



RECYCLING OF DRUGS FROM EXPIRED DRUG PRODUCTS: COMPREHENSIVE REVIEW

ABSTRACT

In general, most of drugs are not toxic when expired, but they can lose their effectiveness over time. The decrease in the concentration of the drug in drug product from 100% to 90% of its concentration is known as shelf life. The medication is used within its shelf-life, it shows maximum efficacy and the safety. The expiration date is the final day that the manufacturer guarantees the full potency and safety of a medication. Recently studies conducted by the U.S. Food and Drug Administration over 100 drugs, prescription and over-the-counter products showed that about 90% of them were safe and effective as long as 15 years past their expiration dates. India's pharmaceutical industry is losing around Rs 500 crore annually on account of destruction of expired drugs, hitting the bottom line of drug manufacturers, especially the small and medium ones. In our present communication, we made an attempt to study different methodologies for recycling active drugs from expired drug products (or) pharmaceutical dosage forms. It is attributed that when a drug product gets expired, it may contain 90% or even above of the Active Pharmaceutical Ingredient(s). Medicine recycling may be a possibility (especially if manufacturers are mandated to blister-package and bar-code individual tablets and capsules). The suitable chromatographic methods and analytical techniques could therefore be adopted for isolation and eventual quantification of active ingredients for the purpose of successful recycling into useful synthetic intermediates or active drugs. This approach would remain cost-effective as well as eco-friendly from the point of view of their industrial applicability and commercial benefits.

Keywords: Shelf-life, Potency, Blister-package, Bar-code, Chromatography

**S. Chand Basha*,
K. Rajesh Babu,
M. Madhu,
Y. Pradeep Kumar,
C.Gopinath**

*Department of Pharmaceutical
Chemistry, Annamacharya
College of Pharmacy, Rajampet
-516126, Kadapa, A.P (INDIA)*

INTRODUCTION

Before discussing about the process of recycling of drugs and requirement of recycling and use of recycling of drugs it is prime important to know about some basic stability studies of API and some key words related to stability study of drugs and expired date of drugs, they are shelf life, half-life, potency efficacy, expired date etc.. Shelf life: The period of time that a drug can be stored and still is considered safe and effective for use. Half-life: The period of time required for the concentration or amount of drug in the body to be reduced to exactly half of a given concentration or amount.

Address for correspondence

Mr. S. Chand Basha
Assistant Professor
Department of Pharmaceutical Chemistry,
Annamacharya College of Pharmacy
New Boyanapalli -516126, Rajampet, Kadapa Dt,
E-mail Id: schandbasha20@gmail.com
Mobile No: +919491410997

Potency: The amount of drug that is needed to produce a given effect. **Efficacy:** The maximum effect that a drug can produce, regardless of dose. **Expiry date:** According to USFDA the expired date indicates the date the manufacturer guarantees the full potency and safety of the drug. At the time of the medication expiry date, the drug must be at least 90% of the original potency under proper storage conditions. Recycling of drugs is the process in which there are many important factors are there which plays an important role in drug expiration, stability studies of drugs and recycling methods which are suitable for specific drugs. In which expiry date is the prime important for an individual drug product.

OBJECTIVE

Many patients, of 1.3 million adults with disabilities, do not take their medications as prescribed because of cost; as a result, more than half reported subsequent health problems. Severe disability, poor health, low income, lack of

insurance, and a high number of prescriptions increase the odds of cost-related compliance. Many people's are not able to afford medication vital to their health and well-being. They either completely does without, skip doses, or fail to refill medication prescribed for chronic medical conditions all because of the perceived high cost of medicines. Another possible supply for expensive medication still under patent exists. It is the unused supply that patients are left with when they stop or change medicines. Could we somehow get those unused tablets and capsules to those in need at a reasonable price? Why not recycle widely used expensive medications like atypical antipsychotics, where each tablet may cost \$7–\$14 each, or *Zofran* (an anti-nausea medication used for cancer patients undergoing chemotherapy), which costs close to \$30 per tablet? How about an effort to recycle *Gleevec* capsules, which cost approximately \$27,000 per year for the treatment of a single patient with chronic myelogenous leukemia, a price based in part on the price of interferon, the next best available drug treatment for that disease. So the high cost of medicines is a problem that seems to be getting worse rather than better, for this we thought to recycle the most useful and expensive medication especially the drugs used for chemotherapy for healthcare development of poor people and economic development of our country for better development in pharmacy field.

TARGET GROUPS

A drug-recycling program might begin with a few high-cost products, what the industry calls "blockbusters." Some important blockbuster drugs are like drugs used for chemotherapy etc. There are some important side effects are there due to this cost effective cancer drugs such as nausea and baldness in males. To overcome these side effects it is necessary to use other anti-nausea drugs like *Zofran* which is also cost effective drug which costs close to \$30 per tablet. The major target site is decreasing the cost of most useful drugs and increasing the stock of cost effective and more useful drugs to serve mankind.

ECONOMIC OUTCOMES

Towards the entire healthcare sector

Many drugs are expired due to over production of same API and other reasons are due to cost effect poor people are not show much interest to buy the specific API majorly because of this reasons the drugs are getting expired. Now in present study we perform experiments to produce more drugs of cost effective API to decrease cost and increase the availability of those cost effective drugs to poor patients. It shows major action on healthcare sector

by fast moving of cost effective drugs and development of healthcare sector economically.

Towards general public/consumers/citizen of the country

Recycling of drugs is also useful directly educate patients about the need for continuing medication for chronic indications such as Cancer, Diabetes, Hypertension, Dyslipidemia, Depression, Schizophrenia, AIDS, etc...

Benefits to the business

Obviously, this recycling program is more effectively useful economically but it is cost-effective process of recycling of drugs. By this it is easy to increase the economic development of pharmacy field and decrease the annual economical lose due to expiration of cost effective drugs.

KEYS TO SUCCESS

a) Implementation strategies

In this recycling process first of all we choose an expired product from this the API was extracted and the qualitative and quantitative assessment was done for this API to evaluate the strength .After that perform in vitro/in vivo pharmacological activities and finally compare the potency of expired product with extracted API.

b) Finances

It is majorly cost effective program. In this experiment we perform recycling of cost effective drugs like ZOFRAN- \$30 per tablet and GLEEVEC capsules which cost \$27000 per year to reduce the cost of those by recycling of API

c) Marketing

India's pharmaceutical industry is losing around Rs 500 crore annually on account of destruction of expired drugs, hitting the bottom line of drug manufacturers, especially the small and medium ones. In our present communication, we made an attempt to study different methodologies for recycling active drugs from expired drug products (or) pharmaceutical dosage forms.

PROTOCOL

The recycling of drugs from expired drug products is the new revolution in the pharmacy field which brings rapid changes and development in future pharmacy education and values of pharmacy education. We assume to

recycle the drugs from expired drug products by following this protocol as follows

1. Marketed expired product.
2. Extraction of API from expired product.
3. Qualitative and quantitative assessment of API.
4. Evaluation of Pharmacological activities by in vitro/in vivo methods.
5. Comparing the potency of expired drug product with extracted API.

CONCLUSION:

Dosage form packaging, details of manufacturer, manufacture date, expiration date, medication name, and dosage would bring us close to the possibility of recycling appropriately chosen medications. Special recycling health care unit would have to work with manufacturers, wholesalers, retail pharmacies, health insurers, and the FDA to work out ways to make the whole process of drug manufacturing and distribution compatible with recycling. No doubt Congress would have to pass new laws and insurance companies would have to determine liability risk. That is a lot of work and a lot of change. Clearly, there would also be the need for the FDA to fully monitor and stop the distribution of recycled medicines that might be adulterated, misbranded, expired, sub potent, contaminated, or counterfeit. Whatever the safeguards, recycled medicine may pose an additional risk to consumers, but so does going without needed medication or skipping doses to save money. It comes down. Although recycling medication may seem like a risky and bizarre idea, new technologies may make it reasonably safe or at least safer than no medicine at all for whole groups of people. Throwing away valuable resources when there is apparently not enough to go around is cavalier and unfeeling, not to mention poor public policy. Either medication prices come down, insurance covers medication for all or we begin a discussion of other options, like recycling. By no means should we ignore patient safety issues or liability concerns. These are thorny issues, yet new technology offers interesting solutions.

Dosage form packaging upon reviewing statistics and the many ways in which recycling is in effect throughout the nation, we can confidently state that recycling is a profitable measure. In addition to these findings, we can also conclude that recycling would gain more profit if consumers had something to gain from recycling.

Acknowledgment

We immensely thanks to Prof. C. Gopinath, Principal, Annamacharya College of Pharmacy for helpful suggestions of this review. We would also like to thanks Assistant Professors Gireesh Kumar E, Madhu. M, Mallikarjuna Rao K for helpful suggestions, help in writing and editing sections of this review.

REFERENCES

1. Lueck S, "Drug prices far outpace inflation," Wall Street Journal. July 10, 2003.
2. Fuhrmans V. Change could be upper for drug makers. Wall Street Journal, July 11, 2003.
3. Kennedy J, Erb C, "Prescription noncompliance due to cost among adults with disabilities in the United States," Am J Public Health, 92: 1120-1124, 2002.
4. IgelhartJK,"Good science and the marketplace for drugs: a conversation with Jean-Pierre Garnier," HealthAff, 22: 119-127, 2003.
5. Mulligan K," Soaring Internet drug sales raise safety and legal concerns," Psychiatric News, June 6, 2003.
6. Harris G, "Pfizer moves to stem Canadian drug imports," New York Times, August 7, 2003.
7. Vasella D, Slater R. Magic Cancer Bullet: How a Tiny Orange Pill is Rewriting Medical History. New York: HarperBusiness; 2003.
8. Lerner S, "A desperate global scavenger hunt to keep AIDS patients alive," New York Times, July 23, 2003.
9. Gardner A, "Unused prescription drugs done to go to waste," Health Day, April 12, 2004.
10. Leslie DL, Rosenheck RA, "From conventional to atypical antipsychotics and back dynamic processes in the diffusion of new medications," Am J Psychiatry, 159: 1534-1540, 2002.
11. Cooper AE, Hanrahan P, Luchins DJ, "Compliance with typical versus atypical antipsychotic medications," Drug Benefit Trends, 15: 34-38, 2003.
12. Tierney R, Melfi CA, Signa W, Croghan TW, " Antidepressant use and use patterns in naturalistic settings," Drug Benefit Trends. 6: 7-12BH, 2000.
13. Avorn J, J, Lacour A," Persistence of use of lipid-lowering medications," JAMA. 279: 1458-1462, 1998.
14. Bender B, "Nonadherence in asthmatic patients is there a solution to the problem ,"Ann Allergy Asthma Immunol. 79: 177-185, 1997

15. Cohen LP, "Safe and effective. Many medicines prove potent for years past their expiration dates," *New York Times*. March 28, 2000.
16. Okeke CC, Bailey L, Medwick T, Grady LT., " Revised USP standards for product dating, packaging, and temperature monitoring ," *Am J Health System Pharmacy*, 57: 1441-1445, 2000
17. Taylor JS, Lyon RC, Prasanna HR, Hussain AS. , "Stability profiles of drug products extended beyond labeled expiration dates," April 8, 2004.
18. Frimpter GW, Timpanelli AE, Eisenmenger WJ, Stein HS, Ehrlich LI., " Reversible "Faconi syndrome" caused by degraded tetracycline ," *JAMA*. 184: 111-113, 1963
19. Altschuler R., "Do medications really expire ," *Medscape Psychopharmacology Today*. *Medscape General Medicine*. April 8, 2004.
20. FDA launches initiative to fight counterfeit drugs. *Drug Benefit Trends*, 15: 24, 2003;
21. Allison JG, Dansereau RJ, Sakr A., "The effects of packaging on the stability of a moisture sensitive compound ," *J Pharmaceutics*. 2001; 221: 49-56.
22. Chen Y, Li Y. , "A new model for predicting moisture uptake by packaged solid pharmaceuticals ," *J Pharmaceutics*. 2003; 255: 217-225.
23. Waterman KC, Adami RO, Alsante KM, "Stabilization of pharmaceuticals to oxidative degradation. ," *Pharmaceutical Dev Technol*. 2002; 7: 1-32.
24. Waterman KC, Roy MC., "Use of oxygen scavengers to stabilize solid pharmaceutical dosage forms," a case study. *Pharmaceutical Dev Technol*. 2002; 7: 227-234.
25. Ching TY, Cai G, Depree C, "Cyclohexene derivative oxygen scavengers with reduced oxidation products for use in plastic films and beverage and food containers ," *Patent International Application WO 48963A2*. 1999;
26. Masson P, Tonello C, Bairy C., "High-pressure biotechnology in medicine and pharmaceutical science," *J Biomed Biotechnol*. 2001; 1: 85-88.
27. Kummerer K., "Drugs in the environment: emission of drugs, diagnostic aids and disinfectants into wastewater by hospitals in relation to other sources," a review. *Chemosphere*. 2001; 45: 957-969.
28. Kuspis DA, Krenzilok EP. , "What happens to expired medications A survey of community medication disposal ," *Veterinary Hum Toxicol*. 1996; 38: 48-49.
29. Kreider K., "The Big Fix How the Pharmaceutical Industry Rips Off American Consumers," Cambridge, 2003.
30. Rosenthal MB, Berndt ER, Donohue JM, Frank RG, Epstein AM., " Promotion of prescription drugs to consumers ," *N Engl J Med*. 2002; 346: 498-505.
31. Harris G., "FDA faults quality of imported drugs," *New York Times*. September 30, 2003.
32. Haderer F., " Should expiration dates be required on patients' prescription labels ," *Am Pharm*. 1986 Aug; NS26 (8):30-35.
33. Brown JL, Brown NP. , "Pharmaceutical expiration dating advice given by retail pharmacists ," *J Am Board FamPract*. 1991 Nov-Dec; 4(6):407-410.
34. U.S. Food and Drug Administration: Expiration Dating and Stability Testing of Solid Oral Dosage Form Drugs Containing Iron
35. FDA: Expiration Dating and Stability Testing for Human Drug Products
36. Johns Hopkins, " Drug Expiration Dates ,"
37. Altschuler, R , " Do medications really expire ," September 9 , 2002
38. Cohen, L.P, " Drugs frequently potent past expiration ," *Wall Street Journal*, March 29, 2000
39. Kramer, T.A.M, " Commentary: Do medications really expire ," August 21, 2003
40. 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.

How to cite this article:

S. Chand basha*, K. Rajesh babu, M. Madhu, Y. Pradeep kumar, C.Gopinath, [Recycling of drugs from expired drug products: comprehensive review](#), 6 (2): 2596 – 2599 (2015)

All © 2010 are reserved by Journal of Global Trends in Pharmaceutical Sciences.