Comparative study of expired and non- expired medicine

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Abstract- The purpose of this study is to examine the efficacy and safety of expired and non-expired medications. The study included 100 animals who were separated into two groups: Group A (non-expired drugs) and Group B (expired medicines). For one month, both groups received the same drug. The medications effectiveness was determined by assessing the improvement in symptoms, and its safety was determined by monitoring any adverse effects. The study finding revealed that both expired and non-expired Medications were beneficial in alleviating symptoms, with no significant difference between the two Groups. However, Group B had a somewhat greater rate of adverse events than Group A. The most Prevalent adverse events recorded in Group B were gastrointestinal disturbances, while in Group it was moderate headache to summaries, this study reveals that expired drugs can be beneficial in treating certain illness, but they should be used with caution due to the possibility of unpleasant consequences. Patients and healthcare providers must appropriately dispose of outdated prescriptions and not use them As a substitute for new medications. More research is needed to determine the long-term implications of Utilizing expired medications.

Keywords: Expiration date; Medication efficacy; Shelf life; Drug stability.

I. INTRODUCTION

The study finding revealed that both expired and non-expired medications were beneficial in alleviating symptoms, with no significant difference between the two groups. The usage of outdated pharmaceuticals is becoming a rising concern around the world. Using expired medication can result in unpleasant responses and health complications. The goal of this project is to conduct a comparison study of expired and non-expired medications to establish their efficacy, safety, and differences. Pharmaceutical products provide effective and safe remedies for a wide range of medical conditions, with the objective of improving human health and well-being. The stability and quality of the active ingredients are just two of the numerous factors that influence a drug's safety and effectiveness after the expiration date. Despite the lack of scientific data on the safety and efficacy of these treatments, patients continue to utilize them. The dissolution and disintegration approach will be used in this study to compare expired and non-expired medicines.[1,2] The use of medicine is essential for the treatment of various diseases and illnesses. However, the effectiveness and safety of medication can be affected by several factors, including the expiration date of the medicine. An expiration date is a date after which a drug may not be as potent or effective as it was when it was manufactured. As a result, there is a common belief that expired medication should be discarded, and non-expired medication should be used for treatment. However, the cost of medicine and the availability of health care services are a major concern in many parts of the world, and people may not always have access to non -expired medication. A comparative study of expired and non-expired medicine is, therefore, crucial to understand the impact of expiration on the potency and effectiveness of medication. The aim of this study is to evaluate the differences between expired and non-expired medication in terms of their pharmacological properties, safety, and efficacy.[2,4] In-process materials should be tested for their physical parameters and its quality attributes, which are later approved or rejected by the quality control department, it is depending on the results of the manufacturing process. Rejected In-process material ought to be distinguished and controlled under quarantine system, designed to prevent their user in manufacturing. Standard operating procedures should be established and followed that describe the in-process controls and tests. During the manufacturing process, certain tests are conducted where the acceptance criterion is identical to or smaller than the release requirement, (e.g., pH of solution) which may

satisfy requirements when the fest is included In the specification. After the manufacturing process Finished Product Controls (FPC) are carried out. These tests are to studybegins with the discovery of a drug molecule having therapeutic value in fighting, controlling, preventing, or curing illnesses. The creation and characterization of such molecules, known as "active pharmaceutical ingredients" (APIs), as well as their examination to provide preliminary safety and therapeutic effectiveness data, are prerequisites for drug development. Bacterial infection can cause degradation in a range of expired and unexpired drugs unfit for use. Pharmaceutical companies produce drugs and medicines to treat a variety of diseases, and they are labeled with an expiry date. The drugs are effective and safe for customers to ingest, but expired medicines are not. The expiry date printed on drugs and medicines indicates the day when the manufacturer guarantees full potency and safety of the drugs. Environmental conditions, microbial contamination, containers in which they are stored all contribute to the degradation of pharmaceuticals in three ways: physical, chemical, or microbial. Color and texture shift as a result of physical instability. Microbial proliferation leads to microbial deterioration, whereas chemical instability leads to oxidation, hydrolysis, and decarboxylation.[3]

Expired Drugs: Medication lapse is the date after which a medication probably won't be effective or suitable for use by patient. Buyers can decide on the usability of a medicine by checking its expiry date printed on the bottle or packet. Medicines which are expired can be ineffective, inadequate or even dangerous

Unexpired Drugs: Still valid or in use and effect but not terminated medicine that is not yet reached its expiration date. For the benefit of our immune system, sometimes we take antibiotic drug, which are chemicals, that go inside our body and attack the pathogenic bacteria so that it cannot live longer and multiply in our body. If the bacteria are susceptible to the antibiotic, then they stop growing and die simply.

II. AIM ANDOBJECTIVE

AIM:_Comparative Study of Expired and Non - Expired Medicines.

OBJECTIVE:

- To establish people's knowledge about expired medicines.
- To understand people's knowledge about the efficacy of medication after expiration and what side effects they may cause.
- To study their point of view on buying short expiry medicines from stores.
- To ensure the protection of patients from potentially ineffective or harmful treatment.
- The efficacy of these drugs to understand the differences between them.

III. NEED OF STUDY

Studying both expired and non-expired drugs is important for several reasons:

1. Safety and Efficacy:
   - Non-expired Drugs: Ensuring that medications are effective and safe until their expiration date is crucial. This involves stability testing, quality control, and regulatory Compliance.
   - Expired Drugs: Understanding the potential risks associated with using expired Medications are important for public safety. Degradation products can be toxic, and the Efficacy of the drug may be reduced, leading to therapeutic failure.
2. Environmental Impact:
   - Disposal of Expired Drugs: Proper disposal methods need to be developed and followed To prevent environmental contamination. Studying how drugs degrade over time helps in Formulating guidelines for safe disposal.
   - Environmental Persistence: Some drugs and their metabolites can persist in the environment, potentially causing harm to wildlife and ecosystems. Understanding these effects helps in mitigating environmental impact.
3. Economic Implications:
   - Cost of Waste: Expired drugs contribute to medical waste, leading to economic losses. Studying the stability and shelf-life extension possibilities can reduce waste andassociated costs
   - Resource Allocation: Proper management of drug inventories can save resources by reducing unnecessary disposal and restocking.
4. Regulatory and Legal Requirements:

➢ - Compliance: Regulatory bodies require comprehensive data on the stability and shelf
Life of medications to ensure public safety, Compliance with these regulations is critical for Pharmaceutical companies.

➢ - Legal Implications: There can be legal consequences for dispensing expired Medications, making it important to study and understand expiration impacts.

5. Improved Drug Formulations:

➢ - Stability Enhancements: Research can lead to improved formulations with longer shelf Lives and better stability under various conditions.

➢ - Innovations in Packaging: Understanding how drugs degrade over time can lead to Innovations in packaging that extend shelf life and maintain efficacy.

IV. PLAN OF WORK

1. Literature review

• Current Knowledge: Review existing studies on drug expiration, stability, and efficacy.

• Regulatory Guidelines: Study guidelines from FDA, EMA, and other regulatory bodies Regarding drug expiration.

2. Selection of Drugs

• Types of Drugs: Choose a variety of drugs, including over-the-counter and prescription Medications.

• Categories: Include different categories such as analgesics, proton pump inhibitors, and Chronic disease medications.

3. Sample Collection

• Non-Expired Drugs: Obtain samples within their expiration date from pharmacies.

• Expired Drugs: Collect expired samples from different sources ensuring a range of Expiration periods.

4. Laboratory Analysis

• A. Physical and Chemical Testing

• Physical Examination: Inspect for changes in color, texture, and odor.

• Chemical Analysis: Use techniques such as UV spectroscopy, HPLC (High-Performance Liquid Chromatography) and GC-MS (Gas Chromatography-Mass Spectrometry) to assess the Active ingredients and degradation products.

5. Data Analysis

• Statistical Analysis: Use statistical methods to compare the stability, efficacy, and safety
Data of expired and non-expired drugs.

• Comparison to Standards Compare results with pharmacopeia standards and guidelines.

6. Result and discussion

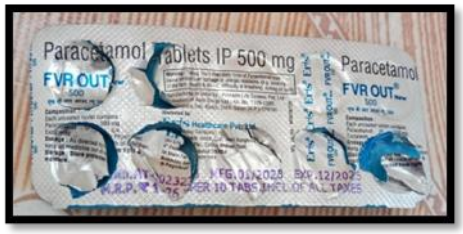
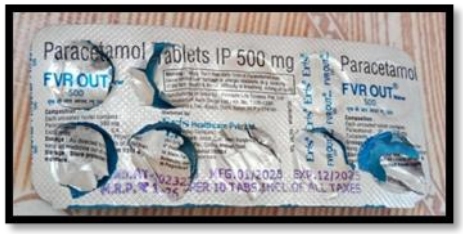
• Results Interpretation: Summarize findings on stability, efficacy, and safety.

• Risk Assessment: Evaluate the potential risks associated with using expired drugs.

• Recommendations: Provide recommendations on the use of expired drugs based on the findings.

V. MATERIALAND METHOD

1. Medicines used for study:

Sr. No.	Name of Medicine	Expired	Non- Expired
1	Paracetamol Tablet		

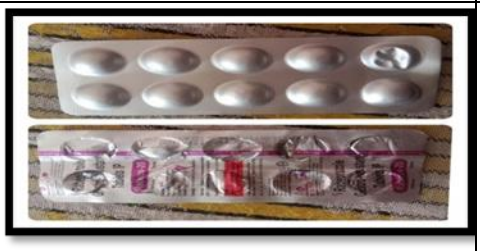
2	Cal+ vit Tablet		
3	Osraten20 Tablet		
4	Telmeros40 Tablet		
5	Rebez20 Tablets		
6	Ring Guard cream		

Table 1: Medicines used for study

2. Method use for analysis:

Physical analysis: Drugs can be checked for any discernible alterations in their Colour, texture, orodour, whether they are expired or not. Any alterations to these metrics could be an indication of the medicine's decomposition or composition.

Instrumental analysis: Both expired and non-expired medications can undergo instrumental testing to detect any changes in the active ingredients or any contaminants that may have developed as a result.

Degradation: The reagents employed will vary depending on the particular medication being examined.

1) Microbiological analysis: It is possible to check for microbial growth in both expired and non-expired medications. If the medicine has gotten contaminated over time, this test can show it. For bacterial, fungal, or other microbial growth, the medication might be checked.

2) Testing for pH: Since pH changes can have an impact on a drug's stability, both expired and non-expired medications can have their pH evaluated,

Spectrophotometric analysis: UV-VIS spectroscopy can be used to evaluate absorbance at particular wavelengths. Any alterations in a drug's absorbance could be a sign that the active ingredient has degraded.

Statistical analysis: It can be used to ascertain whether there is a significant difference between expired and non-expired medications after the data has been gathered.

VI. EVALUATION OF TABLET

Non-official Tests:

1. General appearance :Organoleptic property' Size & Shape
2. Hardness
3. Friability

Official tests:

1. Weight Variation
2. Content uniformity
3. Dissolution
4. Disintegration
5. Spectroscopy

VII. RESULT AND DISCUSSION

Non -official test for tablet

Name of tablet	Colour	Odour	Taste	PH	Shape	Texture
Paracetamol	White	Odorless	Tasteless	7.4	Boots	Smooth
Calcium and Vitamin d Tab	Blue	Odorless	Cal- Bitter	7.3	Boots	Soft
Rabiros20 Tab	Dark brown	Pungent	Tasteless	9.6	Circular	Smooth
Osarten AM Tab	Fresh White	Odorless	Pungent	5.6	Round	Soft
Telmeros 20 Tab	Whitish Yellow	Pungent	Tasteless	7.8	Round	Smooth
Micogel cream	White	Odorless	Tasteless	3.17		Smooth

Table 2:-Non official test for Medicines

Official test for tablet

1. Hardness Test of tablet(Non- Expired)

Sr no.	Name of the tablet (non -expired)	Tab 1	Tab 2	Tab 3	Average hardness (kg)
1)	Paracetamol tab	3.8	4.0	4.6	4.13
2)	Calcium and vitamin d tab	6	7	6	6.33
3)	Rabiros20 tab	9	7.5	7	7.83
4)	Telmeros 20 tab	3.4	4.4	3.2	3.66
5)	Osarten AM tab	3.4	2.6	2.3	2.76

Table3:-Hardness test of Useful Tablets

Hardness of tablet (Expired)

Table 4:-Hardness test of Expired Tablet

Sr no.	Name of the tablet (expired)	Tab 1	Tab 2	Tab 3	Average hardness of tablet (kg)
1)	Paracetamol tab	2.2	2	2.2	2.13
2)	Calcium and vitamin d tab	6	7	6	6.33
3)	Rabiros 20 tab	3.2	3.6	3.8	3.53
4)	Telmeros 20 tab	2.5	3	3.6	2.76
5)	Osarten AM tab	3.4	2.6	2.3	3.03

2. Friability Test of Tablet

Formula:-% Weight Loss = w1-w2÷w1x 100

Where, W1 = Initial Weight

W2 = Final Weight

Non- Expired tablet

Sr no.	Name of tablet	Initial weight of tab (gm)	Final wt of tab (gm)	Friablity (%)
1)	Paracetamol tab	5.850	5.810	0.68
2)	Calcium and vitamin d tab	15.080	15.010	0.46
3)	Rabiros 20 tab	0.810	0.810	0
4)	Telmeros 20 tab	2.740	2.720	0.72
5)	Osarten AM tab	2.390	2.370	0.83

Table 5:-Friability test of Useful Tablet

Expired tablet

Sr no.	Name of tablet	Initial weight (gm)	Finalweight (gm)	Friablity (%)
1)	Paracetamol tab	5.650	5.570	1.41
2)	Calcium and vitamin d	14.740	14.460	1.89
3)	Rabiros 20	1.590	1.560	1.88
4)	Telmeros 20 tab	1.910	1.910	0
5)	OsartenAM tab	1.740	1.670	4.02

Table 6:- Friability test of Expired Tablet

2. Weight variation test of table

Weight Variation (IW-AW)/AW X 100%

Non-Expired tablet

Sr.No.	% deviation				
	Paracetamol	Cal +vit d	Rabiros20	Telmeros 20	Osarten
tab1	2.09	0.79	2.56	-9.44	3.62
tab2	2.09	-0.53	-10.2	-9.44	-1.55
tab3	3.76	2.12	2.56	-5.51	8.8
tab4	7.11	2.12	2.56	-9.44	3.62
tab5	5.43	-1.9	2.56	-5.51	13.9
tab6	-4.6	-0.53	-10.2	-1.57	8.8
tab7	7.11	0.79	-10.2	-1.57	8.8
tab8	5.43	-1.85	2.56	-9.44	13.9
tab9	5.43	-0.53	-10.2	-5.51	13.9
tab10	0.5	0.13	2.56	-9.44	8.8
tab11	-2.92	0.79	2.56	-9.44	8.8
tab12	2.09	-0.53	2.56	-9.44	8.8
tab13	3.76	0.3	-10.2	-9.44	13.98
tab14	5.43	0.79	-10.2	-5.51	3.62
tab15	0.5	-0.53	-10.2	-5.51	8.8
tab16	0.5	0.13	2.56	-1.57	3.62
tab17	2.09	-1.19	-10.2	-5.51	13.9
tab18	3.76	-0.53	2.56	-9.44	13.9
tab19	2.09	0.13	-10.2	-9.44	13.9
tab20	3.76	0.79	2.56	-9.44	8.8

Table7:- Weight Variation test of Useful Tablet

Expired tablet

No. of Tablet	% deviation				
	Paracetamol	Cal+vit d	Rabiros20	Telmeros20	Osarten AM
Tab1	-0.81	-0.169	-8.57	0	-2.29
Tab2	-0.99	-0.84	-14.28	-5.26	-8.04
tab3	-0.81	-0.169	-8.57	-5.26	3.44
tab4	-2.61	-0.84	-14.25	0	9.19
tab5	0.99	0.50	-8.57	0	9.19
tab6	6.40	-0.169	-2.85	0	9.19
tab7	0.81	-0.84	-8.57	-5.26	-2.29
tab8	-2.61	-0.169	-14.28	0-5.26	3.44
tab9	-0.81	0.50	-8.57	0	9.19
tab10	-0.99	1.80	-2.85	0	3.44
tab11	-0.81	0.50	-14.28	0	-2.29
tab12	-2.61	1.18	-2.85	0	-8.04

tab13	-0.99	-0.169	-8.57	-5.26	3.44
tab14	-0.81	-0.84	-14.28	-5.26	9.19
tab15	0.90	-0.169	-8.57	0	-2.29
tab16	-0.81	0.50	-8.57	0	-8.04
tab17	0.90	1.18	-8.57	0	-2.29
tab18	0.99	-0.169	-14.28	-5.26	3.44
tab19	6.40	0.50	-8.57	-5.26	9.19
tab20	0.90	-0.84	-8.57	0	-2.29

Table 8:-Weight Variation Test of Expired Tablet

3. Absorbance of tablet using UV Spectrometer

Non – expired tablet

Sr No.	Name of tablet	Wavelength (nm)	Solvent used	Blank reading	Absorbance (nm)	% Drug content
1)	Paracetamol tab	257	Ethanol	0.003	0.999	95.74
2)	Calcium and vitamin d tab	275	Ethanol	0.001	0.1	98.03
3)	Rabiros 20 tab	283	Ethanol	0.003	0.78	97.37
4)	Telmeros 20 tab	296	Diethyl ether	0.007	0.69	96.36
5)	Osarten AM tab	205	Ethanol	0.002	0.94	94.70

Table 9:-Absorbance of Useful Tablet on UV

Expired tablet

4. Disintegration test for tablet

Sr no.	Name of tablet	Wavelength (nm)	Solvent used	Blank reading	Absorbance (nm)	% Drug content
1)	Paracetamol tab	257	Ethanol	0.003	0.45	81.81
2)	Calcium and vitamin d tab	275	Ethanol	0.001	0.7	86.41
3)	Rabiros 20 tab	283	Ethanol	0.003	0.30	75
4)	Telmeros 20 tab	296	Diethyl ether	0.007	0.49	71.01
5)	Osarten AM tab	205	Ethanol	0.002	0.99	70.71

Non - Expired tablet : Table 10:-Absorbance of Expired Tablet on UV

Sr no.	Name of tablet	Disintegration time (min)	Solvent used
1)	Paracetamol tab	1.56	0.1N HCL
2)	Calcium and vitamin d tab	2	0.1N HCL
3)	Rabiros 20 tab	1.5	Phophate buffer
4)	Telmeros 20 tab	45	Phosphate buffer
5)	Osarten AM tab	3	0.1N HCL

Table11:-Disintegration test of Non Expired Tablet

Expired tablet

Sr no.	Name of tablet	Disintegration time (min)	Solvent used
1)	Paracetamol tab	1.56	0.1N HCL
2)	Calcium and vitamin d tab	2.2	0.1N HCL
3)	Rabiros 20 tab	1.57	Phophate buffer
4)	Telmeros 20 tab	37.5	Phosphate buffer
5)	Osarten AM tab	1	0.1N HCL

Table12:- Disintegration test of Expired Tablets

5. Dissolution test for tablets

Non-expired

Sr no.	name of drug	solvent used	blank reading	absorbance of drug at time (in min)				
				5	10	15	30	45
1	Paracetamol tab	0.1 N HCL	0.001	0.304	0.311	0.515	1.793	1.01
2	Calvit d tab	0.1N HCL	0.024	0.055	0.066	0.067	0.08	0.102
3	Rabiros 20 tab	phosphate buffer	0.014	0.028	0.142	0.622	0.71	0.801

4	Telmeros 20 tab	phosphate buffer	0.001		0.118	0.254	0.256	0.454	0.716
5	Osarten AM tab	0.1 N HCL	0.003		0.255	0.372	0.428	0.464	1.0

Table13:-Dissolution test of Useful Tablets

Expired

Sr. no.	name of drug	solvent used	blank reading		absorbance of drug at time (in min)				
					5	10	15	30	45
1	Paracetamol tab	0.1 N HCL	0.000		0.19	0.25	0.33	0.49	0.55
2	CalVit d tab	0.1N HCL	0.002		0.05	0.06	0.67	0.71	0.81
3	Rabiros 20 tab	phosphate buffer	0.004		0.002	0.066	0.010	0.015	0.040
4	Telmeros 20 tab	phosphate buffer	0.000		0.018	0.020	0.030	0.046	0.069
5	Osarten AM tab	0.1 N HCL	0.001		0.201	1.210	1.33	1.39	1.44

Table14:-Dissolution test of Expired Tablet

Evaluation Test of Cream

Non -Expired

Sr no.	Test	Results
1)	Colour	White
2)	Odour	Slight
3)	pH	3.17
4)	Spread ability (diameter in cm)	5.5

Table15:- basic test of Useful cream

Expired

Sr no.	Test	Results
1)	Colour	Yellowish White
2)	Odour	Pungent
3)	pH	5.82
4)	Spreadablity(diameter in cm)	4.0

Table16:-Basic test of Expired Cream

VIII. SUMMARY AND CONCLUSION

Summary

Expired medication may pose a safety risk to patients due to the potential degradation of active Ingredients, which can cause adverse effects. Additionally, the presence of harmful substances in Expired medication, such as bacteria or fungi, can also cause safety concerns. In contrast, non-Expired medication is expected to be safer due to its chemical composition and quality control During manufacturing. Therefore, a comparative study of expired and non-expired medicine should also evaluate the safety of these drugsA significant amount of unused medications were present at impatient departments of the health Facilities. The study also identified that there was a significant amount of medication wastage at The pharmacy stores of health facilities Health facilities need to monitor health professionals Strictly follow national and international treatment guidelines and monitor the rational use of medications. There should also be a reverse logistics system in the pharmaceuticals supply system Of the country for the proper management of unused medications at the health facilities.

Conclusion

We had observed in the result that the expired drug has provide insufficient satisfication than that of Non Expired drug at the normal dose We Used a variety of sources, including online databases and medical journals, to gather the data for This investigation. We chose different form of expired as well as non expired medicine (Paracetamol tab Cal+vit tab, Rabiros20, Telmeros40, Osarten 20 Cream Ring Guard cream), and we Evaluated the effectiveness and safety of expired and non-expired versions of each drug by performing official and non official test for tablet and basic evaluation test for cream Our findings suggest that non-expired medicine may not be as effective as expired medicine. Some Medications lose some of their strength over time,

which might make them disorders. Furthermore, using outdated medication may be dangerous because it may include compounds that have undergone degradation or have undergone other changes that could lead unfavourable side effects Drug expiration is the date after which a drug might not be suitable for use as intended. Expired drugs have loss of efficacy, safety, potency and formation of harmful products.

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