Deterra® System Deactivation of Unused Drugs: Comparison between Deterra Ingredients and Others Recommended in Federal and SmartRx Disposal Guidelines

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Abstract

In many households and healthcare facilities, medications accumulate over time. Improper storage or disposal of these drugs poses human safety and environmental contamination risks. Federal guidelines provide suggested methods of disposal including use of take-back programs and mixing with undesirable substances prior to throwing into the trash. These methods do not adequately address safety, environmental and convenience issues. A new product, Deterra®, provides a simple and convenient way of complying with federal guidelines, while reducing both the effect on the environment and safety risks associated with normal trash disposal of medications. Deterra® contains activated carbon and renders drugs inactive by adsorption in the presence of water. A first portion of this study examines the ability of Deterra® to deactivate several model drugs and compares the results to those obtained by utilizing ingredients recommended in federal guidelines. On average Deterra® performed more than 4X better than the other adsorbents and was shown to retain and deactivate drugs even in the event the pouch should rupture and be exposed to rainwater in a landfill. A second portion of this study examines the ability of Deterra® to deactivate drugs having enteric coatings, using three model compounds. Deterra® was found to be effective for this application as well.

Introduction

Many households and healthcare facilities accumulate an assortment of unused medications over time. This may be a consequence of changes in prescription, discontinuing use of a medication once symptoms improve, or shelf life expiration. Improper storage or disposal of these unused and expired medications poses a combination of safety risk to individuals, and contamination risk to our environment. Unused pharmaceuticals are a safety danger when retained, and an environmental hazard when disposed.

From a safety perspective, unauthorized access to unused pharmaceuticals represents a significant and potentially deadly hazard. An estimated 71,000 patients are seen in emergency departments each year because of medication poisonings (excluding recreational drug use). Over 80% of these visits were because an unsupervised child found and consumed medications[1].

From an environmental hazard perspective, pharmaceuticals are now well documented as environmental contaminants. As of 2009, there were over 1000 published reports of the occurrence of pharmaceuticals in sewage, surface waters, ground waters, and elsewhere[2]. In one landmark study, in a sample of 139 streams from 30 different states, 80% contained contaminants including pharmaceuticals[3].

To address these issues, the FDA has worked with the United States Office of National Drug Policy to issue guidelines titled: "How to Dispose of Unused Medications." Separately, a partnership between the U.S. Fish and Wildlife Service, the American Pharmacists Association, and the Pharmaceutical Research and Manufacturers of America has established the SmartRx campaign to educate consumers on proper disposal of their medications. Both guidances urge consumers not to flush medications down the toilet or drain. If there are no specific disposal instructions for a medication, consumers are directed to participate in take-back programs or to dispose of medications in the trash by co-mixing with an undesirable substance (such as kitty litter, coffee grounds, or sawdust) to make it less appealing for children and pets to eat. In certain cases, strong narcotics are advised to be flushed in order to minimize the chances of diversion or accidental exposure to children.

While the methods suggested in these guidance documents provide some protection, they do not satisfactorily address safety, environmental and convenience issues. Discarded drugs can still be reclaimed from trash for diversionary purposes and present acute poisonings hazards for wildlife scavengers. Mixing with the currently recommended undesirable substances has not been shown to decrease availability of drugs to groundwater when placed in landfills. The recommended procedure is messy, utilizes materials that may not be available to consumers, and lacks procedure clarity (for example, how much cat litter is required?).

Alternative pharmaceutical take-back programs utilize incineration, which can produce toxic air emissions[4]. Further, take-back and other collection events are not always available, or may require long distance travel, and will encourage consumers to stockpile unwanted medications until it is convenient to make a trip to turn them in. Consumers have expressed concerns regarding take-back programs including convenience, insufficient time, privacy concerns and preferences for alternative routes of disposal (such as flushing). In countries with long-established take-back programs (such as the UK), only a minority of the public makes use of the service[2].

The Deterra® System provides a simple and convenient way of complying with the guidance's listed above, while reducing both the effect on the environment and safety risks associated with normal trash disposal of medications. The system is comprised of a conveniently pre-packaged sealable outer pouch containing a proprietary MAT_{12}® carbon, self-contained in an inner water permeable pouch. Unused tablets, capsules, liquids, or used patches are placed in the outer pouch, water is added, and the pouch is sealed and thrown into normal household trash. In use, the drugs will dissolve into the water and react with the MAT_{12}® carbon in a manner to render it insoluble and therefore inactive. This drug deactivation process starts immediately, and will generally occur over several hours. The full deactivation time will vary, and is dependent on how quickly the drug dissolves into the added water.

In a first portion of this experiment, the ability of Deterra® activated carbon to deactivate several drugs (amoxicillin, dexamethasone, diphenhydramine, ibuprofen, ketoprofen, naproxen, generic Percocet, generic Vicodin, venlafaxine) was ascertained. The drugs evaluated were chosen in order to represent a variety of commonly used medications of different treatment classes, potency, and relative water solubility. As a direct comparison (control), the Deterra product ingredients were compared to other ingredients that have

been recommended in the FDA and SmartRx Guidances (used coffee grounds, kitty litter and sawdust).

Some medications have a barrier (enteric) coating, so as to slow the rate of the medication absorption and/or control the location in the digestive system where it is absorbed. In a second portion of this experiment, the ability of Deterra® activated carbon to deactivate drugs having enteric coatings was evaluated. For this portion of the study, omeprazole magnesium (Prilosec), duloxetine HCl (Cymbalta), and coated aspirin were used as model compounds.

Materials

Amoxicillin (250 mg, Sandoz Pharmaceuticals, Inc., Princeton, NJ), enteric coated aspirin (325 mg, Walgreen Co., Deerfield IL.), dexamethasone (4 mg, Roxane Laboratories, Inc., Columbus, OH), diphenhydramine hydrochloride (25 mg, Equate, Walmart, Bentonville, Arkansas), duloxetine HCl (Cymbalta 60 mg, Eli Lilly, Indianapolis IN), ibuprofen (200 mg, Equate, Walmart, Bentonville, Arkansas), ketoprofen (75 mg, Teva Pharmaceuticals USA, Sellersville, PA), naproxen sodium (220 mg, Equate, Walmart, Bentonville, Arkansas), omeprazole magnesium (Prilosec 20.6 mg, Proctor and Gamble Cincinnati OH), generic Percocet (5/325 mg, Watson Pharmaceuticals, Inc., Parsippany, NJ), venlafaxine hydrochloride (75 mg, Teva Pharmaceuticals USA, Sellersville, PA), generic Vicodin (10/325 mg, Watson Pharmaceuticals, Inc., Parsippany, NJ). granular activated carbon (proprietary), coffee grounds (used, assorted off-the shelf), cat litter (Roundy's Fresh Clear Scent, Rainbow), sawdust (assorted), distilled water.

Method

Deactivating adsorbents (15 grams) and drugs (10) in tablet or capsule form were placed in re-sealable standup foil pouches. Eighty (80) grams of tap water were added to each pouch. Pouches were sealed shut and shaken once a day for 7 days. After 7 days, an additional 250 grams distilled water was added to each pouch in an environmental "washout" test to examine potential for leaching of drugs from adsorbents. Pouches were placed on a reciprocating mixer for a minimum of one hour. Presence of drug in solution was measured the following day by UV-Vis spectrophotometry at optimal absorbance wavelengths for each drug.

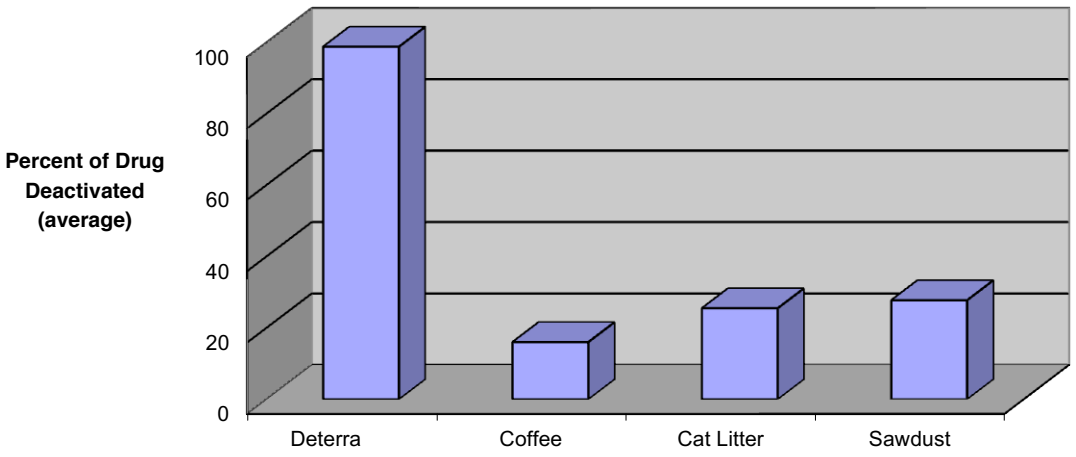
Standards were prepared in the same manner with the exception that adsorbents were not present. Adsorbent blanks were prepared in the same manner with the exception that drugs were not present.

Results

The following table and charts illustrate amount of drug deactivated by each adsorbent. High percentage values equate to greater inactivation of drug, and less leaching in the environmental washout test.

Experiment 1: Comparison Test for Percent of Drug Deactivated				
	Deterra®	Coffee Grounds	Cat Litter	Sawdust
Generic Vicodin, 10/325	99.6	0	0	0
Generic Percocet, 5/325	100	5.3	0	0
Naproxen, 220 mg	99.4	0.9	0	0
Ibuprofen, 200 mg	94.3	0	0	0
Diphenhydramine, 25 mg	99.8	49.2	83.6	67.7
Dexamethasone, 4 mg	99.2	3.5	34.8	67.5
Amoxicillin, 250 mg	97.5	10.8	0	7.9
Effexor XR, 75 mg	98.9	38.8	87.4	59.3
Ketoprofen, 75 mg	99.9	35.6	23.6	47.2
Average	98.7	16.0	25.5	27.7
Standard Deviation	1.8	19.5	36.3	31.7

Comparison of Deactivation for Model Drugs (Generic Vicodin, Generic Percocet, Naproxen, Ibuprofen, Diphenhydramine, Dexamethasone, Amoxicillin, Ketoprofen, Venlafaxine)



Experiment 2: Percent Deactivated for Model Enteric Coated Medications	
	Deterra®
Enteric Coated Aspirin, 325	99.3
Duloxetine 60 mg (Cymbalta)	99.7
Omeprazole 20.6 mg (Prilosec)	99.6
Average	99.5
Standard Deviation	0.21

Discussion

This study was designed to examine the equivalent of 30 tablets exposed to 45 grams adsorbent in a single pouch containing one cup of water. After 7 days the water volume was increased to examine what may happen in a landfill should the pouch rupture.

In all cases Deterra® activated carbon outperformed the FDA and SmartRx alternative recommended adsorbents. **On average Deterra® performed more than 4X better than the other adsorbents**. Deterra® was shown to retain and deactivate drugs even in the event the pouch should rupture and be exposed to rainwater in a landfill. Our results also indicate that Deterra® can be effective for treatment of enteric coated medications

Conclusion

Deterra® is superior to other adsorbents recommended by FDA and SmartRx in deactivating drugs and preventing them from entering the environment.

References

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About the Author:

William Fowler, Principal Scientist at Verde Environmental Technologies, Inc.

Bill has B.A. degrees in Chemistry and Biology from Augsburg College, and an M.S. degree in Genetics from the University of Minnesota. He has over 26 years of experience in the Medical Device and Pharmaceutical industries. Prior to Verde, he served as a Sr. Device Scientist at Travanti Pharma, where he managed R&D and preclinical activities for a self-contained iontophoretic device used in the treatment of pain associated with Lateral Epicondylitis. Prior to Travanti, he worked as a Sr. Product Development Engineer at St. Jude Medical in the development of heart guide catheter systems. Bill is listed as an inventor on 13 US and International patents.