

Medsaway[®] Activated Carbon: Retention of Pharmaceuticals using the Toxicity Characteristic Leaching Procedure Extraction Solution

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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. A new product, Medsaway[®], provides a simple and convenient way of disposing of unwanted medications, while reducing both the effect on the environment and safety risks associated with normal trash disposal of medications. Medsaway contains a proprietary form of activated carbon which renders drugs inactive by adsorption in the presence of water. Previous studies performed at Verde have shown Medsaway to be superior in deactivating drugs when compared to mixing drugs with undesirable substances such as coffee grounds or cat litter. The present study investigated the ability of Medsaway carbon to retain adsorbed drug under simulated landfill conditions by using the sample pre-treatment recommendations and the acidic extraction solution designated in the Environmental Protection Agency's "Toxicity Characteristic Leaching Procedure" (TCLP)¹. In this investigation, three model test drugs were evaluated for leachability from Medsaway activated carbon in direct comparison to leachability from Portland cement, an alternative encapsulation method. Our findings indicate that under acidic conditions that may arise in landfills, the activated carbon in Medsaway demonstrated minimal leaching of adsorbed drug. As a comparison, untreated drugs and drugs encapsulated in Portland cement were shown to be leached to significantly greater extent.

Background

According to a recent report, as many as 50% of Americans take at least one prescription drug in any given month². Of 4 billion prescriptions written yearly, it is estimated that some 40% go unused³. To address the disposal of unused medications, voluntary drug take-back drug programs have been successful in recovering "tons" of these unwanted drugs. However, a recent study has shown that these drug take back programs only account for about 2% of the total unused medications accumulated⁴.

For the home setting, this has an undesired consequence for accumulation of medications in medicine cabinets, representing safety, abuse, and environmental contamination hazards. In the case of opioids, a recent survey has found that 72% of patients that were prescribed opioids reported having leftover amounts, and 71% of those having leftover medication reported that they kept them⁵. These accumulations may be a contributing factor to the recent high incidence of opioid related poisonings, as over 530,000 emergency department visits are made each year for opioid-related poisonings⁶.

In the institutional settings at present, many hospitals and clinics continue to dispose of narcotics and other unwanted medications into the sink, often in direct conflict with

environmental regulations. The costs associated with environmentally responsible disposal of narcotics is prohibitive, and according to a recent article may be as high as \$25,000 to properly dispose of a 50 gallon quantity⁷.

There is a need to find a practical and safe way to destroy drugs 'at-source', so as to provide an economical means for users in both home and institutional settings to dispose of them in an environmentally responsible way.

Medsaway Activated Carbon

Not all activated carbon is the same. The components and recommended capacities of our Medsaway formulations have been carefully selected for optimal pharmaceutical deactivation and have been confirmed effective in independent University studies⁸⁻¹⁰. With Medsaway, we use a significant amount of activated carbon surface area to insure sufficient adsorption and retention properties. Our Medsaway XL (with a capacity of approximately 450 pills), has a total carbon surface area equal to several football fields.

Historical Use of Activated Carbon

In a recent literature search using PubMed (U.S. National library of Medicine/NIH) and the keywords of "activated" and "carbon", over 21,000 publications were cited. Amongst numerous applications, activated carbon is used for removal of pharmaceutical impurities in water treatment processes, and in emergency treatments for deactivation of ingested drugs and other poisons.

The effectiveness of activated carbons use for inactivating/deactivating toxic chemicals was first demonstrated by a French pharmacist in 1831 when he ingested a lethal dosage of strychnine along with 30 grams of activated carbon without ill effect (described in reference 11: Albertson T, Olson K, Fisher C., "The use of activated charcoal in cases of poisonings and drug overdose", *Epitomes-Emergency Medicine* 1985, 142, pp 385-6). The authors of this publication recommend use of activated carbon for treatment of any toxic compound overdose with the exceptions of iron and alcohols, (and possibly acetaminophen when administration of the antidote, N-acetylcysteine, is contemplated).

Activated carbon adsorbs a poison in the gastrointestinal tract and therefore reduces its absorption into the systemic blood circulation¹². The use of activated carbon as a method of treating poisoned patients is supported in the Positions Statement of the American Academy of Clinical Toxicology, European Association of Poisons Centers, and clinical toxicologists¹³. An article by Thakore et. al.¹⁴ also suggests that adsorption of toxins onto activated carbon will inhibit the absorption of those toxins into systemic blood circulation, and further notes that the mean bioavailability of the drug/toxin can be reduced by 88.6% if activated carbon is administered in a timely manner following an overdose (within 30 minutes). The Thakore article also recommends activated carbon as being universally effective with few exceptions (heavy metals, corrosives and volatile agents as noted earlier).

Previous Verde Studies and Goals of this Investigation

Verde has tested a number of model pharmaceutical compounds with different chemical structures, water solubility, formulation, and potency. In a first study, we directly compared the effectiveness of Medsaway activated carbon to the deactivation effectiveness of cat litter, sawdust and coffee grounds¹⁵. In this previous study, Medsaway was shown to be superior in

both deactivation effectiveness and resistance to drug back-extraction in unbuffered aqueous solutions. In a separate study that was conducted in an independent University setting, Medsaway activated carbon was found to be effective in deactivation and excellent in resistant to drug back-extraction in alcohol solutions using the abusable drug fentanyl as a model compound¹⁶.

The prior investigations demonstrate the effectiveness of Medsaway in the deactivation of drugs and prevention of abuse by back extraction in unbuffered aqueous and alcohol solutions. The present study is intended to investigate the environmental benefit that may arise from prevention of leaching of drugs into acidic solutions that may be present in a landfill setting. In this comparison study, three model drugs were evaluated using three treatment methods: 1) untreated, such as if drugs were deposited directly into trash; 2) drug encapsulation in Portland cement prior to trash disposal; and 3) treatment with Medsaway activated carbon prior to trash disposal. The drugs evaluated were in commercially available patient-use form (e.g. obtained from a local pharmacy and used as-is).

Procedure: TCLP Solution Extraction Study

Introduction

The Environmental Protection Agency has published a Toxicity Characteristic Leaching Procedure (TCLP, Method 1311, November 1992) designed to determine the mobility of both organic and inorganic analytes present in liquid, solid, and multiphase wastes. In summary, for wastes containing $\geq 0.5\%$ solids, the solid phase is extracted with an amount of acidic extraction fluid equal to 20 times its weight. The extract is then analyzed for analytes of interest.

Materials

Medsaway pouches containing proprietary activated carbon, acetaminophen (500 mg, Equate, Walmart, Bentonville, Arkansas), ibuprofen (200 mg, Equate, Walmart, Bentonville, Arkansas), naproxen sodium (220 mg, Bayer Healthcare, Morristown, NJ), hydrochloric acid (10%, Spectrum, Gardena, CA), acetic acid (5%, Gedney, Chaska Minnesota), sodium hydroxide (50%, Aldrich, Milwaukee, WI), Portland cement (Type 1, Holcim, Waltham, MA), distilled water (Supervalu, Eden Prairie, MN), fine mesh paint filter (Home Depot, Atlanta, GA).

Method

Drug Adsorption by Activated Carbon. Intact tablets (10 ibuprofen, 10 naproxen, or 6 acetaminophen) were placed in individual Medsaway pouches containing an amount of activated carbon at the recommended Medsaway adsorption ratio for that drug amount. Fifty (50) grams of warm tap water was added to each pouch. Pouches were shaken, sealed and placed on a rocker table for 5 days to ensure drug was adsorbed by the activated carbon. Pouch contents were analyzed for presence of drug by UV-Vis spectrophotometry. The Medsaway carbon adsorbed 99.7%, 100% and 100% of acetaminophen, ibuprofen and naproxen, respectively.

Drug Encapsulation by Portland Cement. Portland cement was mixed with water to a paste consistency (an approximate 2.5:1 ratio). Intact tablets (10 ibuprofen, 10 naproxen, or 6

acetaminophen) were placed in individual 50 ml plastic cups (resulting in total weight of approximately 100 g per cup). The cups were filled with cement and stirred to distribute the tablets. Tablets were not allowed to breach the surface of the cement. Cement was allowed to cure for 4 days. Per EPA Method 1311, the concrete was crushed by hammer to produce particle sizes of 1 cm in the narrowest dimension. Crushed cement samples were allowed to sit an additional day prior to extraction (total 5 days exposure to cement).

Extraction Solution Determination. The choice of extraction solution is dependent on the initial pH of an aqueous extraction of the solid phase. Carbon slurries were removed from each bag and filtered through a fine mesh paint filter. The carbon was dried at 25°C. Carbon (2.5 g) was added to 48.25 ml distilled water, shaken by hand vigorously for 5 minutes, and pH measured. The ibuprofen solution pH was 4.77. According to Method 1311, if the pH <5.0, extraction solution #1 (to be described in next section) was used in the extraction procedure. The pHs of acetaminophen and naproxen solutions were 6.10 and 10.07, respectively. According to method 1311, since the pHs were >5, the solution was brought to 0.035N with HCl (1.75 ml of a 3.5% solution, bringing the total volume to 50 ml with distilled water). The solutions were brought to 50°C for 10 minutes. The resulting pHs were less than 5.0, indicating the use of extraction solution #1 for these samples also. For direct comparison purposes, the same extraction solution was used for the untreated and Portland cement treated samples.

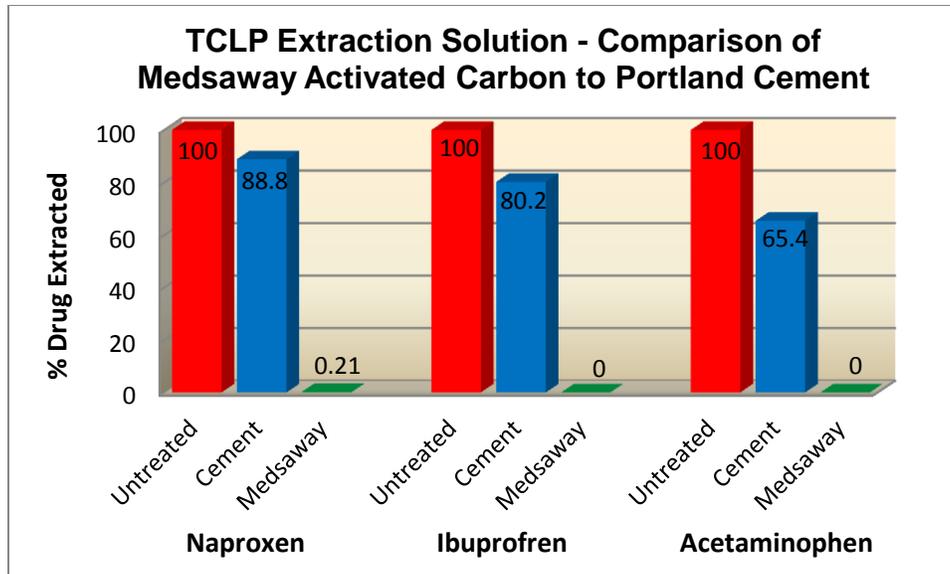
Extraction Procedure. Extraction solution #1 (0.1 N acetic acid brought to pH 4.93 ± 0.05 with sodium hydroxide) was prepared. For Medsaway samples, 15 grams of dried carbon pre-adsorbed with each pharmaceutical were placed in separate plastic jars and 300 grams of extraction solution #1 was added. For Portland cement treated samples, approximately 100 grams of each crushed cement sample (an amount containing the same content of drug as the Medsaway carbon) were placed in separate plastic jars and 300 grams of extraction solution #1 was added to each. Untreated comparison samples were dissolved in extraction solution #1 to an equal drug concentration as those of the test samples.

Jars were capped on test samples and they were then placed on a rocker table for 18 hours. The presence of drug in extraction solution was assayed by UV-Vis spectrophotometry.

Results

The percentage of drug leached from activated carbon was 0.00, 0.00 and 0.21% for acetaminophen, ibuprofen and naproxen, respectively. The percent leached from Portland cement for the same drugs were 65.4, 80.2 and 88.8% for acetaminophen, ibuprofen and naproxen, respectively. As expected, untreated controls did not appear to have any drug retention effect.

Our results for this experiment are graphically depicted below:



Discussion

This study provides direct evidence that pharmaceuticals will be retained within the activated carbon of Medsaway even when exposed to acidic solutions that may be found in a landfill setting. These findings are consistent with other uses of activated carbon, which include the in-situ deactivation of pharmaceuticals within an acidic stomach environment. The Portland cement samples tended to release a significant percentage of the drugs tested. We believe this may be due to the direct exposure of drug when the cement cracks in the sample pre-treatment steps of EPA method 1311.

References

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