

## REVIEW ARTICLE

## A GLIMPSE ON EXPIRY DATE OF PHARMACEUTICAL DOSAGE FORMS

A. PREM SWAROOP<sup>1\*</sup> and D.VARUN<sup>2</sup>

Department of Pharmaceutics, M.E.S College of Pharmacy, Bangalore, Karnataka, INDIA

Department of Pharmaceutics, Hindu College of Pharmacy, Guntur, AP, INDIA

## ABSTRACT

Drug expiration dates are meant to indicate the date at which the drug's potency begins to diminish. The drug does not usually become harmful after the expiration date listed on the box or bottle, but rapid degradation of certain drugs, such as insulin or liquid antibiotics, is possible. Any drug that contains an organic compound is also susceptible to decay. However, most drugs in pill form remain effective beyond the expiration date. In determining an expiry date, a range of characteristics of the product are studied over time. One important characteristic is the chemical stability of the active ingredient. Temperature has a pronounced effect on the rate of degradation of the active ingredient. As the rate of decomposition usually doubles for every 10°C rise in temperature, it is important to comply with the storage conditions specified on the container. The expiry date may be set as a fixed time after manufacture, dispensing or opening of the manufacturer's container. The expiration date does not indicate that a drug will be ineffective or harmful after that date, but rather that said drug is still good on the manufacturer's chosen date; and has little to do with scientific testing. The FDA has little control over the chosen dates. The purpose of this expiration date is to inform consumers about the potency and effectiveness of the drug at the time of purchase. As part of the CGMP regulations, the FDA requires that drug products bear an expiration date determined by appropriate stability testing (21 CFR 211.137 and 211.166). When a firm changes the packaging of a drug product (e.g., from a bottle to unit-dose), stability testing must be performed on the product in its new packaging, and expiration dating must reflect the results of the new stability testing.

**KEYWORDS:** *Stability, Expiration date, FDA, Packaging, Active ingredient, Potency.*

## INTRODUCTION

“Expiration Date” The expiration date identifies the time during which the prescription drug may be expected to meet the requirements of the Pharmacopeial monograph, provided it is kept under the prescribed storage conditions. The expiration date of pharmaceuticals specifies the date that manufacturer guarantees the full potency and safety of a drug. Most medications are potent and safe after the expiration date. Joel Davis, a former FDA

expiration-date compliance chief, said that with a handful of exceptions - notably nitroglycerin, insulin and some liquid antibiotics - most expired drugs are probably effective. Some companies use induction sealing and vacuum/oxygen-barrier pouches to assist in the extension of the shelf life of their products where oxygen causes the loss. Some degradation factors can be controlled by use of appropriate packaging. The "expiry date" or "expiration date" does not indicate a point when a medication loses potency and is no longer effective or becomes harmful. It is

simply a date "required by law" generally set at two to three years after the "manufacture date" of new medicines, usually embossed or printed on the original packaging. For prescriptions filled by the pharmacist, it is usually dated a year after being dispensed from the original container. Studies have been done to test the stability of drugs beyond the expiration date. Stored under reasonable conditions, many drugs retain 90% of their potency for at least five years after the label's expiration date; sometimes, longer. The FDA studied more than 100 drugs. It found that 90 percent of both prescription and over-the-counter medicines were perfectly good to use even after the expiration date. The exceptions are insulin, liquid antibiotics and nitroglycerin. Storing the medications in a cool place, such as a refrigerator, will help extend potency for many years.

#### **EXPIRED MEDICATIONS: WILL THEY STILL WORK?**

We need to take some medication, be it over-the-counter or a prescription, and you find that it has expired. It is tempting to take the gamble that it may still work. This should be avoided. These are chemicals that we trust to heal us and yet we are quicker to take expired medication for a condition rather than eat old pizza to stave off the munchies. Medications are not immortal. Due to their very nature, they react to the environment around them and breakdown over a period of time. That gel cap may look like a defensive shield for the precious contents inside, but it's no more than a water-soluble container, not a titanium ship hull. Always keep track of the location of all medications in the home as well as their expiration dates and dispose of them properly. The most effective way to dispose of medications is by flushing them down the toilet. You may feel that you are destroying evidence, but it's the best protection if you have pets or children who on occasion get into the garbage. Expired medications at best will do nothing. Do not even count on it to work

as it should. Some medications run the risk of becoming toxic after their expiration date as it starts to breakdown. If there is an odor coming from uncoated pills, take the hint and get rid of it. Aspirin, luckily, may smell like vinegar to warn you, but not many medications have clues like that. Gel caps may stick together, pills break apart or change color and ointments may separate. Always look at the expiration dates. The dangers far outweigh the benefits in these situations. Go through the medicine cabinet every six months and get rid of any expired medications. It will be a relief to know what you actually have on hand in case of an emergency.

#### **DRUG EXPIRATION DATES: HOW ACCURATE ARE THEY?**

Since 1979, the Food and Drug Administration (FDA) has required pharmaceutical manufacturers to provide expiration dates on all their products. For the majority of drugs sold in the United States, these dates range from 12 to 60 months from the date they are manufactured. Expiration dates are basically guidelines. Your medications may expire before the expiration date if improperly stored, or they may last well beyond their expiration date, as some studies have shown. While most drugs don't become dangerous when expired, they can still pose a threat to your health. According to Robbe Lyon, Division Director, Division of Product Quality Research, Center for Drug Evaluation and Research, Food and Drug Administration (FDA), Drugs lose their potency beyond their expiration date, and therefore their effectiveness and their ability to dissolve can be affected. For patients who rely on medications to stay alive, like heart medications, expired drugs can be dangerous because they may not be getting the full effectiveness of the drug. Pharmaceutical manufacturers determine a drug's shelf life, or expiration date, through stability testing. This type of testing ensures that a drug's potency and

integrity are intact over a specific amount of time, which becomes the expiration date. Several factors can influence these dates, including type of active ingredients, storage conditions, preservatives, and the kind of container the drug is stored. It is important to note that the manufacturers expiration dates apply only to the original packaging of the drug, and that once opened these dates no longer apply. Each state has different requirements, but all pharmacists must give the consumer some sort of expiration date, sometimes called a beyond use date. This date typically ranges six to 12 months from the date the drug is dispensed, but may be shorter depending on the type of medication or a manufacturers expiration date.

### **Studying Shelf Life**

The accuracy of drug expiration dates has been the subject of much discussion. Since 1987, the FDA has been administering a program called Shelf Life Extension Program (SLEP) for the military. The program tests military stockpiles of drugs to determine stability after the expiration dates have passed. According to Mr. Lyon, Of 119 drug products tested, all except for four or five were stable beyond their original expiration dates. Some were extended for as long as ten years beyond their expiration dates. What does this mean for you? Mr. Lyon, answers, Consumers need to follow expiration dates or beyond use dates very carefully. The impact of the SLEP program was that drugs stored in their original containers in ideal storage conditions can last for long periods of time. But once exposed to the environment, there is no way to predict their effectiveness. Unfortunately, once you bring your medications home from the pharmacy, they are no longer being stored under such controlled conditions.

### **Variability**

Drugs vary widely in terms of dosage, form, and stability. Some drugs, like pediatric liquid antibiotics, insulin, and certain injectables will expire more quickly than medications in other forms, such as tablets. So, remember, your medications will work only as well as they are handled. Taking them safely means storing them properly, reading all specific instructions carefully, and not using them after the recommended amount of time or expiration date.

### **DO DRUGS REALLY EXPIRE? ISN'T THIS JUST A MARKETING PLOY TO SELL MORE DRUGS?**

While it may be true that expiry dates help to sell more drugs for manufacturers and pharmacies, they also serve an important purpose. Countries like Canada and the United States mandate that expiry dates are included on all medications. At the time of the medication expiry date, the drug must be at least 90% of the original potency under proper storage conditions. So if, for example, the expiry date on your Tylenol is October 31, 2007, your medication should be at least 90% as strong as the dose indicates on the label on this date. Using a medication after the expiry date could mean that your medication may be not as strong (do NOT try to increase the dose to make up for this), or it may change in its composition (this is very rare, but very dangerous as it could lead to serious side effects). Where you keep your medication is also an important factor and will alter the expiry of the drug. Improper storage can shorten the expiry date of the medication. For most medications, storing in a cool, dry, dark place (nightstand drawer, bedroom closet) will maximize the lifespan of your medication. Some medications can probably be used after the expiry date, but may not support by the manufacturer if anything goes wrong. Medications where the dose does not need to be 100% of what is

quoted on the label (pain relievers, laxatives) can probably be safely used for a few months after the expiry date if stored properly. But, given that these medications are often inexpensive, and easily obtained, it is recommended that you purchase a new product. However, with critical medications such as antibiotics, seizure medications, heart medications, the expiry date should definitely be heeded. Note that eye drops and eye ointments should not be used beyond 4 weeks after opening, regardless of the expiry date. These products can become contaminated and lead to eye infections, so even the label expiry date is often too long.

#### ARE DRUGS HARMFUL AFTER THEIR EXPIRY DATE?

- First, the expiration date, required by law in the United States, beginning in 1979, specifies only the date the manufacturer guarantees the full potency and safety of the drug -- it does not mean how long the drug is actually good or safe to use.
- Second, medical authorities uniformly say it is safe to take drugs past their expiration date -- no matter how expired the drugs purportedly are. Except for possibly the rarest of exceptions, you won't get hurt and you certainly won't get killed. A contested example of a rare exception is a case of renal tubular damage purportedly caused by expired tetracycline (reported by G. W. Frimpter and colleagues in JAMA, 1963). This outcome was supposedly caused by a chemical transformation of the active ingredient.
- Third, studies show that expired drugs may lose some of their potency over time, from as little as 5% or less to 50% or more (though usually much less than the latter). Even 10 years after the expiration date, most drugs have a good deal of their original potency. The testing, conducted by

the US Food and Drug Administration (FDA), ultimately covered more than 100 drugs, prescription and over-the-counter. The results showed that about 90% of them were safe and effective as far as 15 years past their original expiration date.

#### EXPIRATION DATE DEPENDS ON:

**Degradation** -The expiry date depends on specified storage conditions. Not all drugs have the same rate of decomposition, thus expiry dates will differ. Amoxicillin suspension has an expiry date of 14 days when stored at room temperature (25°C). Trimethoprim / sulphamethoxazole combination tablets have a shelf-life of 5 years when stored below 30°C. Degradation processes include hydrolysis, oxidation and degradation by light. This is because of the chemistry of many of the functional groups in drug molecules and the ubiquitous presence of water and oxygen. Even when factors such as water, oxygen and light have been controlled, degradation will still occur, but at a reduced rate.

**Hydrolysis**- The rate of hydrolysis is affected by access to water and is prevented or lowered by reducing exposure to water. If a drug must be formulated in water, the solution is often buffered to a pH where the rate of hydrolysis is minimal. Substances which are particularly susceptible to hydrolysis are often packed in individual dose units e.g. soluble aspirin tablets are individually encased in foil. Tablets, capsules, unreconstituted syrups and injections have a shelf-life at room temperature of at least two years. However, once reconstituted, the syrups have a shelf-life of 14 days at room temperature, and the injections should be used immediately. The reconstituted syrup has a longer shelf-life than the injection because the syrup is a suspension of amoxicillin with the pH buffered to minimize hydrolysis. Injectable amoxicillin is

hydrolyzed rapidly as it is a solution with no buffering agent.

**Oxidation and photo degradation-** Many drugs will react with atmospheric oxygen, so oxidation is a prime cause of degradation. A well known oxidation is the conversion of wine into vinegar; the ethanol is oxidized to acetic acid. Photochemical degradation is usually discussed with oxidation as both processes occur mostly via free radical or free radical-like pathways. Oxidation is reduced by the exclusion of oxygen. If a drug which is susceptible to oxidation is present in aqueous solution at 1 mg/mL in a 1 mL ampoule, there would be sufficient oxygen in the head-space above the liquid and dissolved in the water to completely decompose the drug. Therefore, oxygen is usually removed from the solution and the head-space by flushing with an inert gas before the ampoule is sealed. Control of the pH and protection from light may reduce the rate of oxidation of injectable solutions. If appropriate, antioxidants or chelating agents may also be used. The plastic bubble component of the chlorpromazine packaging is also colored to provide protection from light. The absorption of light energy may result in photo degradation. When light is absorbed by a molecule, it is either re-emitted or transformed into physical or chemical energy. Physical energy is usually lost as heat. Chemical energy may be sufficient to cause either cleavage or rearrangement of the molecular bonds. Protection from light is achieved by packaging the products in amber glass bottles or by using coloured film for blister packed products.

**Formulation-** The formulation of a drug may have a pronounced effect on the shelf-life because of the effect of excipients used in manufacturing. Some drugs may be quite stable in the pure form, but may undergo degradation rapidly when combined with certain excipients. Excipients affect the stability

of drugs by acting as surface catalysts, altering the pH of the moisture layer and/or undergoing direct chemical reactions with the drug. Occasionally, two drugs which are to be included in one dose form interact. If recognized, the problem can be partially overcome by manufacturing a layered tablet, which minimizes the contact of one drug with the other. Some cold and flu relief products are presented as layered tablets.

**Storage and transport** - Stability is a significant issue, and the importance of temperature on the chemical stability of a pharmaceutical product cannot be over-emphasized. The rate of chemical reactions doubles for every 10°C rise in temperature. Reconstituted amoxicillin syrup is stable for 14 days if stored at room temperature (25°C) and even longer if refrigerated. If, however, it is stored out of the refrigerator on very hot days, its stability may be reduced to a week or less. For some drugs, e.g. glyceryl trinitrate, the loss of potency on storage is due not only to intrinsic instability, but also to adsorption onto and absorption into containers and other packaging materials. Products which are to be stored in the refrigerator, e.g. vaccines and insulin, should be transported in refrigerated containers or vehicles. Although not a stability problem as such, the efficacy of some transdermal products such as oestradiol patches may be reduced in humid climates because of the effect of heat and humidity on the adhesive.

#### HOW DO PHARMACEUTICAL COMPANIES ARRIVE AT EXPIRY DATES FOR MEDICINES?

Most of the drugs used in modern medicine are organic molecules, which have, apart from their pharmacological properties, diverse physical and chemical properties. The utility of a drug depends on the availability of the active molecule in blood

circulation for curing or controlling the disease. Due to various factors including the structure of the molecule, the formulation the packing and environmental factors these molecules undergo decomposition and degradation over time. To determine the period over which the degradation will lead to reduction in the availability of the drug to levels below what is required, studies are conducted under what are called accelerated stability tests. These tests simulate the long term effects of these factors on the stability of the active drug and the formulation in acute experiments lasting up to 45 days at temperatures of 45 degrees or more and humidity of 70 per cent or more. From the correlative data available, it is possible to predict the stability of the drug over long periods of even up to five years.

#### **EXPIRATION DATING AND STABILITY TESTING OF SOLID ORAL DOSAGE FORM- GUIDANCE FOR INDUSTRY:**

As part of the CGMP regulations, the FDA requires that drug products bear an expiration date determined by appropriate stability testing (21 CFR 211.137 and 211.166). The stability of drug products needs to be evaluated over time in the same container-closure system in which the drug product is marketed. In some cases, accelerated stability studies can be used to support tentative expiration dates in the event that full shelf life studies are not available.

- When a firm changes the packaging of a drug product (e.g., from a bottle to unit-dose), stability testing must be performed on the product in its new packaging, and expiration dating must reflect the results of the new stability testing.
- The firm sets an expiration date for tablets and capsule drug products packaged in unit-dose packaging based on the following: (1) the expiration period does not exceed 75 percent of the expiration dating period of the smallest version (usually the least stable) of the previously accepted product package and (2) the expiration period for the unit-dose container does not exceed 18 months
- The firm maintains appropriate stability data that support the expiration dating period used on the smallest version of the previously accepted product package.
- The solid oral dosage form product put into unit-dose packaging is manufactured and formulated in the same manner as the product put into the previously accepted packaging.
- The unit-dose packaging complies with either the Class A or Class B standard described in USP 23, under "Single Unit Containers and Unit-Dose Containers for Capsules and Tablets."
- The firm monitors the long-term stability of each marketed lot of the unit-dose products throughout the expiration dating period for all appropriate specifications, including the strength of active ingredients, by testing each lot at least once every three months. The firm performs the initial (time-zero) testing on a sample that has been packaged in unit-dose packaging for the purpose of evaluating the effect of heat sealing on the product. Once data to support the expiration dating period of up to 18 months have been generated using appropriate stability testing on at least three lots, the firm may discontinue testing every marketed lot in unit-dose packaging.
- If any of the testing, examinations, or investigations performed by the firm reveal that a product may not meet appropriate specifications prior to the expiration date assigned to the product, the firm will reevaluate the expiration dating period for the product. If, based on the reevaluation, the firm determines that a shortened expiration dating period is

appropriate, it will use the shortened period for subsequent marketed lots of the same product.

- The firm conducts a prompt recall of any lot that falls outside of appropriate specifications.

#### **FDA RULES, EXEMPTIONS AND TIPS:**

- **FDA Expiration Date Rules**

1. The FDA has the power to regulate drug expiration dates. The Food and Drug Administration (FDA) regulates the expiration dates on all medical drugs.
2. The Federal Food, Drug, and Cosmetic Act give FDA the power to regulate drugs.
3. The laws regulating expiration dates and other aspects of medical drugs protect consumers from ineffective drugs.
4. The FDA mandates that all drug companies test the expiration process of their drugs.
5. A closed-container system is used by these companies to study how the drug ages. Scientists observe the rate at which the drug remains chemically potent. The closed-container environment must mimic the containers the drugs are bought and sold in. The tests also mimic the ideal storage areas the drug should be placed in, usually a cool, dry area.
6. Drug expiration dates are meant to indicate the date at which the drug's potency begins to diminish.
7. The drug does not usually become harmful after the expiration date listed on the box or bottle, but rapid degradation of certain drugs, such as insulin or liquid antibiotics, is possible.
8. Any drug that contains an organic compound is also susceptible to decay. However, most drugs in pill form remain effective beyond the expiration date.

9. The purpose of this expiration date is to inform consumers about the potency and effectiveness of the drug at the time of purchase.

- **FDA Exemptions**

1. The FDA grants some exemptions for certain drugs. Any drug that uses a company's previous stock of tested chemicals can accelerate the testing process.
2. This saves the company time and money. At one point the FDA gave an exemption to drug companies that had to reduce the amount of iron in their medications.
3. The iron in the drugs needed to be reduced, but in order to minimize manufacturer burdens the FDA allowed drug companies to skip shelf-life testing.

- **FDA Tips**

1. Some expired drugs may become discolored or become powdery after a certain amount of time and should be discarded.
2. Even if it is relatively safe to ingest some medications after the expiration, the FDA and doctors do inform consumers about the dangers of ingesting some expired drugs.
3. Expired drugs that are emitting an odor should be thrown out.

#### **SOME PHYSICIANS FEEL COMFORTABLE DOUBLING THE TIME OF USE, FROM MANUFACTURE TO EXPIRATION DATE:**

In impoverished areas, where the choice is to treat with "expired" medications or NO treatment, the choice is a 'no-brainer.' But if there is a choice, where potency is further brought to question because of weather and storage and cost not a problem, there are certain conditions where 100% absolute certainty of

potency is preferable - for heart conditions, strokes, TIAs, and life-threatening infections. Aspirin potency may not be as important for the simple ache or headache as it would be in a TIA, stroke prevention or heart conditions. Antibiotic potency might not be as critical in the empiric treatment for suspected sinus infections as they might be for respiratory infections in the elderly and lung-compromised patients. So, when the urgency of clinical situation dictates, or when the conditions of storage are of concern, together with length of time beyond expiry date - until technology can gadget up some time-and-cost-effective way of determining drug potency - for both over-the-counter and prescription pharmaceuticals, opt for the new bottle or the new prescription.

#### STABILITY OF SIX PHARMACEUTICALS POST EXPIRY DATE AFTER EXTENDED ANTARCTIC STORAGE AND TRANSPORTATION:

The time spans involved in Antarctic logistics with regard to medical supplies often means that

#### Results:

Item	Time post expiry date	% remaining
Epinephrine (1mg/ml)	6 months	85.47
Nalbuphine HCL	12 months	100.69
Amoxicillin (500mg)	4 months	104.95
Aspirin Tablet (300 mg)	11 months	103.42
Aspirin Tablet (300 mg)	31 months	94.15
Penicillin VK (250mg)	3 months	101.31
Penicillin VK (250mg)	26 months	101.2

#### Discussion:

With the exception of epinephrine (1mg/mL), which did show unacceptable loss of efficacy, all drugs tested were stable beyond their

drugs that have exceeded their stated shelf life may have to be used due to necessity. A previous pilot study on six drugs which were returned to the Pharmacy Department after 12 months use in the Antarctic (including transport to and from the research station) indicated acceptable levels of efficacy post expiry date. Often the shelf life of drugs is insufficient to cover the period required for research trips, so necessitating extra shipments of drug supplies. We wanted to determine potential loss of drug efficacy when the shelf life is exceeded by 1 week - 31 months under these conditions. Results may have an impact on future requirements for extra drug supplies to be transported to research stations.

#### Methods:

Drugs returned to the Pharmacy Department were tested against new batches of drugs. Six samples of each returned batch were assayed using stability-indicating HPLC methods.

stated shelf-life. Further testing will be performed to verify these findings. This study only considers pharmacological efficacy and does not look at other possible causes of drug expiry.

## PREVENTING MEDICATION ERRORS: THE IMPORTANCE OF CLEAR EXPIRATION DATES

To assure that a drug meets standards of identity, strength, quality, and purity before use, the US Code of Federal Regulations (CFR) (Title 21, Part 211.137) sets forth the conditions under which an expiration date must be listed on drug product labels. With few exceptions, companies must list an expiration date on the immediate container and any outer packaging if the date is not legible through the outer packaging. When single-dose containers are packed in individual cartons, the expiration date may appear on the carton instead of the immediate container. Unfortunately, the CFR does not specify how expiration dates must be expressed. Thus, confusion sometimes occurs. For example, one pharmaceutical company listed "JN05" as the expiration date on a suppository package label; but does "JN" mean "January" or "June"? Another company used an atypical abbreviation for April, "AL," and produced a code which read "AL 05," meaning "April 2005." Yet another company's poliovirus vaccine (inactivated) listed an expiration date of "06 MAR 04." Practitioners became confused, however, as to whether it meant the drug expired on March 6, 2004, or March 4, 2006. In the last case, such problems did not arise until 2001. For example, when "99" appeared with "05," it was clear that the year of expiration was 1999. Before 2001, the year could not be mistaken as a day; now, the numbers used for the day and year may overlap until the year 2032. A medication error has occasionally resulted from a misinterpreted expiration date. In one instance, a night nurse thought that vials of magnesium sulfate had expired. The expiration date was listed as "1-06," but the product lot number, 2002, appeared right before the expiration date. Not knowing that "2002" was a lot number, the nurse thought the drug expired on 1/06/02. Treatment was delayed while

the nurse attempted to obtain a new vial. Similar problems may occur with OTC products. Under the CFR, expiration dates for OTC products are not enforced if their labeling does not bear dosage limitations and if they are stable for at least 3 years. When they do appear, expiration dates may be difficult to decipher. For example, one company's packaging of one of its liquid nutritional supplements (a medical food supplement) did not list an expiration date, but rather, used a 4-digit code for the month and year of production (i.e., "0504" for "May 2004"). This had been misinterpreted as an expiration date. Although not explained in the packaging, the user was supposed to add 270 days to the production date to determine the expiration date. In the 2005 US Pharmacopeia (USP)-National Formulary General Notices (pg 11), expiration dating is addressed in a way that might facilitate the FDA's ability to clarify the above ambiguity. Under the section Expiration Date and Beyond-Use Date, it states: "The label of an official drug product or nutritional or dietary supplement product shall bear an expiration date. All articles shall display the expiration date so that it can be read by an ordinary individual under customary conditions of purchase and use. The expiration date shall be prominently displayed in high contrast to the background or be sharply embossed and easily understood (eg? EXP 6/89,? Exp June 89,? or? Expires 6/89)." The Consumer Healthcare Products Association has also published "Voluntary Codes and Guidelines of the OTC Medicines Industry." The guidelines offer specific procedures related to the display, location, and legibility of expiration dates; expiration statements that are understandable to consumers (eg, "Exp 6/99," "Expires 6/99"); the avoidance of packaging features that might interfere with their legibility (eg, end seals on shrink-wraps); and emerging technologies for the application of expiration dating (eg, improved debossing techniques, advances in ink printing). Clearly,

standards are needed for expressing dates in a uniform sequence that does not confuse the practitioner or the patient.

## CONCLUSION

Medications are not immortal. Due to their very nature, they react to the environment around them and breakdown over a period of time. According to the FDA drugs “expire” on the date they’re projected to have lost 10 percent of their potency, which means they are still 90% effective, although the outdated drug is not as effective as the “fresh” drug. Factors that will shorten the lifespan of a drug are moisture, increased temperature, manufacturing impurities, and, for some drugs, light, so storing your medicines correctly has a big effect on the long – livety of your medications. Drugs such as Phenobarbital, dilantin (for epilepsy), lidocaine (local anesthetic) and theophylline (asthma drug), lose potency fairly quickly and aren’t as effective once they’ve expired. Eye & ear drops should be discarded 2 weeks after they are opened, regardless of expiry dates as they lose their potency very quickly. Never use a medication (expired or not) that has changed color or consistency. As tetracycline (a commonly used antibiotic) breaks down it forms epitetracycline, which is known to cause problems. Store all your oil based medications (especially Vit E & Omega 3’s) in a cool, dark place. Preferably a fridge, as rancid Vit E oil (including foods containing Vit E such as wheat germ) is highly toxic. Generally speaking most over-the-counter household medications are still safe if stored correctly, but may not be as effective as time increases. Liquid drugs such as solutions and suspensions are generally not as stable as solid forms of medicine. Solution drugs such as injections, which have become cloudy or discolored, should not be used. Always take note of the manufactures storage recommendations. Always keep track of the location

of all medications in the home as well as their expiration dates and dispose of them properly. Specific instructions should always be followed. Your pharmacist may also give you additional storage instructions in the form of a label on the bottle or on a handout. Remember, your medications will work only as well as they are handled. Taking them safely means storing them properly by reading all specific instructions carefully. Both doctors and pharmacists should clearly explain the need and importance of Expiry date to every patient.

## REFERENCES

1. [www.askyourpharmacist.ca/medication\\_expiry\\_dates](http://www.askyourpharmacist.ca/medication_expiry_dates).
2. Haderler F. Should expiration dates are required on patients' prescription labels? *Am Pharm*. 1986 Aug; NS26 (8):30–35.
3. Brown JL, Brown NP. Pharmaceutical expiration dating advice given by retail pharmacists. *J Am Board Fam Pract*. 1991 Nov–Dec; 4(6):407–410.
4. Cortlandt Forum. July2005. Consultations. Susan Kashaf, MD. *medLettDrugsTher*.2002; 44:93-94 Harvard Medical School: Family Health Guide.
5. U.S. Food and Drug Administration: Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron
6. FDA: Expiration Dating and Stability Testing for Human Drug Products
7. Johns Hopkins: Drug Expiration Dates.
8. <http://www.vhpharmsci.com/vhformulary/Policies/5.6-Expiry-dates-of-sterile-pharmaceuticals>.
9. [http://www.scholarshipsinindia.com/answer/expiry\\_date\\_in\\_medicines](http://www.scholarshipsinindia.com/answer/expiry_date_in_medicines).
10. Altschuler, R. (2002, September 9). Do medications really expire?

11. American Medical Association. (2008, February). Report 1 of the Council on Scientific Affairs (A-01): Pharmaceutical expiration dates.
12. Cohen, L.P. (2000, March 29). Drugs frequently potent past expiration. Wall Street Journal.
13. Family Health Guide. (2003, November). Drug expiration dates – do they mean anything? Harvard Health Publications.
14. Kramer, T.A.M. (2003, August 21). Commentary: Do medications really expire? Medscape Psychopharmacology Today.
15. Current good manufacturing practice for finished pharmaceuticals. US Food and Drug Administration. Center for Drug Evaluation and Research  
<http://www.fda.gov/cder/dmpq/cgmpregs.htm#211.137>. November 11, 2003.
16. From test tube to patient: improving health through human drugs [special report]. US Food and Drug Administration. Center for Drug Evaluation and Research  
<http://www.fda.gov/cder/about/whatwedo/testtube-full.pdf>. November 12, 2003.
17. Report 1 of the Council on Scientific Affairs (A-01): pharmaceutical expiration dates. American Medical Association. <http://www.ama-assn.org/ama/pub/article/2036-5073.html>. November 5, 2003.
18. Taylor JS, Lyon RC, Prasanna HR, Hussain AS. Stability profiles of drug products extended beyond labeled expiration dates. US Food and Drug Administration. Center for Food Safety and Applied Nutrition .
19. [www.health.harvard.edu/fhg/updates/update1103a.shtm](http://www.health.harvard.edu/fhg/updates/update1103a.shtm).
20. [www.associatedcontent.com](http://www.associatedcontent.com) > Health & Wellness.
21. [www.thirdage.com/.../drug-expiration-dates-how-accurate-are-they](http://www.thirdage.com/.../drug-expiration-dates-how-accurate-are-they).
22. [www.stuartxchange.org/ExpirationDates.html](http://www.stuartxchange.org/ExpirationDates.html).
23. [medicine61.blogspot.com/.../what-does-expiration-date-on-drugs-m](http://medicine61.blogspot.com/.../what-does-expiration-date-on-drugs-m).
24. [healthlibrary.epnet.com/GetContent.aspx?token=b93d114e](http://healthlibrary.epnet.com/GetContent.aspx?token=b93d114e).
25. [www.walgreens.com](http://www.walgreens.com) > Pharmacy > Pharmacist FAQ.
26. [en.wikipedia.org/wiki/Prescription\\_medication](http://en.wikipedia.org/wiki/Prescription_medication).
27. [www.fitsugar.com/What-Do-Drug-Expiration-Dates-Mean-8863378](http://www.fitsugar.com/What-Do-Drug-Expiration-Dates-Mean-8863378).
28. [www.doctorsolve.com/.../drugs-past-their-expiration-d... - United States](http://www.doctorsolve.com/.../drugs-past-their-expiration-d...).
29. [www.fda.gov/Drugs/DrugSafety/](http://www.fda.gov/Drugs/DrugSafety/).
30. [www.adoptionarticlesdirectory.com/Expiration-Dates Medication](http://www.adoptionarticlesdirectory.com/Expiration-Dates_Medication).

**ADDRESS FOR CORRESPONDENCE****[swaroop.confident@gmail.com](mailto:swaroop.confident@gmail.com)**