USP.

Preparation of Syrups

Syrup is a concentrated solution of sugar, such as sucrose in water or other aqueous liquid used as a vehicle or base solution to mask the taste of drugs. The high concentration of sugar in syrups provides preservative property as well.

Syrups are used as solution vehicles.

- Simple syrup contains only sucrose and purified water (Syrup USP).
- Flavoring syrups containing pleasantly flavored substances (Tutti Frutti Syrup, Grape Syrup)
- Medicinal syrups are those to which therapeutic compounds have been added (Zyrtec Syrup)

Syrups should be carefully prepared with clean. Three methods may be used to prepare syrups.

1. Solution with heat
2. Agitation without heat
3. Percolation

Although the hot method is quickest, it is not applicable to syrups of volatile ingredients. When using heat, temperature must be carefully controlled to avoid caramelization (decomposing and darkening) of the syrup.

Sucrose is the sugar most frequently employed in syrups, although in special circumstances, it may be replaced in whole or in part by other sugars or substances such as sorbitol, glycerin, and propylene glycol.

Solution with Heat

Syrups are prepared by this method when it is desired to prepare the syrup as quickly as possible and when the syrup's components are not damaged or volatilized by heat.

- Sugar is added to the purified water
- Heat is applied until the sugar is dissolved
- Other heat-stable components are added to the hot syrup,
- The mixture is allowed to cool, and its volume is adjusted to the proper level by the addition of purified water
- If heat-labile agents or volatile substances, such as volatile flavoring oils and alcohol, are to be added, they are generally added to the syrup after the sugar is dissolved by heat, and the solution is rapidly cooled to room temperature.

Agitation without the Aid of Heat

To avoid heat-induced inversion of sucrose, a syrup may be prepared without heat by agitation. On a small scale, sucrose and other formulated agents may be dissolved in purified water by placing the ingredients in a vessel larger than the volume of syrup to be prepared, permitting thorough agitation of the mixture. This process is more time consuming than the use of heat, but the product has maximum stability.

Percolation

In this process, purified water or an aqueous solution is allowed to pass through a bed of crystalline sucrose. A pledget of cotton is put in the neck of the percolator and purified water or aqueous solution is added in the percolator containing sucrose. The flow rate is controlled by the stopcock and maintained such that drops appear in rapid succession. If required, a small portion of liquid is re-passed through the percolator to dissolve the sugar completely in the liquid or aqueous solvent.

Definitions

*Elixir—A*n elixir is a clear, sweetened, alcohol-containing solution that is used mainly for drugs that are insoluble in water alone. It is usually not as sweet and less viscous than a syrup. The alcohol content of elixirs makes it a less desirable vehicle or base solution for preparing extemporaneous formulations in pediatric patients.

Levigating agent—A levigating agent is used to moisten and soften a tablet to facilitate the preparation of a liquid, especially when a large number of tablets is required or the tablets are extremely difficult to crush. Preferably, the vehicle or base solution used for the product is used as the levigating agent.

Simple syrup—Simple syrup is a sucrose solution that is made with purified water alone.

Solution—A solution is a liquid containing medication that is dissolved in water or other liquids.

Suspending agent—A suspending agent is used to prevent agglomeration of the dispersed particles and to increase the viscosity of the liquid. This allows for slow settling of the drug particles to ensure uniform distribution and accurate measurement of the dose.

Suspension—A suspension (two-phase system) is a dispersion containing fine insoluble particles suspended
in a liquid medium.

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