

HARAR HEALTH SCIENCE COLLAGE

Department of pharmacy

Orientation on Federal licensure and competency exam

and

Feedback on Internal licensure and competency exam

December 2020

1. Orientation on Federal licensure and competency exam

1.1 Pharmacy Domains

S. N o	Domain	Recommendat ion	PROCESS					
1	Dispensing	1.GDP (Good dispensing practice)Man ual,EFDA 2 .Pharmacolog y	Handling of pharmace uticals	prescriptio n analysis	Selection & manipulati on	La bel ing & su ppl y	Coun selin g	D oc u m en ta tio

								n
2	Drug information service	1.NATIONAL DRUG INFORMATION SERVICE TRAINING COURSE FOR PHARMACISTS,EFDA 2.DIC	Receiving the request	Categorizing the request type	Searching & evaluation	Responding or dissemination	Documentation	
3	pharmaceutical care	1. Therapeutics Text books 2. Dipro 3. koda	Assessment	Drug therapy problem Identification	Care plan preparation and recommendation	Monitoring and evaluation		
4	Supply chain management	1. IPLS SOP 2. DSM 3. GSP & GDP	Selection	Quantification	Procurement	Storage	distribution	

		(Good storage practice and Good distribution practice)					
5	Manufacturing	1.Industrial pharmacy 2 .pharmaceutical analysis 3. IPP 4. GMP	Design & dev't of formulation	Quality control	Production packaging	Storage and Distribution	
6	Regulatory service	1.Guideline for Adverse Drug Events Monitoring (Pharmacovigilance) 2.Guidance on Waiver of In vivo Bioequivalence 3. Guideline for Submission of Post-approval variations medicines	Pre licensing Inspection	Licensing and relicensing Accreditation	Pharmacovigilance		

		application				
7	Professionalism and ethics	1 .Professional Ethics	Consent and Confidentiality	Accountability, responsibility and collaboration		
8	Public Health	1.Research methodology	Assessment and plan	Strategy	Intervention	Monitoring Evaluation

1.2Assessment / exam Format

- The Multiple choice questions (MCQ) assesses application of knowledge and problem-solving ability of graduates (Clinical decision-making skills)
- The Number of questions for each cadre is 180/200
- It is taken in both Morning and Afternoon

1.3Components of an Item

- Stem
- Lead in
- Options (four in number)
 - ✓ Answer key
 - ✓ Distracters

Sample MCQ

A 24 year-old university student came to see you because she is missing several days of school each month because of severe dysmenorrhea unresponsive to the OCP and NSAIDS. She also complains of deep

dyspareunia and has a tender uterosacral nodule on the pelvic examination. **(Stem)**

what is the most likely responsible for the patient symptoms?

(Lead-in)

A) Chronic PID

B) Endometriosis

C) Adenomyosis

D) Fibroids

**Option
set**

1.4 How Do the Exam develop ?

Licensure Exam Development Process Contains

1. Task analysis
2. Exam Blueprinting
3. Exam items development
4. Reviewing and validating exam items
5. Exam scoring and Item Analysis

***Adapted from HEI's student representatives sensitization meeting ,
NHPCALD , March, 2019***

2. Internal Licensure exam Feed back on DSM , Dispensing and Regulatory service

Resources

- ✚ **Standard Operating Procedures (SOP) Manual for the Integrated Pharmaceuticals Logistics System in Health Facilities of Ethiopia ,Second Edition , Addis Ababa, Ethiopia , November, 2015**
- ✚ **Guidance on Waiver of In vivo Bioequivalence , EFDA ,December, 2015**
- ✚ **Good Dispensing Practice and pharmaceutical supply chain management , EFDA participant's manual , January, 2019 , Addis Ababa, Ethiopia**
- ✚ **Guideline for Submission of Post-approval variations medicines application, EFDA First Edition , December, 2015**

➤ **NOTE** - Answers are **BOLDED** .

1. what are the essential data items that are required to run a logistics system and must be captured by the logistics Management Information System (LMIS) ?

A . Stock on Hand The quantity of pharmaceuticals used during the reporting period.

B. Consumption Data Quantities of usable stock available at a particular point in time.

C . Losses/Adjustments Losses are the quantities of products removed from your stock for anything other than in the provision of services to patients or issuing to another facility

D. All

ANS

Three essential data items are required to run a logistics system and, therefore, must be captured by the LMIS. These three essential data items are:

1. Stock on Hand: Quantities of usable stock available at a particular point in time.
2. Consumption Data: The quantity of pharmaceuticals used during the reporting period.
3. Losses/Adjustments: Losses are the quantities of products removed from your stock for anything other than in the provision of services to patients or issuing to another facility (e.g. expiry, lost, theft, or damage) and are recorded as negative (-) numbers. Adjustments are quantities of a product received from any source other than PFSA, or issued to anyone other than your health facility. An adjustment may also be a correction due to an error in mathematics. An adjustment may be a negative (-) or positive (+) number.

2. which of the following is correct about the reporting frequency at different level of health facilities

A. Health Post reports to Health Centre every 2 weeks until the 5th day after the reporting period

B. Health Centre (Direct) reports to Woreda Health Office / PFSA every month until 10th day after the reporting period

C. Hospital Regional reports to Health Bureau / PFSA every 2 months 10th day until after the reporting period

D . Hospital Regional reports to Health Bureau / PFSA every 4 months 15th day until after the reporting period

Table 9: Reporting frequency at different level of health facilities

Unit	Reports to/Orders from	Every	Until the	Using this report form
Health Post	Health Centre	month	5 th day after the reporting period	Health Post Monthly Report and Re-supply Form
Health Centre (Direct)	Woreda Health Office / PFSA	2 months	10 th day after the reporting period	Report & Requisition Form
Health Centre (Non-direct)	Woreda Health Office	2 months	5 th day after the reporting period	Report & Requisition Form
Woreda Health Office (for non-direct delivery Health Centres)	PFSA	2 months	10 th day after the reporting period	Individual Health Centre Report & Requisition Form
Hospital	Regional Health Bureau / PFSA	2 months	10 th day after the reporting period	Report & Requisition Form

3. which of the following is **true**

- A. The maximum months of stock is the smallest amount of each pharmaceutical a facility should hold at any one time.
- B. The maximum months of stock is the level of stock at which actions to replenish inventory should occur under normal conditions.
- C. The emergency order point is the level where the risk of stocking out is likely, and an emergency order should be placed immediately.**
- D. The emergency order point is the level of stock at which actions to replenish inventory should occur under normal conditions .

ANS

- The maximum months of stock is the largest amount of each pharmaceutical a facility should hold at any one time. If a facility has more than the maximum, it is overstocked and risks having stocks expire before they are used.
- The minimum months of stock is the level of stock at which actions to replenish inventory should occur under normal conditions.
- The emergency order point is the level where the risk of stocking out is likely, and an emergency order should be placed immediately.

4. which of the following is **correct** about VEN analysis of pharmaceuticals

- A. It is system of setting priorities, in which pharmaceuticals are classified according to their health impact and decisiveness to the service
- B. Vital pharmaceuticals are potentially lifesaving, the best tool to curb the morbidity of the area
- C. Essential pharmaceuticals are effective against less severe but significant illness,
- D. none essential/less essential pharmaceuticals are effective for minor illnesses
- E. All**

VEN stands for:

V = Vital:

- Potentially lifesaving, the best tool to curb the morbidity of the area: in the absence of this pharmaceutical, the patient may die, or may be hurt.
- Crucial to provide the basic health services; without which it is impossible to deliver the basic services in a specific area
- It is mandatory 24 hours of a day, 7 days of a week, and or 12 months of a year
- Known, easily manageable by the health care team and is the most fit with the clinical setup of the facility than the other alternatives.

E = Essential:

- Effective against less severe but significant illness,
- In the absence of these items, it may be difficult to deliver the service; somehow one may deliver the service by using alternatives
- Are manageable by the medical staff and fits in a better way to the clinical setup of the facility than the other alternatives

N = none essential/less essential:

- Effective for minor illnesses
- But may have high cost compared to its therapeutic advantage
- The service will not be stopped due to the absence of N items
- Cannot be managed by the clinical setup and medical staffs even if it is the best pharmaceutical

5. The inventory control system of Ethiopia is

A. Forced-ordering max-min system

B. Continuous review max-min system

C. Standard max-min system

ANS

The inventory control system for the IPLS is a Forced Ordering Maximum/Minimum inventory control system. This means that all facilities are required to report on a fixed schedule (monthly at health posts, every other month at health centres and hospitals) for all products. In addition, all products are re-supplied each time a report is completed. In emergencies, an emergency order can be placed. In practice, this means that:

6. which of the following is correct about ABC analysis

A. Method for determining and comparing pharmaceutical consumption and costs within the health facility

B. A medicines—low-cost items

C. C medicines—Moderate cost and moderate number of items; important items

D. B medicines—Small amount of funds spent on the majority of the inventory

ANS

“A” pharmaceuticals:

- High percentage of funds spent on large-volume or high-cost items
- Greatest potential for savings
- Greatest potential for identifying expensive pharmaceuticals that are overused

“B” pharmaceuticals:

- Moderate cost and moderate number of items; important items

“C” pharmaceuticals:

- Small amount of funds spent on the majority of the inventory

7. Calculate the estimated quantity consumed based on the following information

Beginning Balance: 50

Quantity Received : 35

Borrowed from other Dispensing unit : 10

Ending Balance : 12

A. 107

B. 99

C. 86

D. 83

Example #1:

Beginning Balance(A): 50

Quantity Received (B) : 35

Borrowed from other Dispensing unit (C): 10

Ending Balance (D): 12

$$A + B + C - D = E \quad 50 + 35 + 10 - 12 = 83$$

Calculated Consumption = 83

8. Most products have the expiration date already labeled on them , If the expiration date is not available which measure is WRONG ?

A. If you are unsure of the shelf life of a product, make an inquiry; then determine and write the expiration date once the manufacture date is known

B. for products which doesn't have expiry date assume its safe to use for a year

C. By knowing the manufacture date and the shelf life of the product, one is able to determine the expiration date of the product.

D. if you receive an item with a manufacture date of February 2006, add the shelf life (for example, 18 months) to this date.

ANS

If the expiration date is not available, look for the manufacture date on the carton, packaging, or product. By knowing the manufacture date and the shelf life of the product, one is able to determine the expiration date of the product. For example, if you receive an item with a manufacture date of February 2006, add the shelf life (for example, 18 months) to this date. The expiry date would then be August 2007. Once the expiration date is determined, write it in large numbers on the outer carton with a marker for easy identification. If you are unsure

9. which of the following is **INCORRECT** about pharmaceutical storage

- A. Clean the storeroom regularly
- B. Store pharmaceuticals in a dry, well-lit, well- ventilated storeroom – out of direct sunlight
- C. Stack supplies off the floor on pallets at least 5 cm high and 30 cm away from walls as moisture can seep through walls and floors.**
- D. Store latex products away from electric motors and fluorescent lights.

ANS

Protect storeroom from water penetration. Water can destroy both supplies and their packaging. If the packaging is damaged, the product is still unacceptable to the patient even when the pharmaceutical is not damaged. Repair the storeroom so that water can not enter. Stack supplies off the floor on pallets at least 10 cm high and 30 cm away from walls as moisture can seep through walls and floors. ARV drugs and fluconazole are particularly sensitive to moisture.

- 10 . which of the following is NOT correct according to Good storage guideline
- A. Store pharmaceuticals to facilitate FEFO procedures and stock management
 - B. Store pharmaceuticals to facilitate FIFO procedures and stock management**
 - C. Store flammable products separately from other products
 - D. Limit storage area access to authorized personnel and lock up controlled substances.

ANS

Store pharmaceuticals to facilitate FEFO procedures and stock management. FEFO (First Expired, First Out) is a method of arranging drugs in a storage facility where the drugs are managed by their expiry date. Drugs that will expire first are issued first, regardless of when they were received at the health facility.

11. When conducting a visual inspection, be sure to check the following

- A. check for damage to packaging (tears, perforations, water or oil) and products (unexpected odor, caking on bottles, change in color, broken bottles)
- B. Check Manufacturing defects as incomplete supply, missing or illegible identification information.
- C. Make sure that products are labeled with the date of manufacture or expiration, lot number and manufacturer's name

D. All

12 . which of the following is true about De junking of pharmaceuticals

- A. De junking means getting rid of the —junk in a storage facility,
- B. De junking is also a time for reorganizing a storage facility and getting bin cards and stock record cards up to date.
- C. De junking can greatly increase storage space.

D. the De junking process doesn't need a special protocol or special guideline

ANS

II. Steps in De junking

De junking means getting rid of the “junk” in a storage facility, including DEPS (Damaged and Expired Products) and any other items that do not belong in storage facility for health products. (These items can include old furniture, outdated forms, fuel barrels, vehicle parts, etc.) De junking is also a time for reorganizing a storage facility and getting bin cards and stock record cards up to date. De junking can greatly increase storage space.

13 . which of the following is true about conducting a Physical Count

- A. physical count (also called *Physical Inventory*) is an actual count of the quantity of each supply at any given time

- B. physical count of pharmaceuticals in the storeroom ONLY should be conducted cyclical or annually
- C. If the quantity on the Bin Card or the Stock Record Card does not match the quantity on the shelf, the Bin Card and the Stock Record Card should be updated and an adjustment should be entered
- D. should be performed at least every 6 month at the Health Post level , at least every year at the Health Centre/Hospital level**

ANS

When to perform: At least every quarter at the Health Post level
At least every 6 months at the Health Centre/Hospital level
Any time you suspect that products have been lost

14 . which of the following is NOT according to handling damaged or expired pharmaceutical Stocks guideline

- A. expired or damaged stocks found at any time during a visual inspection or physical count should be immediately removed from the inventory
- B . should be moved to a separate place, so that they cannot be dispensed or used
- C. be disposed of according to the established guidelines.

D. none

15 . using consumption method calculate the amount of Ampicillin 500 mg capsule for the next **six month** (procurement period) based on the following data

- o CT=100,000 capsule
- o So=50,000
- o Dos= 34 days
- o Use adjustment for 6 month=5%

- o Loss adjustment for 6 month=10%
- o SI=90,000
- o LT=3 month

$$Q_o = C_p \times (LT + PP) + SS - (S_i + S_o)$$

PP=procurement period

S_i = stock now in inventory, in BU (Basic Unit)

S_o = stock now on order, in BU

S_s = safety stock

- $Q_A = Q_o + (Q_o \times AL)$, finally adjust with loss adjustment 10 % .

A. 96,597 cap **B.126,279 cap** C.114,799 cap D. 20,466 cap

16 . Answer question number 16,17 and 18 based on the data given on question number 15
what is the average monthly consumption ?

$C_A = C_T / (R_M - (D_{os}/30.5))$, divide total consumption during the review period (C_T) by review period . (if there were days of stock out calculate the difference b/n R_M & D_{os} .

Review period is 6 months .

D_{os} is divided by 30.5 because the stock out days needs to be used in month SI unit instead of days SI unit through out the calculation .

A. 96,597 cap **B.**

20,466 cap

C.114,799 cap D.

126,279 cap

17. based on the information what is the

calculate the safety stock needed for each drug ?

ANS - lead time is the time between when new stock is ordered and when it is received and available for use therefore multiply C_A (average monthly consumption) by L_T (lead time) to have safety stock needed .

$$SS = C_A \times L_T \dots\dots\dots$$

Where SS = safety stock

C_A = average monthly consumption, adjusted for stock out

L_T =average lead time

- A. 54,654 cap B. 20,466 cap **C. 61,398 cap** D. 60,990 cap

18 . calculate estimated costs for each drug and total costs , considering 1 pack contains 1000 capsule

and probable price of one pack to be 300 birr .

$$QA / 1000 \times 300 \text{ birr}$$

- A. 37,000 ETB **B.37,883 ETB** C. 29100 ETB D.43,449 ETB

19. Applying morbidity quantification method estimate the total quantity of Cotrimoxazole suspension required for the treatment of Otitis Media based on the following information.

- o Last total No. of contacts (C)= 3,123,408
- o 5% expected rate of increase
- o Frequency of Otitis Media (per thousand) = (106 for <5, 29 for >5)

Treatment for Otitis Media

$$Q_E = D_{CU} \times N_D \times L_D$$

$$C_E = C + (C \times A_U)$$

$$E_T = C_E \times F$$

$$Q_T = E_T \times Q_E \times P_T$$

Under 5

- Cotrimoxazole suspension
5ml BID for

10 days

- Paracetamol sol/n of 120mg/5ml, 1.5ml QID for 10 days
- Pseudoephedrine syrup 2.5ml QID for 5 days

Above 5

- Cotrimoxazole 800/160 mg tab BID for 10 days
- Paracetamol 500 mg tab, 2 tab QID for 5 days
- Pseudoephedrine 60 mg tab QID for 5 days

QT=quantity of drugs needed

ET= number of treatment episodes

QE=quantity of drugs for each treatment episode, BU

PT=percentage of cases that are treated with that specific regimen

N_D=Number of doses per day

L_D=length of treatment per episode

A. 34,763,531 B. 32,797,990 C. 13,905,412 d 20,858,119

20. based on the data given on question number 19 calculate total quantity of Paracetamol 120mg/5ml required for the treatment of Otitis Media based on the following information

A. 20,858,119 B. 34,763,531 C. 32,797,990 D. 13,905,412

21. based on the data given on question number 19 calculate total quantity of Pseudoephedrine syrup required for the treatment of Otitis Media based on the following information

A. 20,858,119 **B. 13,905,412** C. 32,797,990 D. 34,763,531

22. _____ is Procurement method with formal procedure by which quotation are invited from any manufacturer or its representative on a local or worldwide basis .

- A. Open tender** B. Restricted tender (closed bid or selective tender)
C . Reverse auction D. Competitive negotiation or negotiated procurement

23 . which of the following is NOT true about **Direct procurement** method

- A. direct purchase from single supplier either at the quoted or negotiated price
B. Simplest procurement method
C. most expensive method of procurement

D. buyer approaches a limited number of selected supplier

24 .which of the following is CORRECT about prescribing indicator

A. Determining average number of drugs per encounter is to measure the degree of poly pharmacy.

- B. The target for percentage of medicines prescribed by generic name target is 50 % .
C. The target for percentage of encounters with an antibiotic prescribed is 5- 15 % .
D. Percentage of encounters with an injection prescribed is expected to be < 50 % .

✓ **prescribing indicators**

Average number of drugs per encounter

Target: < 2 per encounter

Percentage of medicines prescribed by generic name

- Target: 100%

Percentage of encounters with an antibiotic prescribed

- Target: 20-30 %

Percentage of encounters with an injection prescribed

- Target: <25%

Percentage of Medicines Prescribed from health facility medicine list

- Target: 100%

Completeness of prescriptions

- Target: 100 %

25 . one is true about maintaining the Bin Card and stock card

A. One *Bin Card* should be maintained for each pack size, form or presentation of pharmaceuticals

B. The *Bin Card* should be kept with the product in the storage area.

C . The Bin Card is used at all health facilities

D. Stock Record Card is used at all health facilities

ANS

The Bin Card is used at all health facilities (Health Post, Health Centre and Hospital); the Stock Record Card is used only at the health centres and hospitals.

26. Which of the following is not true about autonomy?

- A .The autonomous person is respected
- B. The autonomous person must be able to determine personal goals
- C. The autonomous person has the freedom to act upon the choices
- D. none**

27 .which of the following is components of unethical behavior .

- A .Corruption B. Smuggling C. Mistreating the patient **D . All**

28.....Means keeping the patient related information secret.

- A. Non-maleficence B. Beneficence C. Justice **D. Confidentiality**

29 . A pharmacist in relation to his patient should **Except**

- A. Respects the covenantal relationship
- B .Be morally obliged in a response to the gift of trust received from the society
- C. show partiality between his patrons.**
- D .Not abuse his/her relationship with the patient for personal gain

30 . Which of the following is a requirement to be registered as a pharmacist ?

- A. Age B .Education C .Good moral character **D . All**

31. which of the following is not a ground for revocation of license

- A. Drug addiction B. Mental illness C .Physical condition D .Violation of law governing the sector **E . none**

32 . why is license needed for health professional ?

- A. To ensure proper management and utilization of pharmaceuticals.
- B. To ensure the fulfillment of requirements/ standard .
- C. To ensure the quality, safety and efficacy of pharmaceuticals.

D . All

33. Inspection is

- A.verification of performance and data
- B. Determination of conformity to specified requirements
- C. Observation of premises, product, professional and practice

D. All

34 is the type of inspection undertaken to ensure the fulfillment of requirement by pharmaceutical establishment before a license is issued.

- A .Pre-licensing inspection** B .Post-licensing inspection C. Routine Inspection
- D.Special Inspection

35. One of the following is not appropriate relation of Pharmacist to other Health professionals

- A. Respect the skills and competence of other health care providers
- B. Strive to maintain the confidence and trust placed in other health professionals by patients
- C. Not enter into any secret arrangement or negotiation

D. May cooperate any act of malpractice

36 . Which of the following categories, or schedules of substance is related with high degree of drug abuse

- A. Schedule II B. Schedule III **C. Schedule I** D . Schedule IV

37. One of the following is true about clinical trial to be conducted

A. Nursing and pregnant women are a candidate to establish the safety of the drugs

B. Persons under the age of 18 is a candidate to establish the safety of the drugs

C. Prisoners and insane persons are not forced and used in the clinical trials

D. Clinical trial is conducted even if it is not authorized by the executive organ

38. _____ is the study of health profile of a single individual with unusual medical occurrences using a careful and detailed report by one or more clinicians

A. Case series

B. case report

C. cross sectional

D. Cohort

39. which of the following is true about cohort study

A. is an epidemiologic design that identifies comparison groups according to their exposure status

B. often used to detect the emergence of new disease or an epidemics

C. could provide information about the magnitude of diseases or other health related condition by furnishing a 'snapshot' at a specified time

D. major type of descriptive study designs

40. which of the following is not among problems of intervention studies ?

A. More difficult to design and conduct

B. Ethical issues

C. very expensive

D. Generalizability

41. Based on guideline for **submission of post approval variation medicine** Application for replacement or addition of the site where batch control/testing takes place needs to adhere to these condition Except

- A. Site has approval from EFDA to conduct quality control testing of finished pharmaceutical product concerned.
- B. The site is accordingly approved for GMP/GLP by the NDRA.
- C. Transfer of the method from the old to the new site or to the new test laboratory has been successfully completed.
- D.** The site is accordingly approved for GDP

ANS

Replacement or addition of a manufacturing site of manufacturing process of finished pharmaceutical product

Conditions

1. Site has approval from EFMHACA for the packaging or manufacturing of the pharmaceutical form and the product concerned.
 2. Site accordingly approved for GMP by a NDRA (to manufacture the pharmaceutical form and the product concerned).
42. which of the following is true about documentation content regarding change of dimensions of tablets, capsules, suppositories or pessaries without change in qualitative or quantitative composition and mean mass
- A. Detailed drawing or written description of the current and proposed appearance.
 - B. Samples of the finished pharmaceutical product.
 - C. Justification for not submitting a new bioequivalence study according to the current

guidelines on bioequivalence

D. All

E. None

ANS

Change of dimensions of tablets, capsules, suppositories or pessaries without change in qualitative or quantitative composition and mean Mass

Documentation

1. Detailed drawing or written description of the current and proposed appearance.
 2. Comparative dissolution data on at least one pilot-scale/production batch of the current and proposed dimensions
 3. Justification for not submitting a new bioequivalence study according to the current guidelines on bioequivalence
 5. Where applicable, data on breakability test of tablets at release must be given together with a commitment to submit data on breakability at the end of the shelf-life.
 6. Release and shelf life specifications of the finished product.
43. The prescriber prescribes a combination of amoxicillin and clavulanate and mentions the dose as take 5ml twice a day. It is available as amoxicillin 125mg + clavulanic acid 31.25mg and amoxicillin 200mg + clavulanic acid 28.5mg. What you are going to do?
- A. dispense as amoxicillin 125mg + clavulanic acid 31.25mg
 - B. dispense as amoxicillin 200mg + clavulanic acid 28.5mg
 - C. refuse to dispense

D. contact the prescriber

Discussion : If no strength is mentioned, it cannot be assumed that the lowest or highest strength has to be dispensed. This is because many times the lower strength may not be sufficient to treat the condition or higher strength may lead to toxicity. If the strength is not stated on the prescription, mostly it may be necessary to contact the prescriber for confirmation of the appropriate strength.

44. On December 7, 2017, the patient brought the prescription which read as follow; 'metformin 500 mg tablets p.o 1 tablet twice daily for 3 months' for a chronic patient who has been taking the medicine since 3 years ago. The stock available of metformin 500 mg tablet in the pharmacy has an expiry date of January 2018 and no fresh stock is available. What are you going to do?

- A. Dispense the required quantity for 3months
- B. Dispense the required quantity for until January 1st
- C . Dispense the required quantity for until January 31st**
- D. Dispense the required quantity for until January 30 st

Remember if the expiry date of a product is labeled as January 2018, then the product can be used until the end of January 31st 2018.

45. Ato Abebe , pharmacist, has filled some prescriptions for carbimazole on one working day. On the same day a customer, epileptic patient, presented him a prescription for carbamazepine. Glancing at it, Abebe thinks it is carbimazole once again, and that is what he dispensed .which dispensing error occurred here ?

- A . picking error B. packing error **C. misreading the prescription error** D. billing error

46 . went to a drug shop and made verbal request for ampicillin and cough syrup for her 8 years old daughter with complaints of cough and poor appetite. As she did not have enough amount of money, she

wanted to purchase only ten capsules of ampicillin and one bottle of cough syrup suspension. The dispenser fulfilled her request. which dispensing error occurred here ?

A . picking error B. packing error **C. The dispenser should have asked her a prescription at least for ampicillin** D. verbal communication error

Discussion: Woizero Aster made a verbal request for a prescription drug (ampicillin) and an OTC cough syrup. The dispenser should have asked her a prescription at least for ampicillin.

Secondly, dispensing inadequate quantity of ampicillin even with prescription is irrational. Such clients should be referred to authorized prescribers.

47 . Ato Kebede went to a pharmacy with a prescription for nitroglycerin sublingual tablets. The pharmacy worker repackaged the prescribed number of tablets in paper envelopes and dispensed with appropriate instructions for use. Some other day, Ato Kebede consulted the pharmacy professional about decreasing efficacy of the drug dispensed.

which dispensing error occurred here ?

A . picking error **B. packing error** C. Misreading the prescription error D. verbal communication error

Discussion : Nitroglycerin is volatile drug. It should be packaged in tightly closed containers(bottles). The use of paper envelopes for repackaging leads to a reduced efficacy of nitroglycerin, a possible reason for the complaint of Ato Kebede.

Table 5-5 Common pharmaceutical dispensing errors

Common dispensing errors	Possible Causes
Misreading the prescription	Maybe due to a large number of prescriptions, illegible handwriting, careless attitude of dispensing staff, or a bad dispensing environment.
Errors during verbal communication	Due to sound-alike name e.g. metolazone/methazolamide
Picking error - picking the next medicine	Due to similar packing or not being on the shelf attentive or due to some distractions.
Counting error i.e. dispensing the wrong quantity of medicines	Due to interruption during counting or because of work overload/ rush hours
Billing error - entering details on the bill incorrectly. Example, name or strength of the medicine, or entering the patient's name incorrectly.	Due to distraction or inattention while billing, or having bill prepared by a newly appointed staff member who is not well acquainted with the billing system.
Packing error: mix parcels, or putting somebody else's medicine in parcel	Due to similar patient names or same total on the bill, or due to distractions while handing over the parcel.
Expiry error i.e., dispensing expired medicines	Improper attention/careless attitude while dispensing, not checking carefully. The letters or writing on the strip are not easy to read (name of medicine and potency). Strip or cut strip may accidentally be put in a box of a similar looking product.

48 . A patient presents with a prescription which orders for a drug name Da.....l (illegible handwriting) , what will be your measure ?

A. dispense daonil B. dispense dalteparin C. refuse to dispense **D. contact the prescriber**

ANS

When handwriting is illegible, the best thing to do is to contact the prescriber over the phone and confirm. Remember, you are dealing with medicines and thus, the lives of patients. So be sure of what you are dispensing.

49. which of the following is among reasons for refusal to dispense ?

- A. Essential information is missing or doubtful, and the prescriber cannot be contacted.
- B. Safety of the medicines is doubtful.
- C. The prescription does not conform to legal requirements.

D. Fake or illegal alteration of the prescription is suspected

E . All

ANS

5.4 Refusal to dispense prescriptions

The pharmacy professionals should politely refuse to dispense a prescription if:

- Essential information is missing or doubtful, and the prescriber cannot be contacted.
- Safety of the medicines is doubtful.
- The prescription does not conform to legal requirements.
- Fake or illegal alteration of the prescription is suspected
 - ❖ prescriptions calling for large quantities of potent medicines
 - ❖ prescriptions written by unfamiliar prescribers for patients unknown to the pharmacy professionals or for any other reason that is apparent, and which prohibits the pharmacy professionals from dispensing the medicines prescribed.

50. A male patient that had chlamydial infection and dyspepsia came to a pharmacy with a prescription for tetracycline capsules and an antacid (magnesium hydroxide suspension). Because the dispenser was busy, no instruction about the usage was given to the patient. After two weeks, the patient consulted his physician for no improvement of the chlamydial infection although he was taking both drugs together for the specified duration. Based on the case, which of the following statement is false

- A. Tetracycline and antacid should not be prescribed together
- B. Loss of the efficacy of tetracycline was possibly due to its interaction with magnesium hydroxide
- C. Instruction on how to take drugs is important for avoiding such type of drug interactions

D. B and C

51. which of the following is the responsibility of health professionals in pharmacovigilance ?

- A. Healthcare professionals should monitor for medication errors whilst prescribing, transcribing dispensing and administering medicines to patients.
- B. Health professionals should make physical inspections of the medicinal product to be dispensed or administered
- C. If an ADR is suspected, the patient should be informed about the suspicion of the ADR and what actions are planned
- D. Report as soon as possible

E . All

Healthcare professionals should monitor for medication errors whilst prescribing, transcribing dispensing and administering medicines to patients.

Health professionals should make physical inspections of the medicinal product to be dispensed or administered. Pharmacy professionals have an important role in the work of detecting product quality defects. Color changes, separating components, powdering, crumbling, caking, molding, change of odor, incomplete pack, suspected contamination, poor packaging/poor labeling should be acknowledged.

52. which of the following is NOT true about the responsibility of marketing authorization holders (MAH) in pharmacovigilance .

- A. pharmaceutical industry, importer, wholesaler and distributor has the prime responsibility to monitor safety of their marketed products

B. Serious ADRs, unexpected and expected, must be reported as soon as possible but no later than 60 calendar days of initial receipt of the information by the MAH.

C. Non-serious ADRs must be sent within **120 days** after he/she granted knowledge of the event.

D. For new medicines, a Periodic Safety Update Report (PSUR) should be submitted to FMHACA every 6 months the first two years after market approval and thereafter annually for three years.

- **Serious** ADRs, unexpected and expected, must be reported as soon as possible but no later than **15 calendar days of initial receipt of the information by the MAH.** Efforts must be taken to send a report that is as complete as possible.
- **Non-serious** ADRs must be sent within **90 days** after he/she granted knowledge of the event.

