

Treatability & demonstration testing of cement-based solidification/stabilization technology applications for unusable pharmaceutical products

Technical report

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Published in 2016

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Executive summary

Introduction, background & technology recommendations

The collection, treatment, and disposal of large volumes of unusable pharmaceutical products (UPP) comprising expired drugs and medicinals, test kits, laboratory reagents, and the like typical pose substantial and difficult challenges. This is particularly the case in most developing countries where UPP generators are widely dispersed and with available or viable UPP treatment and disposal options being very limited and very costly. Although UPP does not generally pose a serious threat to public health or the environment, improperly disposed UPP could potentially contaminate local and community water supplies. In addition, improperly managed and/or disposed UPP could be pilfered from warehouses and transport vehicles or scavenged from insecure landfills and subsequently diverted to black or grey market resale or misused in some other way. Accordingly, a project was commissioned to identify, evaluate, and recommend the best, most efficient, and most cost-effective system or technology for treating and disposing of these large volumes of UPP on an on-going basis.

Various international publications identify landfilling, incineration, and immobilization followed by landfilling as viable options for treating and disposing of UPP. Due to the substantial disadvantages associated with incineration and landfilling, immobilization followed by landfilling appears to be the most viable and most cost-effective option, and the process termed inertization appears to be the most practicable immobilization alternative. However, publications referencing or discussing inertization contain minimal details about the process itself and they present no data to determine or justify recommended percentages of cement, water, and lime additives.

The inertization process is much more commonly termed a solidification/stabilization (S/S) process and, more specifically, a cement-based S/S process. This technology was first used in the 1950s for the solidification of radioactive wastes, and it has since been widely applied for treating a broad range of waste types and categories. In short, it involves the intermixing of waste, such as UPP, with Portland cement, water, and aggregates such as rock, sand, or clay thereby yielding a solid, inert, stable product or residue that is considered safe for handling and landfill disposal.

Cement-based S/S systems are particularly attractive in comparison to other potentially viable UPP treatment processes because:

- They have very low capital and operating costs;
- They are easy to operate and maintain;
- They pose negligible adverse effects or impacts on the environment and public health;

- They have minimal space and infrastructure requirements; and
- They can be procured, installed, and made fully operational within a very short time.

The recommended cement-based S/S technology is a relatively simple process primarily involving a few basic components; namely,

- A granulator for rendering the UPP unrecognizable by breaking it to small particle sizes, and
- A processor unit for intermixing UPP with cement, water, aggregates, and other additives.

However, other components should also be included as part of a fully-integrated system to ensure proper, safe, and reliable operations without extraordinary labor requirements. These include:

- An **automated materials handling system** for loading granulated UPP and other process materials into the processor unit;
- An automatically controlled water feed system;
- A fugitive dust-control system integrated with granulator operations; and
- A controls and instrumentation system operated through a centralized main panel.

Demonstration testing program

Although cement-based S/S is a recognized and long-proven waste treatment technology, published data on its application for treating pharmaceutical type waste are minimal and of negligible value. Accordingly, a testing program was commissioned for the purpose of demonstrating proof-of-concept of this technology for processing relatively high volumes of UPP, as well as for determining essential operational data such as the ratios and usage rates of Portland cement, water, aggregates, and other additives for attaining treated residues of varying qualities.

A key step before commencing with the testing program was to establish criteria or qualities of residues discharged from the various test runs that would be considered safe and suitable for general handling purposes and landfill disposal. Such criteria then served as the basis for determining proper or optimum percentages or ratios of concrete, water, and additives that should be added during processing.

It was known that the recommended S/S system would render UPP unrecognizable because of the granulation process followed by the intermixing of finely granulated UPP with cement and other additives, but it was necessary to define criteria with respect to residue handling and stability qualities. These were as follows:

1. Residue handling criteria

This criterion relates to the physical properties of concrete-like residues discharged from the S/S processor with respect to general handling purposes and for ease of containing, working, and forming it into selected shapes. This is typically termed workability and it typically refers to the degree of wetness; i.e., if too much water the residue would be too wet for containment and handling, and if too little water or too much sand or aggregate the residue would be too dry for ease of handling. Accordingly, residue handling criteria is strictly subjective and for the testing program it was based on empirical experiences as to what is considered acceptable concrete workability.

2. Residue stability criteria

This criterion relates to the structural integrity or the compressive strength of the residues upon drying or curing. Stability criteria were generally defined and evaluated for two extremes as follows:

High structural quality residues

These are residues having high compression strength such that they potentially could be solidified to a block-like form for possible use in construction type activities.

Minimal acceptable quality residues

These are residues that would be considered sufficiently stable and suitable for handling and general landfill disposal but with structural properties being of no particular importance. Residues were deemed to having met this criteria if had a consistency comparable to that for a relatively high grade soil cement whereby they would be capable of being formed or slightly compressed to achieve some degree of rigidity if so desirable.

A demonstration testing program was subsequently conducted at the facilities of Maxon Industries, Inc., in Milwaukee, Wisconsin (Maxon), between May 5 and June 18, 2015. The program comprised a series of bench scale and full-scale demonstration test runs involving the processing of a total of 450 lb (204.1 kg) of representative UPP that consisted of a mixture of placebo tablets and capsules, or pills, comprised of cellulosic type fillers. The Maxon testing equipment included a high-speed granulator; a small, electric-drive, portable processer for bench scale testing; and a one cubic-yard (0.77m3) processor for full-scale testing.

The test runs, 12 in total, involved varying weights and percentages of UPP product along with cement, water, and varying additive types and quantities. Additives included rock as an aggregate; an accelerant for strength improvement and reduced curing times; corn starch to better replicate typical UPP compositions; washed sand; and bentonite as representative of typical indigenous soils. The main purpose of varying the process compositions and weights

was for assessing the ability of the system to process UPP with resultant residues having either high structural properties for possible construction applications or of minimal acceptable quality for safe handling and general landfill disposal. Residue samples from bench scale and full-scale test runs were collected in test cylinders that were analyzed by an independent materials testing laboratory for compression or structural strength.

The testing program comprised four parts as follows:

- Granulation testing. This involved loading the granulator unit with varying ratios of placebo
 tablets and capsules in order to evaluate the capabilities of the granulator for breaking down
 the placebo pills to very small particle sizes, within a relatively short time period and without
 significant operational problems.
- 2. **Initial bench scale testing.** This comprised five test runs with the primary purpose of determining the percentages of cement, water, aggregates, and other additives for intermixing with granulated placebo pills during full-scale demonstration testing that would result in attaining high structural quality residues.
- 3. **Full-scale demonstration testing.** This comprised three test runs with each involving the processing of 100 lb (45.4 kg) of placebo pills and corn starch to simulate the large volumes of UPP to be treated and disposed throughout most countries. The objective was also to attain residues having a high structural quality.
- 4. Post demonstration bench scale testing. This comprised four test runs having two objectives; namely, to determine process mixes and ratios that would provide residues having minimally acceptable qualities and to evaluate the capabilities of treating fully packaged pharmaceutical products.

Testing program summary & findings

Exhibit 1 includes a summary tabulation of the tested UPP products and mixtures, process additives, and the results reported for each of the bench scale and full-scale test runs. Details, descriptions, and test photographs are included in the Appendices.

Residue quality options

The testing program not only served to demonstrate the suitability of cement-based S/S technology applications for processing large volumes of UPP but also to identify the ratios and usage rates of Portland cement, water, aggregates, and other additives needed for attaining treated residues having widely different qualities; namely, high structural quality residues and

residues having minimally acceptable qualities. However, it should be noted that the indicated values should not be considered exact or precise to be used or relied upon for any particular application or for any particular UPP type or composition of mixture. Instead, they should be considered reasonably accurate and acceptably representative values for guidance and for planning purposes. Bench scale testing should be used for any particular S/S system installation to determine the best process ratios for differing or unusual UPP types, products, or compositions.

Process time estimates & residue quantities

1. Operations for high structural quality residues

Based on test data results and the use of a recommended processor unit having a nominal one cu-yd (0.76 m3) loading capacity, about 1,200 lb (544.3 kg) of UPP could be processed per 8-hour day of operation which equates to a nominal UPP volume of about 30 cu-ft (0.9 m3) per day of operation.

Such operations would result in about 20,400 lb (9,253.3 kg) of residues per day which is equivalent to about 136 cu-ft (3.9 m3) of residues per day. If these were formed into blocks having an average weight of 65 lb (29.5 kg), about 315 such blocks would be generated per day of operation.

2. Operations for minimal acceptable residues

Based on test data results and the use of a recommended processor unit having a nominal one cu-yd (0.76 m3) loading capacity, about 4,200 lb (1,905.0 kg) of UPP could be processed per 8-hour day of operation which equates to a nominal UPP volume of about 105 cu-ft (3.0 m3) per day of operation.

Such operations would result in about 25,440 lb (11,539.4 kg) of residues per day which is equivalent to about 136 cu-ft (3.9 m3) of residues per day. If these were formed into blocks having an average weight of 65 lb (29.5 kg), about 390 such blocks would be generated per day of operation.

Summary of key testing program findings

- 1. It successfully demonstrated the viability of using a cement-based S/S technology for processing UPP and rendering it suitable for safe handling and disposal in a general landfill.
- 2. It demonstrated the ability of cement-based S/S systems to process large volumes of UPP at a high rate or capacity so as to be considered suitable for the large quantities of UPP generated and in quarantine storage throughout most countries.

- 3. It provided important, well-documented information and data for use in the design of a cement-based S/S system, associated components and the granulator, in particular, for best ensuring reliable, trouble-free operations, and optimum performance when processing UPP.
- 4. It provided essential operational data of requirements for processing UPP to attain residues of widely varying quality ranges; namely, residues having a high structural quality and those having minimal acceptable qualities.
- 5. It provided important information with respect to the quantities, discharge rates, and characteristics of residues that would be collected, formed, and handled for different UPP process rates and for attaining residues of both high structural and minimal acceptable qualities.
- 6. It demonstrated that a cement-based S/S technology could be effectively used to process both unpackaged and fully packaged UPP to residues having nearly identical qualities.

Other potential pharmaceutical waste processing applications

Based on many technical publications, US EPA documents, and the results of the testing program, it appears that a cement-based S/S technology should be readily capable of treating or processing virtually every type of pharmaceutical waste, whether fully packaged or unpackaged, with a resultant residue suitable for safe handling and disposal in a general landfill.

There appear to be only two limitations or restrictions to the use of this technology for treating pharmaceutical waste. The first includes the processing of UPP in metal or very hard containers that could cause damage or stoppage of the granulator blades. The second includes UPP that are considered or defined being acutely toxic, such as antineoplastic drugs, because the handling of such products poses unacceptable occupational exposure risks.

Glossary

Accelerant or set accelerator: A chemical additive or admixture used in making concrete or mortar to reduce the time needed for proper curing and for enhancing strength development.

Additives: Aggregates, such as sand and rock, water, and admixtures, such as accelerants, that are added and mixed with cement to make concrete.

Aggregates: Inert granular materials, such as sand, gravel, or crushed stone, that are intermixed with water and cement to make concrete. Aggregates serve to strengthen concrete by acting as a type of reinforcement.

Bentonite: An adsorbent, clay-like mineral product that is typically mined from quarry deposits. For the UPP testing program covered in this report, it was used to represent indigenous soils that are widely available throughout the world.

Cement: A powdery substance most often comprised of calcined lime and clay that is mixed with water to form mortar or mixed with aggregates and water to make concrete. This is usually understood to mean Portland cement which is the most common type of cement in general use throughout the world.

Concrete: A mixture of cement, water, and aggregates. Aggregates typically comprise 60 to 75 percent of the mixture and cement and water make up the rest. Chemical admixtures, such as set accelerators, may be added to modify properties of the concrete or to effect curing for particular applications.

Curing: The process during which ingredients in the concrete, cement, water, aggregates, and additives chemically react thereby allowing the concrete to form properly and achieve desired properties such as strength and permeability.

Encapsulation: A pharmaceutical waste treatment process described in various World Health Organization documents whereby such waste is immobilized or solidified to a solid block form within a plastic or steel drum via the addition of a cement mixture or similar product.

Form or concrete form: A solid barrier or enclosure that holds concrete in place and forces it to assume a certain shape upon curing and drying.

Granulator: A device or equipment used to reduce the size of pharmaceutical waste, such as UPP and/or other types of waste to a small, granular size typically about 40 mesh (0.016-in or about 0.42- mm) or smaller.

Immobilization: A process described in various World Health Organization documents whereby pharmaceutical waste is solidified via either encapsulation or inertization such that

potentially harmful or hazardous constituents are prevented from migrating or dispersing into the environment during handling, transport, storage, and/or disposal procedures.

Inertization: A process described in various World Health Organization documents as a variant of encapsulation whereby unpackaged pharmaceutical waste is crushed by a "grinder or road roller" and then mixed with certain percentages of cement, lime, and water to produce a solid concrete residue suitable for landfilling.

Legacy waste: Waste remaining or in storage from previous activities for which there is no immediately responsible party or individual that can be held liable for its impacts, ultimate disposal, or any pertinent remediation work. This typically refers to hazardous waste and includes disposed, unwanted, or unusable pharmaceutical products.

Portland cement: The most common type of cement in general use around the world. It is a fundamental ingredient of concrete and mortar.

Quarantined waste: Pharmaceutical products that are unwanted or unusable and which have been physically isolated or stored in restricted access areas pending decisions as to how they should be disposed.

Residues: The end product or materials discharged from a waste treatment process. This includes the concrete-like material or product discharged or removed from cement-based solidification/stabilization processes.

Soil cement: A mixture of pulverized natural soil with small amounts of Portland cement and water that is typically processed in a mixer and compacted to high density for use as construction material such as for road and pipe bedding as a subbase layer. It has good compressive and shear strength but is prone to cracking because it is brittle and has low tensile strength.

Solidification: A change in the physical properties of a pharmaceutical waste or UPP by which it is rendered or converted to a solid, stabile form comparable to that described for encapsulation and inertization processes. Physical changes typically include an increase of compressive strength, a decrease of permeability, and a binding of hazardous or physically dangerous constituents or components.

Stabilization: Chemical changes of hazardous constituents within pharmaceutical waste or UPP by which they are converted into a less soluble, less mobile, or less toxic form.

Solidification/stabilization (S/S): The use of Portland cement and aggregates combined with the granulation of pharmaceutical waste to render a residue that is stable, solidified, unrecognizable, and suitable for safe disposal in a conventional sanitary landfill.

Waste processing: The use of physical, chemical, mechanical, thermal, or other processes or combinations of processes to change the characteristics, composition, or nature of a waste or waste streams for a particular purpose. Waste processing is used for such purposes as weight or volume reduction, destruction, detoxification, sterilization, disfigurement, recycling, reuse, and the like. Waste processing systems and equipment vary widely and include shredders, granulators, compactors, incinerators, sterilizers, dryers, gasifiers, composters, solidification/stabilization units, and the like. The term is considered synonymous and often used interchangeably with the term waste treatment.

Waste treatment: This term is often used interchangeably with the term waste processing but it typically refers to processes that are used to render or convert wastes that are considered or regulated as being hazardous, toxic, infectious waste, radiological, pathological, physically dangerous, and the like to a residue that is considered safe and suitable for general landfill disposal.

Unusable pharmaceutical products (UPP): Pharmaceuticals such as drugs and medicines that can no longer be used due to being expired, withdrawn, recalled, damaged, contaminated, or for any other reason. UPP, which is also often termed pharmaceutical waste, must ultimately be disposed in a proper, safe manner, and such disposal almost always requires processing or treatment depending on whether they are considered or regulated as hazardous or potentially hazardous and/or as a means of preventing them from being scavenged and resold or used.

Introduction & background

The collection, treatment, and disposal of large volumes of unusable pharmaceutical products (UPP) comprising expired drugs and medicinals, test kits, laboratory reagents, and the like typical pose substantial and difficult challenges. This is particularly the case in most developing countries where UPP generators are widely dispersed and with available or viable UPP treatment and disposal options being very limited and very costly. It has been reported that a number of countries have as much as about 200 metric tons of unpackaged UPP, or legacy waste, accumulated in warehouses or in quarantine storage with as much as about 60 metric tons being generated annually such that warehousing capacities and UPP management capabilities are grossly overtaxed and strained on an ongoing, accumulative basis.

Although UPP does not generally pose a serious threat to public health or the environment, improperly disposed UPP could potentially contaminate local and community water supplies. In addition, improperly managed and/or disposed UPP could be pilfered from warehouses and transport vehicles or scavenged from insecure landfills and subsequently diverted to black or grey market resale or misused in some other way.

Accordingly, in view of the above issues and concerns, a project was commissioned to identify, evaluate and recommend the best, most efficient and most cost-effective means for treating and disposing of large volumes of UPP and to develop associated Standard Operating Procedures (SOPs). As part of that project, this report includes a summary discussion of UPP treatment and disposal options, recommendations of what appears to be the best option and a presentation of the results of a demonstration testing program for the recommended option.

Recommended UPP treatment technology

Treatment & disposal options

Technical reports and documents published by a number of international organizations, such as the World Health Organization, identify landfilling, incineration, and "immobilization" followed by landfilling as potentially viable options for treating and disposing of unwanted medicinals and pharmaceuticals which is herein referred to as UPP. However, landfilling of untreated UPP is not recommended because of potential pilfering, scavenging, and water contamination problems, and there are major disadvantages associated with UPP incineration which make it a highly undesirable option. Specifically, the use of on-site, local, or regional incineration facilities for UPP disposal is not recommended because of exceptionally high capital and operating costs; difficult and highly complex operational and maintenance requirements; and the need for extensive and costly air pollution control equipment to meet stringent emission standards such as those enacted by the European Union. Also, the use of an off-site, centralized, or commercial incineration facility is very costly and poses problematic UPP collection and transport problems as were encountered during the waste drive campaign. Accordingly, by process of elimination, immobilization followed by landfilling appears to be most viable UPP treatment and disposal option.

Immobilization processes

The aforementioned international publications identify two types of immobilization processes for the treatment and disposal of unwanted pharmaceuticals that are termed "encapsulation" and "inertization." Encapsulation is described as a process whereby wastes are immobilized or solidified to a solid block form within a plastic or steel drum via the addition of a cement mixture or similar product. However, such a process is limited to treating relatively small, discreet volumes of waste, and therefore it is not considered suitable for treating the large volumes of UPP being generated and in quarantine throughout many countries.

Inertization is described as a variant of encapsulation whereby unpackaged UPP are crushed by a "grinder or road roller" and then mixed with specified percentages of cement, lime, and water to produce a solid concrete residue suitable for landfilling. In general, this appears to be the best option for treating the large volumes of UPP generated and in quarantine. However, minimal details are presented to describe the process or the recommended equipment, and no data or documentation is presented or available to justify or substantiate the specified percentages of cement, water, and lime.

Recommended inertization process – solidification/stabilization

Process description

The inertization process described in the various international publications is much more commonly termed a solidification/stabilization (S/S) process and, more specifically, a cement-based S/S process. This process or technology was first used in the 1950s for the solidification and safe disposal of radioactive wastes, and it has since been widely applied for treating a broad range of waste types and categories. In 1980, the US Environmental Protection Agency (US EPA) identified S/S as an acceptable, viable means for treating various types of hazardous waste.

Although the terms solidification and stabilization sound similar, they describe different mechanisms used to immobilize waste constituents of concern. Solidification refers to changes in the physical properties of a waste and includes such changes as an increase of compressive strength, a decrease of permeability, and the encapsulation or fixation of hazardous constituents. Stabilization refers to chemical changes of hazardous constituents and includes such changes as conversion of the constituents to a less soluble, mobile, or toxic form.

In essence, S/S technology involves the thorough intermixing of waste, such as UPP, with Portland cement, water, and aggregate materials such as rock, sand, or clay thereby yielding a solid, inert, stable product or residue that is considered safe for disposal in a conventional, general, or sanitary type landfill. The quality of residues from S/S applications, including consistency and structural properties, can vary widely depending on the nature and characteristics of the waste being treated and the ratios or percentages of cement, water, aggregate, and other additives used during processing operations. The determination of optimum process ratios or the best percentages of water and cement to be added to the waste or UPP, and the possible need of various additives for processing wastes of varying types, compositions, and characteristics are typically derived from local or site-specific bench scale testing.

Recommended S/S system & equipment

On the surface, cement-based S/S is a simple process comprising a few basic components; mainly a granulator for rendering the UPP unrecognizable by breaking it down into small particle sizes and a processor unit for thoroughly intermixing UPP with cement, water, aggregate, and other additives to render a stable residue safe for handling and general landfilling. However, in order to effectively process large volumes of UPP such as those generated and in storage in most countries in a controlled, reliable manner and under safe operating conditions, a cement-based S/S system should also comprise a number of other components all of which should be fully integrated as a well-designed system. Such additional components include the following:

- An automated materials handling system comprising a hopper and hopper dumper for loading granulated UPP, cement, and additives into the processor unit;
- An automatically controlled water feed system;
- A fugitive dust-control system integrated with granulator operations; and
- A centralized controls and instrumentation system for operating the complete system through a centralized main panel.

Cement-based S/S systems have a number of very substantial advantages when compared to other potentially viable technologies for treating large volumes of UPP as follows:

- Very low capital and operating costs;
- Easy to operate and maintain;
- Negligible, if any, adverse effects or impacts on the environment and public health;
- Minimal space and infrastructure requirements; and
- Complete systems can be procured, installed, and made fully operational within a very short time period.

Treatability & demonstration testing program

Test program & objectives

Although cement-based S/S is a recognized and long-proven waste treatment technology, published data on the application of this technology for treating pharmaceutical type waste are scanty, of negligible value, and include no referenced sources or performance data for percentages of concrete, water, and other additives recommended therein. Accordingly, it was deemed necessary that treatability and demonstration testing be conducted using this technology for processing representative UPP materials and with the basic components as described and recommended above. Specifically, such testing was considered necessary both for verifying and demonstrating proof-of-concept and for deriving important operational and performance data for determining and evaluating the following:

- Operational characteristics and potential issues of concern related to the UPP granulation process;
- System, equipment and component selection, design, and sizing criteria for processing and effectively treating UPP at a selected rate or capacity;
- The proper or optimum ratios and respective usage rates of Portland cement, water, aggregates, and other additives as needed for attaining treated residues of acceptable quality and having varying degrees of structural properties; and
- Quantification and qualification data of treated UPP residues such as residue density and volumes, discharge properties and consistency, curing times, ease of handling, and other relevant information.

Residue quality criteria

The primary purpose of using a cement-based S/S system for UPP treatment would be to render it to a product residue that is considered safe and suitable for general handling purposes and landfill disposal. Accordingly, a key step before commencing with the testing program was to establish criteria or qualities of residues discharged from the various test runs that would be considered sufficient for achieving that purpose. In turn, such criteria served as the basis for evaluating and determining proper or optimum percentages or ratios of concrete, water, and additives that should be added during processing.

It was known before testing that a S/S system, as recommended, would render UPP unrecognizable because of the granulation process followed by the thorough intermixing of finely granulated UPP with cement and other additives. However, it was also known that adding either excessive or inadequate quantities of cement, water, and/or additives during processing would either result in residues having unacceptable qualities or inefficient operations. As examples,

adding excessive cement and/or additives would generate excessive residue volumes for disposal and would be wastage of resources, and adding insufficient cement and/or additives could generate unstable or difficult to handle residues. In consideration of these variables, the following criteria were identified as the basis for evaluating the effectiveness of the various test program runs:

1. Residue handling criteria

This criterion relates to the physical properties or characteristics of the concrete-like residues discharged from the S/S processor with respect to general handling purposes and for ease of containing, working, and forming it into selected shapes. In concrete handling operations this is typically termed workability and it is typically taken to mean the degree of wetness.

The percentages or ratios of water and sand are the two main factors affecting residue workability. If too much water is added, the residue would be too wet or of a soup-like consistency whereby it would be difficult to contain and handle. If too much sand or aggregate and/or too little water are added, the residue would be too dry and of too dense of a consistency for ease of handling. Accordingly, residue handling criteria is strictly subjective and, for purposes of the testing program, it was based on empirical experiences as to what is considered acceptable concrete workability.

2. Residue stability criteria

This criterion relates to the structural integrity or the compressive strength of the residues upon drying or curing. Stability criteria were generally defined and evaluated for residues of two extremes; namely, those having high structural qualities and those having minimally acceptable qualities. These are discussed below.

a. High structural quality residues

This refers to residues having high compression strength or high structural properties such that they potentially could be solidified to a block-like form for possible use in construction type activities. The compression strength identified as being minimally acceptable was 2,500 PSI (175.8 kg/cm²) based on criteria specified in the International Building Code.

b. Minimal acceptable quality residues

This refers to residues that would be considered sufficiently stable and suitable for handling and general landfill disposal, but with structural properties being of no particular importance. Residues were deemed to have this criteria if they were found to have a consistency comparable to that for a relatively high grade soil cement, whereby they would be capable of being formed or slightly compressed to achieve some degree of rigidity if so desirable. Soil cement is a construction-quality material that is capable of

being compacted to a high density, and it is commonly used in road construction and pipe bedding as a sub-base layer.

In construction applications such as use in road bedding, soil cement is subject to specific ASTM Standards. However, it should be noted that residues categorized during the testing program as having minimal acceptable qualities were not evaluated or tested with respect to conformance with any particular strength criteria or soil cement standards. If so desired for any particular facility or application, site-specific bench scale testing and analysis could be conducted to determine or verify a compositional mixture that would provide residues having construction-quality properties in conformance with published soil cement standards.

Testing facility

The facility selected for testing was Maxon Industries, Inc., in Milwaukee, Wisconsin (Maxon). Maxon is a prestigious, nationally-prominent firm founded in the 1930s that designs and manufactures a complete line of systems and equipment for mixing, transporting, remixing, conveying, and placing concrete. Maxon also designs and manufactures a specialty line of pharmaceutical waste processing systems that combine granulation with cement-based S/S. A copy of Maxon's Pharmaceutical Waste Processing System brochure for their MAXPRO SPU unit is included in the Appendices.

It was determined and verified that Maxon had the necessary testing equipment in place, as well as extensive experience in conducting pertinent and comparable bench-scale and demonstrating testing programs. Accordingly, Maxon was awarded a contract to provide the requisite testing program based upon a quote submitted in response to a request for proposal that described program requirements in detail.

Primary testing equipment

Testing equipment at the Maxon facilities basically included the following:

- A high-speed, rotary drum type granulator with cutting knives, a particle sizing screen, a Plexiglas loading hopper, a motor drive, and a bottom collection bin;
- A 16 cu-ft (0.45 m³), electrically driven, portable processor mixer unit for bench scale testing; and
- A one cu-yd (0.77 m³) processor unit (MAXPRO SPU Model 2.0) for full-scale demonstration testing.

Test capsules & tablets

To replicate actual UPP processing to the extent possible and at a sufficiently large rate to be representative of the capacity of a recommended processing system, it was first necessary to obtain bulk quantities of capsules and tablets, collectively termed "pills," for testing that would be sufficiently representative of UPP to be processed in most countries. Initial efforts involved contacting various pharmaceutical firms and contract pill manufacturing firms to see if unusable or off-specification pills were obtainable, but those efforts were not successful due to product liability concerns. Subsequent efforts involved the solicitation of quotes from contract pill manufacturers for purchasing as much as 500 lb (222.8 kg) of placebo capsules and tablets. Very few of such manufacturers had an interest in making such a small quantity of pills, and quotes from those that were interested were far too costly for consideration.

Eventually, an order was given to Makers Nutrition, a vitamin and food supplement vendor located in Hauppauge, New York, to manufacture and ship 450 lb (204.1 kg) of placebo pills to Maxon. The pills were entirely comprised of fillers such as microcrystalline cellulose and rice flour. The tablets were in the shape of a standard adult multivitamin tablet, and the gelatin capsules were standard 00 size. The shipment to Maxon comprised 18 cases containing about 150,000 capsules and about 153,000 tablets.

Testing program summary

Testing was conducted at the Maxon facilities between May 5, 2015, and June 18, 2015. This was followed by 28 days of curing of test cylinders collected during the test runs for compression or strength testing by an independent materials testing laboratory.

Test additives

Additives or materials used during bench scale and full-scale testing included the following:

- Size No. 2 coarse aggregate or rocks which are defined as having a nominal size range of 1.5-in to 2.5-in (3.8-cm to 6.4-cm);
- Pre-packaged, ready-mix, high-strength, 4,000 psi (281.2 kg/m³) concrete;
- Set accelerator or accelerant for strength improvement and accelerated curing time;
- Corn starch as an additive to placebo pill mixes during various test runs as needed to reduce the percentages of cellulosic sugar and to better replicate typical UPP compositions;
- Washed sharp sand which is sand that has been washed of impurities, such as clays and salts, and which is comparable to beach sand whereby the sand grains are angular in shape; and

Bentonite for use as a clay-like material to replicate the use of local indigenous materials.

Specification sheets for the concrete, accelerant, and corn starch are included in the Appendices.

Testing program details

The testing program comprised four parts; namely,

- 1. Granulation testing,
- 2. Initial bench scale testing,
- 3. Full-scale demonstration testing, and
- 4. Post demonstration bench scale testing.

The bench scale and full-scale testing program comprised a total of 12 separate runs with each run involving different combinations, weights, and ratios of placebo pill mixes and additives. The runs were given identification (ID) numbers with initial bench scale testing run Nos. 101.1 through 102.3; with demonstration testing run Nos. 103.1 through 103.3 and with post demonstration bench scale run Nos. 104.1 through 104.4. Values for the feed rates of placebo pills and other products, aggregates, water, and additives, as well as for resultant residues and test laboratory results for each of the 12 runs are summarized on Exhibit 1.

The Appendices include detailed descriptions and dates for the entire testing program and for each test run, as well as photographs, specification sheets for various additives, testing laboratory report results, and a PowerPoint presentation of testing as prepared by Maxon.

The following is a general description and overview summary of the testing program.

1. Granulation testing & findings

Granulation testing basically involved loading the granulator unit with varying ratios of placebo tablets and capsules. The main objective of this testing was to evaluate the capabilities and effectiveness of the granulator for crushing or breaking down the placebo pills to nominal particle sizes of about 0.125-in (0.32-cm), within a relatively short time period and without significant operational problems. Primary findings of the granulation testing are as follows:

a. When loaded into the granulator in controlled quantities the pills were granulated finely to about the target particle size and within a matter of seconds regardless of the

compositional mixture of tablets and capsules. This accordingly served to demonstrate the viability of using a mechanical granulator for pill disfigurement and size reduction prior to S/S processing.

- b. When capsules were loaded into the granulator in increasingly higher concentrations and quantities their outer gelatin casings tended to block over or plug the granulator sizing screen, thereby slowing down or temporarily interrupting the process and necessitating manual intervention to clear the screen. It was obvious that this problem was due to limitations of the granulator being used; i.e., it was a basic unit that had not been specifically designed or selected for the application. Based on observations, this problem can readily be prevented by a combination of using a larger sizing screen, a higher capacity granulator drive motor, and by providing jogging or reversing capabilities for the granulator rotor assembly.
- c. It was determined that the granulator unit should not be loaded when it is in operation or under rotation, but only when idle and stopped. Failure to do so would enable partially granulated pills to be ejected outward, thereby posing potential worker hazards and cleanup problems.
- d. It appears necessary to provide a dust collection system to control fugitive emissions or discharges of finely granulated UPP into ambient areas during granulator operations. However, it is possible that such emissions could also be minimized to acceptable levels by other means such as by the use of a lower speed, higher torque granulator.
- e. Two test runs (Nos. 104.1 and 104.2) were performed using packaged, unopened, over-the-counter pharmaceutical products of various types, sizes, and packaging materials, and all of the products were successfully granulated to about the same fine particle size as the placebo pills and within about the same time period.

2. Initial bench scale testing & findings

The primary purpose of initial bench scale testing was to preliminarily evaluate the effectiveness of using various proportions or percentages of cement, water, aggregate, and other additives for intermixing with granulated placebo pills during full-scale demonstration testing. The initial objective was to determine the best or optimum ratios of pills, cement, and water that would result in residues having high structural qualities and which could potentially be solidified to a block-like form for possible use in construction activities. To that end, bench scale as well as full-scale demonstration testing also included the collection of residue samples in test cylinders that were sent to an independent materials testing laboratory for compression stress or strength testing using ASTM Standard Methods. Additionally, a

form box was used to collect and solidify residues from various test runs into block shapes measuring 8-in by 8-in by 12-in (0.20-m by 0.30-m) for assessing and demonstrating the use of such forms as an operational option.

Initial bench scale testing comprised five runs which are summarized below.

a. The first two bench scale test runs (Nos. 101.1 and 101.2) involved the processing of placebo pill batches using pill to cement ratios of two extremes; namely, the first used a very low pill to cement ratio and the second used a much higher pill to cement ratio. The resultant solidified residues from both runs were found to be suitable for landfill disposal, but both were found to have insufficient strength for possible use in construction type activities.

The curing or setting times for the residues from the two initial runs were found to be exceedingly long and took well beyond 24-hours. The reason for this was concluded to be the high concentrations of cellulosic fillers in the placebo pills which, acting like sugars, inherently retard curing times and reduce the structural properties of concrete. Accordingly, to offset this problem, a set accelerator, or accelerant, was added to the process mixtures for the next three bench scale test runs and the three full-scale demonstration test runs.

In addition, corn starch was added to process mixtures for one of the initial bench scale test runs and two of the full-scale demonstration test runs to better replicate typical UPP compositions and to reduce sugar-like concentrations of cellulosic fillers in the placebo pills. Corn starch is commonly used in pill manufacturing as a tablet binder, as capsule filler, and as a disintegrant in concentrations of up to 75 percent or more.

b. The next three bench scale test runs (Nos. 102.1 through 102.3) served to evaluate the effectiveness of using process mixtures comparable to that of the first run but with accelerant and corn starch added. The solidified residues from these runs were found to be suitable for landfill disposal, but none of the residues were found to have sufficient strength for possible use in construction type activities. Also, the discharged residues from the first two of these runs (Nos. 102.1 and 102.2) were found to have an overall consistency that was either too wet or too dry for general handling purposes.

The residue from the third of these runs (No 102.3), which involved the addition of corn starch and a liquid accelerant, was found to be of an acceptable quality for general handling purposes. It was also determined to have an appreciable strength value that provided a key indicator as to the best compositional ratios to be used during full-scale demonstration testing.

3. Full-scale demonstration testing & findings

Demonstration testing comprised three runs (Nos. 103.1 through 103.3) whereby each involved the processing of 100 lb (45.4 kg) of test product, or placebo pills, to simulate the large volumes of UPP to be treated and disposed throughout most countries. Each of these runs had equal percentages, by weight, of capsules and tablets, but corn starch was added to comprise 25 percent and 50 percent, by weight, of the total test product mix for the second and third runs. The percentages of sand and aggregate were the same for the three runs, but less cement and water were added for the third run.

The total processing time for each run was about 20 minutes, and the resultant residues from each run were found to be acceptable for general handling and placing into forms, as well as for landfill disposal. Additionally, the structural or compression strength of the residues from the three runs, based on the analysis of two test cylinders for each, ranged from about 2,700 psi to about 4,400 psi (189.8 to 309.4 kg/cm²) which are considered more than suitable for use in residential and commercial type construction activities where the acceptable strength range is 2,500 to 4,000 psi (175.8 to 281.2 kg/cm²). In short, the full-scale test runs sufficiently demonstrated and verified proof-of-concept for the recommended S/S treatment technology.

4. Post demonstration bench scale testing & findings

Four additional bench scale testing runs were conducted after full-scale demonstration testing (Nos. 104.1 through 104.4). The objectives of these were two-fold; namely, to determine process ratios that would provide residues having minimal acceptable qualities, and to evaluate the capabilities of treating fully packaged pharmaceutical products using the recommended treatment technology. These are discussed and summarized as below.

a. Testing for minimal acceptable quality residues

Two bench scale test runs (Nos. 104.3 and 104.4) were conducted to determine and verify process compositional ratios that would result in residues that would be considered stable and suitable for handling and general landfill disposal as described above under the criteria for minimal acceptable quality. The basic objective of these two runs was to determine the lowest quantity or percentage of cement that could be used for processing UPP with only adding low grade, indigenous sand, and/or clay as an aggregate. The residue quality for the first of these runs (No. 104.3) was too dry for general handling purposes, but residue from the last run (No. 104.4) was found to be acceptable for general handling purposes and of a consistency comparable to relatively high-grade soil cement.

b. Testing of packaged pharmaceutical products

Two bench scale test runs (Nos. 104.1 and 104.2) were conducted using an assortment of over-the-counter pharmaceutical products in various sizes and with different packaging materials including both foil and plastic blister packs. The resultant residues from both runs were found to meet the criteria for minimal acceptable quality very comparable to the residues from the test runs involving placebo pills with similar additives and compositional ratios. However, it appears almost certain that high structural quality residues could be attained if process ratios comparable to those used during full-scale demonstration testing were applied.

These findings indicate that it is not particularly necessary for UPP to be removed from packaging and containers for successful processing via the recommended S/S technology. However, it is recognized and understood that factors such as concerns over potential pilferage and black or gray market resale may dictate the need for removing UPP from original packaging.

Test program summary & findings

Test result summary

Exhibit 1 includes a tabulated summary of the tested UPP products and mixtures, additives, and the results reported for each of the bench scale and full-scale test runs as discussed above and as shown in detail in the Appendices.

Residue quality options

As discussed above, the testing program not only served to demonstrate and document the suitability of cement-based S/S applications for treating large volumes of UPP, but also to identify the ratios and usage rates of Portland cement, water, aggregate, and other additives needed for attaining residues having widely different qualities as defined above in Section 3.2.2; namely, those having high structural qualities and those having minimally acceptable qualities.

The values shown tabulated on Exhibit 1 for the three full-scale demonstration testing runs, Nos. 103.1 through 103.3, are representative of S/S operations to attain high structural quality residues, and the values shown tabulated for the last bench scale test run, No. 104.1, are representative of S/S operations to attain residues having minimal acceptable qualities.

It should be noted that the cement, water, and aggregate and additive values or process ratios determined during the testing program should not be considered exact or precise to be used, applied, or relied upon for any particular application or for any particular UPP type, composition of mixture. Instead, they should be considered reasonably accurate and acceptably representative values for guidance and for planning purposes. Bench scale testing should be used for any particular local S/S system installation to assess the best process ratios for differing or unusual UPP types, products, or compositions.

Consumables requirements & usage estimates

As indicated in Exhibit 1, there are substantial differences in consumable or additive requirements and usages for attaining residues having high structural qualities versus those having minimal acceptable qualities. For illustration and comparison, the process additive values for the three full-scale demonstration runs were averaged as being representative and reasonably accurate of process ratios for high structural quality residues, and the process additive values for bench scale test 104.4 were assumed reasonably accurate and representative or typical of process ratios for attaining minimal quality residues. Using these values, Table 1 presents an estimate of consumable or additive usage requirements for attaining residues of each quality per ton (tonne) of UPP processed.

Table 1Estimated additive requirements & consumption rates per ton (tonne) of UPP processed

	LINUTO	HIGH STRUCTURAL QUALITY RESIDUES	MINIMAL ACCEPTABLE QUALITY RESIDUES
PROCESS ADDITIVES	UNITS	USAGE PER TON (TONNE) OF UPP	USAGE PER TON (TONNE) OF UPP
Cement	Lb (Kg)	5,800 (2,368)	1,470 (600)
	60 lb bags	95	25
Rock	Lb (Kg)	15,600 (6,368)	0
Sand	Lb (Kg)	10,400 (4,245)	4,400 (1,796)
Accelerant	Gal (L)	30 (122)	0
Bentonite (Clay)	Lb (Kg)	0	2,900 (1,184)
Water	Gal (L)	380 (1,555)	75 (307)

Cost estimate comparison

Table 2 presents a comparative estimate of the costs for processing one ton of UPP for attaining residues of each quality range exclusive of costs for operating labor and power generation. The indicated costs are based on the consumption rates shown tabulated in Table 1.

Table 2
Comparative budgetary cost estimates per ton of UPP processed

PROCESS	UNIT COSTS		URAL QUALITY ESSING COSTS	MINIMAL ACCEF RESIDUE PROC	
ADDITIVES	(USD)	USAGE PER TON OF UPP	COSTS PER TON OF UPP	USAGE PER TON OF UPP	COSTS PER TON OF UPP
Cement	\$0.05/lb	5,800 lb	\$290.00	1,470 lb	\$73.50
Rock	\$14/ton	15,600 lb	\$109.00	0	0
Sand	\$12/ton	10,400 lb	\$62.40	4,400 lb	\$30.80
Accelerant	\$2/ gal	30 gal	\$60.00	0	0
Bentonite (Clay)	\$35/ton	0	0	2,900 lb	\$52.50
Water	\$2/1,000 gal	380 gal	\$0.57	75 gal	\$0.11
Total Cost per Ton	of UPP Processe	ed	\$232.17		\$83.11
Total Cost per Lb or	f UPP Processe	d	\$0.12		\$0.04

The cost values shown above on Table 2 indicate that it is about three times more costly to generate treated residues having high structural qualities as compared to generating residues having minimal acceptable qualities.

Process time estimates

The total process times required for each of the full-scale demonstration test runs averaged about 20 minutes which consisted of about 10 minutes for initial start-up and process loading, about 5 minutes for process mixing, and about 5 minutes for the discharge or removal of treated residues. However, it should be noted that demonstration testing runs were limited to processing a batch of about 100 lb (45.4 kg) of product per run and, therefore, significant stoppage was required between runs to allow for end-of-run cleanup and the set-up for subsequent runs. During operations at actual S/S installations, UPP loadings would not need to be completely stopped for extended times between batch loadings, but about 15 minutes would be needed after each batch process load in order to discharge and collect residues from each batch into form boxes.

a. Process rate estimates for high structural quality residues

Based on test data results and assuming a processor unit having a nominal one cu-yd (0.76 m³) loading capacity, two 100 lb (45.4 kg) batches or about 200 lb (90.7 kg) per

hour of UPP could be processed with the goal of attaining a residue having high structural properties. At this rate, and conservatively allowing about one hour for system start-up and pre-load container handling plus about one hour for end-of-day system shutdown and cleanup operations, about 12 batch loads could be processed over a normal 8-hour shift of system operation. This equates to processing about 1,200 lb (544.3 kg) of UPP per day of operation. At an average pill density of about 40 lb/cu-ft (640.7 kg/m³), this equates to processing about 30 cu-ft (0.9 m³) of UPP per day of operation.

b. Process rate estimates for minimal quality residues

Again, based on test data results and assuming a processor unit having a nominal one cu- yd (0.76 m³) loading capacity, about 350 lb (158.8 kg) of UPP can be loaded into the processor unit for each batch and up to about two batches or about 700 lb (317.5 kg) per hour of UPP could be processed with the goal of attaining a residue having minimal acceptable properties. Likewise, conservatively allowing about one hour for system start-up and pre-load container handling plus about one hour for end-of-day system shutdown and cleanup operations, about 12 batch loads could be processed over a normal 8-hour shift of system operation which equates to processing about 4,200 lb (1,905.0 kg) of UPP per day of operation. At an average density of about 40 lb/cu-ft (640.7 kg/m³), this equates to processing about 105 cu-ft (3.0 m³) of UPP per day of operation.

Residue quantities & form requirements

a. High structural quality residue quantities

Based on test data results for using a process mix to attain high structural quality residues, the processing of each 100 lb (45.4 kg) batch load of UPP would result in about 1,700 lb (771.1 kg) of such residues. At an average residue density of 150 lb/cu-ft (2,402.8 kg/m3), this equates to a residue volume of about 11 cu-ft (0.3 m3) per batch load of UPP.

The processing of 1,200 lb (544.3 kg) of UPP per operating day for attaining high structural quality residues, as described above under Process Rate Estimates, would result in about 20,400 lb (9,253.3 kg) of such residues per day of operation, and this is equivalent to about 136 cu-ft (3.9 m3) of residues per day of operation.

Assuming that these residues were collected within form boxes and that the weight of each block of solidified residue should be no more than about 65 lb (29.5 kg), each block would need to be formed to a size of about 0.43 cu-ft (0.012 m3), and about 315 blocks of this size would be generated per day of operation.

b. Minimal quality residue quantities

Based on test data results, using a process mix to attain minimal acceptable quality residues, the processing of each 350 lb (155.8 kg) batch load of UPP would result in about 2,120 lb (961.6 kg) of such residues. At an average residue density of 150 lb/cu-ft (2,402.8 kg/m3), this equates to a residue volume of about 14 cu-ft (0.4 m3) per batch load of UPP.

The processing of 4,200 lb (1,905.9 kg) of UPP per operating day for attaining minimal quality residues, as described above under Process Rate Estimates, would result in about 25,440 lb (11,539.4 kg) of residues per day of operation, and this is equivalent to about 170 cu-ft (4.8 m3) of residues per day of operation.

Minimal quality residues need not be compacted and could be collected loose in any manner or in forms of any particular size for convenient handling after they have sufficiently cured or dried. However, if they were to be collected within form boxes comparable to that described above for high structural quality residues with each block weighing no more than about 65 lb (29.5 kg), about 390 of such blocks would be generated per day of operation.

Other potential pharmaceutical waste processing applications

As discussed above, US EPA reports and many other technical publications have documented and confirmed the acceptability of cement-based S/S for treating a wide array of hazardous waste of virtually all types, compositions, and characteristics. These have included waste containing toxic chemicals, heavy metals, disposed pesticides and herbicides, and a myriad of volatile and semi-volatile compounds. These have also included such waste in many forms including solids, sludges, and liquids in a wide range of concentrations. Accordingly, it appears that a cement-based S/S technology should be readily capable of treating or processing virtually every type of pharmaceutical waste with a resultant residue suitable for safe handling and disposal in a general landfill. Also, based on the test program results discussed above involving the processing of fully packaged over-the-counter pharmaceutical products, it appears that this technology does not require UPP to be removed from packaging prior to processing.

There appear to be only two limitations or restrictions to the use of this technology for treating pharmaceutical waste. The first includes the processing of UPP in metal containers, such as certain inhalants or breathalyzers, or in very hard or ridged containers that could cause damage or stoppage of the granulator blades. The second includes the processing of UPP that are considered or defined as being acutely toxic, such as antineoplastic drugs, because the handling of such products poses unacceptable occupational exposure risks.

Summary of findings

The key findings or conclusions of the UPP testing program as described herein are as follows:

- 1. It successfully demonstrated the viability of using a cement-based S/S technology for processing UPP and rendering it suitable for safe handling and disposal in a general landfill.
- 2. It demonstrated the ability of cement-based S/S systems to process large volumes of UPP at a high rate or capacity so as to be considered suitable for the large quantities of UPP generated and in quarantined storage in most countries.
- 3. It provided important, well-documented information and data for use in the design of a cement-based S/S system and associated components for best ensuring reliable, trouble-free operations, and optimum performance when processing UPP.
- 4. It provided essential operational data of requirements for processing UPP for attaining residues of having widely varying qualities ranging from those having high structural qualities to those having minimally acceptable qualities. Such operational data included the optimum ratios and respective usage rates of Portland cement, water, aggregates, and other additives.
- 5. It provided important information with respect to the quantities, discharge rates, and characteristics of residues that would be collected, formed, and handled for different UPP process rates and for attaining residues of both high structural and minimal qualities.
- 6. It demonstrated that a cement-based S/S technology could be effectively used to process both unpackaged and fully packaged UPP to residues having nearly identical qualities.

Exhibit 1

Solidification/stabilization test result summary - unusable pharmaceutical product (UPP)

Testing Conducted at Maxon Industries Facilities, Milwaukee, WI, May 5 through June 18, 2015

		BENCH SC	SCALE (PRE-E	EMONSTRAI	ALE (PRE-DEMONSTRATION) TESTING UNITS	SUNITS	DEMON	DEMONSTRATION TESTING	ESTING	BENCH SC	BENCH SCALE POST-DEMONSTRATION TESTING	MONSTRATIO	N TESTING
SON Q		101.1	101.2	102.1	102.2	102.3	103.1	103.2	103.3	104.1	104.2	104.3	104.4
PHARMACEUTICAL PRODUCT TESTED	TESTE												
Capsules	೨	3.40	10.00	3.40	3.40	1.70	50.00	38.00	25.00	-	1	6.80	6.80
Tablets	요	3.40	10.00	3.40	3.40	1.70	50.00	37.00	25.00		•	6.80	6.80
UPP Mixture	೨	6.8	20	6.8	6.8	3.4	100	75	50	6.8\a	6.8\a	13.6	13.6
Starch (Additive)	ವಿ	0	0	0	0	3.4	0	25	50	0	0	0	0
Total Quantity Tested	Q	6.8	20	6.8	6.8	8.9	100	100	100	6.8 \a	6.8\a	13.6	13.6
Total Volume Tested \b	cu-ft	0.2	0.5	0.2	0.2	0.2	2.4	2.4	2.4			0.3	0.3
PROCESS ADDITIVES													
Cement	೦	10	10	10	10	10	344	324	200	10	5	5	10
Water	gal	-	2.25	-	-	-	20	20	17	-	0.5	0.5	0.5
Structure Accelerant	gal	0	0	0.25	0.25	0.25	1.5	1.5	1.5	0.25	0	0	0
Rock (Aggregate)	2	30	30	30	30	30	780	780	780	30	15	0	0
Sand	೭	20	20	20	20	20	520	520	520	20	10	30	30
Bentonite (Clay)	೨	0	0	0	0	0	0	0	0	0	0	30	20
Total Sand & Aggregate	ವಿ	20	90	90	90	90	1,300	1,300	1,300	20	25	09	50
PRODUCT TEST RESULTS													
Residue Handling Quality		Acceptable	Acceptable	Too Dry	Too Wet	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Acceptable	Too Dry	Acceptable
Slump Test Values (Est)	ï	3 to 5	3 to 5	1 to 2	10	4 to 6	3 to 5	9.2	9	3 to 5	3 to 5	p/	p/
No. of Test Cylinders		1	1	1	1	1	2	2	2	1	1	0	1
Strength Value No. 1	PSI	2,080	0	0	0	1,200	4,430	4,140	3,000	0	0	-	0
Strength Value No. 2	PSI						3,300	2,940	2,720				
FINDINGS													
Suitable for Structural Use		Z	Z	Z	Z	Z	У	У	У	Z	Z	Z	Z
Suitable for Land Disposal		>	>	>	\	\	>	>	>	\	>	\	>
a Over-the-Counter, boxed and containerized pharmaceutical mixture	contain	erized pharma	aceutical mixtu	Je Je									

VerTrie-Volutier, boxed and contamentation prior recognism.

\text{No Volume prior to granulation; capsules @ 21.5 lb/cu-ft and tablets @ 60 lb/cu-ft}

\text{Volume prior to granulation; capsules @ 21.5 lb/cu-ft and tablets @ 60 lb/cu-ft}

\text{Volume prior to granulation; capsules @ 21.5 lb/cu-ft and tablets @ 60 lb/cu-ft}

\text{Volume prior to granulation; capsules @ 15 lb/cu-ft and tablets only to provide low-strength, compactable residues comparable to a soil cement that is suitable for landfilling

\text{Volume prior to granulation}

Exhibit 1.1: Metric Values

Solidification/stabilization test result summary - unusable pharmaceutical product (UPP)

Testing Conducted at Maxon Industries Facilities, Milwaukee, WI, May 5 through June 18, 2015

		BENCH	SCALE (PRE-D	BENCH SCALE (PRE-DEMONSTRATION) TESTING UNITS	ION) TESTING	S UNITS	DEMON	DEMONSTRATION TESTING	STING	BENCH SC,	BENCH SCALE POST-DEMONSTRATION TESTING	MONSTRATIO	N TESTING
ID NOS.		101.1	101.2	102.1	102.2	102.3	103.1	103.2	103.3	104.1	104.2	104.3	104.4
PHARMACEUTICAL PRODUCT TESTED	CT TESTED												
Capsules	kg	1.54	4.53	1.54	1.54	72.0	22.65	17.20	11.30	1	1	3.08	3.08
Tablets	kg	1.54	4.53	1.54	1.54	0.77	22.65	16.80	11.30	-	-	3.08	3.08
UPP Mixture	Вy	3.08	90'6	3.08	3.08	1.54	45.3	34	22.7	3.08\a	3.08 \a	6.16	6.16
Starch (Additive)	kg	0	0	0	0	1.54	0	11.3	22.7	0	0	0	0
Total Quantity Tested	kg	3.08	90.6	3.08	3.08	3.08	45.3	45.3	45.3	3.08 \a	3.08 \a	6.16	6.16
Total Volume Tested \b	m-no	900:0	0.014	900:0	0.006	900:0	0.067	0.067	0.067			0.008	0.008
PROCESS ADDITIVES													
Cement	kg	4.5	4.5	4.5	4.5	4.5	155.8	155.8	9.06	4.5	2.3	2.3	4.5
Water	ı	3.78	8.52	3.78	3.78	3.78	75.70	75.70	64.35	3.78	1.89	1.89	1.89
Structure Accelerant	ı	00:00	00:00	0.95	0.95	0.95	5.68	5.68	5.68	0.95	00:00	00:00	00:00
Rock (Aggregate)	kg	13.6	13.6	13.6	13.6	13.6	353.3	353.3	353.3	13.6	6.8	0	0
Sand	бy	9.1	9.1	9.1	9.1	9.1	235.6	235.6	235.6	9.1	4.5	13.6	13.6
Bentonite (Clay)	бy	0.0	0.0	0.0	0.0	0.0	0:0	0.0	0.0	0.0	0.0	13.6	9.1
Total Sand & Aggregate	kg	22.7	22.7	22.7	22.7	22.7	588.9	588.9	588.9	22.7	11.3	27.2	22.7
PRODUCT TEST RESULTS													
Residue Handling Quality		Good	Good	Too Dry	Too Wet	Good	Good	Good	Good	Good	Good	Too Dry	Good
Slump Test Values (Est)	cm	7.6 to 12.7	7.6 to 12.7	2.5 to 5.1	25.4	10.1 to 15.2	7.6 to 12.7	24.1	15.3	7.6 to 12.7	7.6 to 12.7	Þ	Þ
No. of Test Cylinders		1	1	1	1	1	2	2	2	1	1	0	1
Strength Value No. 1	kg/cm2	146.2	0	0	0	84.4	311.5	291.1	211.0	0	0	-	0
Strength Value No. 2	kg/cm2						232.0	206.7	191.2				
FINDINGS													
Suitable for Structural Use		Z	Z	Z	Z	Z	У	У	у	N	Z	Z	Z
Suitable for Land Disposal		٨	\	\	\	Α	٨	Y	>	\	У	У	\
\a Over-the-Counter, boxed and containerized pharmaceutical mixture	d container	ized pharmac	eutical mixture										

Volume prior to granulation; capsules @ 344.4 kg/m3 and tablets @ 961.1 kg/m3
First run used powder accelerant; remaining runs used liquid accelerant
Slump test values not relevant; test run additives only to provide low-strength, compactable residues comparable to a soil cement that is suitable for landfilling

References

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- 11. *International Building Code*, Chapter 19 Concrete, Section 1904.2, International Code Council, 12th Edition.
- 12. "Procurement Specification for a Cement-Based Solidification/Stabilization System for the Treatment & Disposal of Unusable Pharmaceutical Products," Doucet, L. G., for PFSCM, October 2016.

Appendices

Maxon test report summary & photographs Maxon test result summary

• Attachment 1: PFSCM pharmaceutical waste disposal test results

Maxon test report attachments

- Attachment 2: Details on bulk placebo capsules & tablets
- Attachment 3: GeoTest report results strength test of sample cylinders
- Attachment 4: Details on Sakrete used in various batches
- Attachment 5: Details on set accelerator for concrete
- Attachment 6: Specification sheet on Maxon MAXPRO SPU
- Attachment 7: Details on corn starch
- Attachment 8: Slump test procedures
- Attachment 9: Details on bentonite used in bench scale test 104.3 on 104.4

Maxon PowerPoint presentation

Maxon test report summary & photographs



Dates: May 5th, 2015 to June 18th, 2015

Introduction:

Over a two month period of time, Maxon Industries, on behalf of Hydro Environmental, organized, prepared and tested the destruction and disposal of pharmaceutical waste. The primary testing was conducted at Maxon's facility in Milwaukee. Testing included both bench scale and full scale implementation for both the deconstruction and the disposal of these products.

Location: Maxon Industries, Inc.

3204 West Mill Road Milwaukee, WI 53209

Date: May 5th to June 14th, 2015

1.0 Bench scale testing equipment: To determine the feasibility of full scale pharmaceutical waste disposal, we established a bench scale (small batch, reduced equipment configuration for controlled process) to provide mix design confirmation and product application. Equipment included.



1.1 Crusher: Crusher included a charge hopper with viewing window, primary drum with carbide cutters, screen for particle sizing, and a removable tray for deconstructed pharma waste. Pharma waste is fed into the top, crushed, and collected. Complete unit is electrically powered and includes an optional dust collection system.



1.2 Dust collector: Dust collector used for the bench scale during pilot testing is a 1/3 H.P. dual bag suction. 1 (one) micron dust filter collection bag on top of dust collector, plastic collection bag on bottom.



1.3 Scale: A digital bench scale was used to measure pharma placebos, processed material after crushing, and all other products used as part of mix design.



1.4 Processor: Processor for mixing deconstructed pharma waste with various products for final disposal.



1.5 Test sample: Test cylinders were collected for each mix. Test samples were labeled to coincide with mix design spread sheet.



1.6 Form box: A single form box was built and used to replicate a possible field solution for disposal of the deconstructed and processed pharma waste.

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2.0 Bench scale testing:



- **2.1 Pharmaceutical waste**: PFSCM shipped 450 lbs. of unpackaged placebo tablets and capsules to Maxon. Tablets and capsules were supplied by Makers Nutrition, and consisted of bulk capsules and tablets in cases. The product is intended to simulate pharmaceutical waste.
- **2.1.1 Tablets:** Uncrushed tablets had an approximate bulk density of 60 lbs. per cubic foot.



2.1.2 Capsules: Uncrushed capsules had an approximate bulk density of 21.5 lbs. per cubic foot.



2.1.3 Pharma products: As part of our bench scale testing, we used actual over-the-counter pharmaceutical products including pain relievers and cold medications. Materials came packaged in cardboard boxes, plastic bottles, and blister packs.

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2.2 Crusher: Maxon weighed out 6.8 lbs of waste for processing with the crusher. Objective of the crusher was to reduce the waste from tablet/capsule size, breaking the waste down to .125" nominal size.



2.2.1 Crusher components: The crusher was equipped with a collection hopper at the bottom of the hopper to catch deconstructed pharma waste.



2.2.2 Pharma waste transfer: After the pharma waste was deconstructed, it was transferred to a plastic tote for weighing and processing.

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2.2.3 Pharma weight: Input weights, processing time, and output was recorded. For each lot, we varied the input rate and made adjustments to the crusher and screen to optimize output.



2.3 Pharma waste processing: Once the pharma waste was deconstructed and weighed, it was then processed with cement, sand, aggregate, water, and additives. Shown to the left is the bench scale processor used to mix the pharma waste.



2.3.1 Sakrete: For most tests, pre-packaged ready-mix concrete was used. The Sakrete material selected for this application was Mastercraft 4000 psi concrete mix in 60 lbs. bags. The mix design consisted of 30 lbs. of number 2 rock, 20 lbs. of sand, and 10 lbs. of cement. (See attachment 4 for complete details.)



2.3.2 Set accelerator: In order to improve strength, on some mixes, we used a set accelerator, also known as a superplasticizer or concrete additive, to improve concrete properties. Tests were run both with and without the accelerator. (See attachment 5 for complete details.)

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2.3.3 Mixing process: Depending on the mix design, usually one (1) bag of Sakrete was added to the mixer, then the water in accordance with the test criteria was added. For specific mix designs, see attachment 1 for reports, and section 4 thru 8 of this report for notes on each mix. (See attachment 1 for mix designs)



2.3.4 Mixing time: Prior to adding the pharma waste, the bench scale processor was allowed to thoroughly mix the Sakrete and water. Time averaged 1 minute.



2.3.5 Accelerator: If required, accelerator was added to the processor prior to the introduction of pharma waste.



2.3.6 Pharma waste: Pre-measured weights of pharma waste were then added to the mixer.

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2.3.7 Mixing and discharge: After processor mixed the Sakrete with the pharma waste, the final product was discharged into a wheel barrow.



2.3.8 Test cylinders: Once material was discharged from the processor, test cylinders were collected for further analysis. (See attachment 3 for test results.)



2.3.9: Sample of processed material: Shown to the left is a sample of the processed pharma waste. The material was collected by hand and squeezed into a ball. As shown, the material would hold form, and had no free liquids.



2.3.10 Test cylinder: Shown to the left is both the sample test cylinders used for collecting processed pharma waste, and a form box used to collect pharma waste and replicate field disposal.

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2.3.11 Form box: View of top of form box and processed pharma waste is discharged into form.



2.3.13: Released form box: After 24 hours, the form box was released, exposing the formed blocks of processed pharma waste.



2.3.14: Formed blocks: After being removed from the form box, the formed blocks could be stacked and stored for future disposal. Depending on the mix design, blocks measured 8" x 8" x 12" and weighed 55 lbs.

3.0 Full scale testing equipment



3.0 Full scale testing: With the results of bench testing completed and analyzed, Maxon adjusted the test procedures and scale up testing for a simulated full batch. The equipment used was as close as possible to representing expected field processing, including the use of the proposed crusher, processor, material handling equipment, and formworks.



3.1 Processor: During full scale testing, the small bench scale processor was replaced with a Maxon MAXPRO SPU Processor. The SPU is a 1 cubic yard capacity pharma waste processor. (See attachment number 6 for details.)



3.1.1 Processor: View to the left is from the top, and shows the processor mixer shaft, a full sweep 16 paddle configuration, for complete mixing.

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3.2 Full scale testing: For proof of concept at full scale, material handling equipment was introduced including a skid steer loader and fork lift for both loading and discharge.



3.2.1 Pharma waste: The same pharma waste that was used for the bench scale testing was also used for full scale test. Pharma was placebo tablets and capsules shipped to Maxon in bulk. (See attachment 2 for details on supplier of bulk placebo pharma waste)



3.2.2 Pharma waste: View to left shows capsules.



3.2.3 Loading crusher: View to left shows capsules and tablets being loaded into the crusher in bulk. Material was loaded into the crusher, then the crusher was turned on. Crusher was loaded with approximately 25 lbs. of material at a time.

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3.2.4 Top view of crusher: View looking into crusher.



3.2.5 Operation of crusher: View to left shows crusher in operation, Plexiglas viewing window shows action of crusher with tablets.



3.2.6 Measuring deconstructed pharma waste: After crushing, the pharma waste was weighed.



3.2.7 Measuring deconstructed pharma waste: To establish bulk density of deconstructed pharma waste, material was weighed in a 1/8th cubic foot box and calculated to approximate bulk densities.

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3.2.8 Additional testing equipment: As part of the testing process, mix designs were measured with an ASTM slump cone to determine the workability of the final mix. Also shown in the photo is a Hudson sprayer filled with "Concrete Form Release." The Maxon MAXPRO SPU and the form boxes were sprayed with form release to prevent processed waste from sticking to the surfaces of the equipment.



3.2.9 Maxon MAXPRO SPU: View of the pharma waste processor. Unit is hydraulic drive, 40 H.P., with bi-rotational agitator shaft, and hydraulic operated discharge gate and hoist cylinder.



3.2.10 Maxon MAXPRO SPU: View of the pharma waste processor discharge gate. Gate is shown closed.



3.2.11 Charging MAXPRO SPU: The MAXPRO was charged with a dump hopper and forklift. The dump hopper was used to load the sand and the aggregate.

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3.2.12 Charging MAXPRO SPU: Sand is being loaded into the unit.



3.2.13 Charging MAXPRO SPU: Water was premeasured into five gallon pails and loaded during each batch. Cement was loaded into buckets and premeasured by weight.



3.2.14 Charging MAXPRO SPU: Water was loaded into unit.



3.2.15 Use of starch: The placebo tablets and Capsules were filled primarily with sugar. To better replicate the fillers used in most pharmaceutical prescriptions, we substituted starch for a percentage of the placebo tablets/capsules. Shown here is the starch being pre-measured by weight. (See attachment 7 for details on starch.)

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3.2.16 Deconstructed pharma waste and starch: For each test, both deconstructed pharma waste and starch were pre-measured and containerized for easy and fast loading to the MAXPRO SPU.



3.2.17 Charging MAXPRO SPU: Both the pharma waste and starch were loaded into the MAXPRO SPU manually.



3.2.18 MAXPRO SPU processing: Once materials were loaded into the processor, mixing was initiated for up to five (5) minutes. View shows material after mixing for a few minutes.



3.2.19 Discharging MAXPRO SPU: After complete mixing, processed pharma waste was discharged into the hopper of a skid steer loader.

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3.2.20 Form box and test cylinders: Processed pharma waste was loaded both into yellow test cylinders for further testing and into a form box. Each block in the form box is 8" x 8" x 12" and designed to be liftable once set by hand, and to be stacked for transportation and future disposal. (See attachment 3 for test results on yellow test cylinders)



3.2.21 Processed blocks: View shows the form stripped and the blocks being removed after 24 hours of set time.



3.2.22 Processed blocks: All blocks were labeled and identified by the batch sequence. (See attachment 1 for test sequences 101.0 through 104.4)



3.2.23 Additional processed pharma waste: Maxon only had one (1) set of forms to accommodate 8 blocks. The balance of processed pharma waste was discharged into a form box to make a "Jersey Barrier."

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3.2.24 Additional processed pharma waste: View of block 24 hours after, with the forms stripped.



3.2.25 Slump test: At time of discharge of processed pharma waste, ASTM slump tests were taken of the material to assist in determining the workability of the material after discharge. (See attachment 8 for procedures related to concrete slump tests.)



3.2.26 Slump test: View shows measurement for slump. Slump is recorded in inches, which represents the amount of drop in the wet concrete, when the cone is lifted off the wet concrete. The higher the slump reading, the wetter the concrete, the more the concrete "settles."



3.2.27 Test cylinders: For each batch conducted, test cylinders were sampled from the processed pharma waste. Test cylinders were marked in accordance with the batch sequence, and sent to an independent lab for testing. (See attachment 3 for test results.)

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3.2.28 Test cylinders: View shows several test cylinders cut in half to expose material for further visual inspection and analysis.



3.2.29 Test cylinders: Group of test cylinders, waiting for 28 day curing, before final testing.



3.3.0 Pharma waste testing: After the completion of testing with placebo capsules and tablets and starch, we preformed a test using actual over-the-counter pharma products purchased at the local Walgreens. Material included pain and cold medication, plastic bottles, and blister packs.



3.3.1 Pharma waste testing: All packaging and pharma waste was fed into the crusher. Final product was significantly lighter than previous tests, mostly due to the packaging and related materials. (See Attachment 1, batch 104.1 and 104.2 for results.)

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3.3.2 Pharma waste testing: Bench scale testing was performed on the pharma waste and recorded.



3.4.0 Soil cement batch testing: To replicate field conditions where ideal materials may not be available to make a concrete type output, Hydro Environmental requested us to produce a low cement base material that could be easily reproduced. Instead of concrete quality sand and stone, we used a "dirty sand" (dug straight from the ground, not washed or processed), a low percentage of cement, and bentonite as a substitute for clay. (For test results, see attachment 1, batch 104.3 and 104.4.)



3.4.1 Soil cement with bentonite: For testing purposes, we used bentonite and processed clay to replicate indigenous solidification materials. (See attachment 9 for details on material used.)



3.4.2 Soil cement batch testing: Similar testing procedures were followed for bench scale testing with low percentage cement and bentonite. The material output was dry, could be compressed and disposed of, but could not be formed into a product with strength.

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3.4.3 Soil cement batch testing: View of material after mixing, in wheelbarrow.



3.4.4 Soil cement batch testing: View of material in bench scale processor. Note the "balls." Caution must be used with bentonite or other clay materials.

Maxon test result summary

• Attachment 1: PFSCM pharmaceutical waste disposal test results

PFSCM Pharmaceutical Waste Processing System Test

- **4.0 Crusher tests:** To determine the requirements for the crusher, Maxon performed a series of tests on various pharma wastes and at various capacities to determine the necessary equipment requirements.
 - **4.1 Crusher test 1:** Conducted with capsules only, in small quantities. Results: Not recommended to add pharma waste while crusher is rotating, as it creates flying objects. Stop crusher and load unit, then restart crusher.

Capsules have an approximate bulk density of 21.5 lbs. per cubic foot prior to crushing.

The plastic outer shell of the capsule is light, and does not easily pass through the crusher (has a tendency to float on top of the crusher). Adding more capsules will assist with "pressing" the capsules through the crusher.

4.2 Crusher test 2: Repeated process with capsules, with cover closed and unit stopped.

Results: Fugitive dust is a problem. We added a small one micron 1/3 HP dust collector to the system, and were able to capture all fugitive dust.

4.3 Crusher test 3: Conducted with tablets only, in small quantities. Results: Tablets have an approximate bulk density of 60 lbs. per cubic foot prior to crushing.

Nature of tablets as used created more dust than the capsules. Fugitive dust collection is necessary.

- **4.4 Crusher test 4:** Repeated tablet only test.
- **4.5 Crusher test 5:** Added capsules and tablets together.

Results: Initial crusher tested showed that screen size allowed proper sizing of all material to ensure complete deconstruction of all tablets and capsules. No material was identifiable after crusher.

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5.0 Bench scale testing: After completion of crusher testing, we proceeded to perform bench scale testing to determine the proper mix designs and alternatives for fixation of deconstructed pharma waste.

Bench scale testing was performed with a small 16 cubic foot capacity electric power processor. Mix designs were based on best practices knowledge for industry research and project experience.

5.1 Concrete batch 101.1: First test was with a low ratio of pharma waste to cement. 6.8 lbs. Pharma to 10 lbs. cement.

Results: Without the pharma waste, the mix design should have been a 4,000 psi strength mix design. With the introduction of the pharma waste, the strength was reduced to 2,080 lbs. (See attachment 3, page 1, Spec Nbr. 1). It is possible that with standard pharma waste, with less sugar the strength could be higher.

5.2 Concrete batch 101.2: Second test was with a higher ratio of pharma waste to cement. At 20 lbs. pharma waste to 10 lbs. cement, when we attempted to perform strength tests, we were unable to reach a value. (See attachment 3, page 1, Spec Nbr. 2)

Results: While the material produced was suitable for disposal, it had no significant structural properties.

After performing the first two tests, it was determined that we should consider using a concrete additive to increase strength.

5.3 Concrete batch 102.1: To maintain consistent testing criteria, we used a constant 6.8 lbs. of pharma waste, and varied the remaining materials. In 102.1, we used the same ratio of 6.8 lbs. of pharma waste to 10 lbs. of cement, and we added a box of concrete mix accelerator in power form from Akona (*See attachment 5*).

Results: Power format of accelerator caused final product to be too dry, and not workable (unable to fill the forms easily, and unable to get it into the plastic test cylinders without great effort). When comparing the test results the cylinder failed to gain measureable strength after 28 days (*Attachment 3, page 2, Spec Nbr. 1*).

5.4 Concrete batch 102.2: Again, 6.8 lbs. of pharma waste was used, but a liquid additive was introduced. We held the water at 1 gallon per mix (same as 102.1)

Results: The test cylinder failed. We observed that the material was very wet, indicating that we had too high a water/cement ratio. With the addition of the additive, we could have reduced the water content, and possibly increased the strength of the material. (Attachment 3, page 2, Spec Nbr. 2)

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5.5 Concrete batch 102.3: During this test, we reduced the pharma waste by 50%, replacing it by equal weight of starch. This was done to more closely replicate actual fillers in many pharmaceutical drugs. Reducing the placebo by 50% meant that we reduced the sugar by 50%. Sugar naturally causes concrete to set slower. (See attachment 3, page 2, Spec Nbr. 3)

Results: Keeping all things equal other than the starch versus the placebo pharma waste, we were able to increase the strength of this batch to 1,200 lbs. The mix was still very wet. We believe with further testing, we could reduce the water content, and therefore the water cement ratio, thus increasing the strength of the test cylinders at 28 day test cycle.

- **6.0 Proof of concept testing:** After testing multiple mix designs, we moved forward with full scale proof of concept testing with full scale equipment. Testing was performed with a Maxon MAXPRO SPU 1 cubic yard capacity processor.
 - **6.1 Concrete batch 103.1:** With 100 lbs. of pharma waste, sand, aggregate, and cement, along with additive and water, we produced a full scale mix over a 30 minute period of time. (See attachment 3, page 3, Spec Nbr. 1-2)

Results: With a pharma waste to cement ratio of 1:3.4, we were able to produce a 4,430 lbs. strength concrete. This is more than acceptable for many types of structural concrete applications. With more refining, we could reduce the cement concentration, and the water/cement ratio in order to save cement and reduce the waste output.

We took two cylinder tests: one at 4,430 lbs., one at 3,300 lbs. Further testing would be necessary to determine if the testing interval impacted the spread on strength.

6.2 Concrete batch 103.2: We replaced 25 lbs. of pharma waste with starch, and reduced the waste-cement ratio to 1:3.2 (See attachment 3, page 3, Spec Nbr. 3-4)

Results: Strength was measured at 2,940 lbs. and 4,140 lbs. Again, this mix was still very fluid. The water could be reduced, reducing the water-cement ratio, and increasing the potential strength. While we introduced starch as a product versus placebo pharma waste, we also reduced the cement concentration.

6.3 Concrete batch 103.3: In this test, we used equal amounts of placebo pharma waste and starch, and significantly reduced the amount of cement. (See attachment 3, page 3, Spec Nbr. 5-6)

Results: Of the two cylinders tested, one did not generate enough strength, but the second reached 2,720 lbs, enough to serve as some low grade construction applications. The mix was still workable, yet it would be possible to reduce amount of water, to reach a mix that might approach 3,000 psi (suitable for light traffic applications).

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- 7.0 Bench scale testing: After proof of concept testing, we returned to the smaller processor to test additional mix designs.
 - 7.1 Concrete batch 104.1: To determine the impact of true pharma waste, we purchased a small quantity of over the counter pharma products and ran them through the crusher complete with their packaging. (See attachment 3, page 5, Spec Nbr. 1)

Results: On testing, no strength was recorded. This is probably the result of the paper packaging that we introduced as part of the mix design. We were able to prove that we could run the complete package of pharma waste through our crusher, and process it, without unpacking the drugs.

7.2 Concrete batch 104.2: A second test was performed with actual pharma waste, and reduced cement concentration. (See attachment 3, page 5, Spec Nbr. 2)

Results: Again, no strength was recorded. We were able to create a solid block of deconstructed actual pharma waste that could be disposed of in landfills, that would render the drugs totally unusable and unidentifiable.

- 8.0 Bench scale testing for soil cement consistency: Two additional tests were performed on placebo pharma waste to consider economical disposal options for deconstructed material.
 - **8.1 Concrete batch 104.3:** Using a higher percentage of pharma waste and a very low level of cement, combined with virgin sand and clay, we preformed a bench scale test. (See attachment 3, page 5, Spec Nbr. 3)

Result: We used too high a ratio of clay (bentonite) with the sand, cement, and pharma waste. When we went to mix it, the material "balled" up in the mixer. While this did not prevent mixing and discharge, it did not provide a consistent product output. When we broke apart the "balls," the material was uniform throughout.

8.2 Concrete batch 104.4: We reduced the percentage of clay, and were able to produce a uniform mix. (See attachment 3, page 5, Spec Nbr. 4)

Results: While both tests 104.3 and .4 did not produce any strength, the output material was workable, and could be disposed of by discharging the material into a cardboard box or other disposable container. The material would hold form but break apart easily by hand.

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Conclusion:

After two months of bench and full scale testing, Maxon has been able to identify various possible mix designs to be used in the field, along with proof of concept for bench scale testing and full scale processing of pharmaceutical waste.

Crushing, mixing, and disposal are all feasible with low cost equipment and virgin materials in the host country.

Thank you for the opportunity and your confidence in Maxon Industries, we look forward to working with you in the future.

Prepared and submitted by: Bill Maxon President



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Maxon text report attachments

- Attachment 2: Details on Bulk Placebo Capsules & Tablets (page 51)
- Attachment 3: GeoTest Report Results Strength Test of Sample Cylinders (pages 52-58)
- Attachment 4: Details on Sakcrete Used in Various Batches (pages 59 60)
- Attachment 5: Details on Set Accelerator for Concrete (page 61)
- Attachment 6: Specification Sheet on Maxon MaxPro SPU (pages 62 65)
- Attachment 7: Details on Corn Starch (page 66)
- Attachment 8: Slump Test Procedures (page 67)
- Attachment 9: Details on Bentonite Used in Bench Scale Test 104.3 on 104.4 (page 68)



PACKING SLIP

Prepared By:	JS
Order #:	2193-186
Date:	04/30/15
Customer:	Hydro-Enviro

SHIP TO: Maxon Industries, Inc

Attn: Bill Maxon 3204 W.Mill Rd Milwaukee, WI 53209

Email: bmaxon@maxon.com

PRODUCT	DESCRIPTION	UNIT TYPE	SHIP QTY.
Bulk Placbo Capsules	Bulk Capsules	15 M PER CASE	10
Bulk Placebo Tablets	Bulk Tablets	20 M PER CASE	7
Bulk Placebo Tablets	Bulk Tablets (Partial)	13.4 M PER CASE	1
1			

SPECIFICS	
Packaging:	18 CASES
Capsule Piece Count:	150,000 Bulk
Tablet Piece Count:	153,400 Bulk
WEIGHT:	450 LBS
Carrier:	PICKUP 1 SKID

373 Smithtown Bypass Suite #331 - Hauppauge NY 11788 - P: (844) Makers-1 F:631-456-5398

Attachment 3

 $\bullet \ \ GeoTest\ Report\ Results - Strength\ Tests\ of\ Sample\ Cylinders$



2135 South 116th Street West Allis, WI 53227 414-321-8378 Page 1 of 1

REPORT: Concrete Compression - Contractor Made

LAB NO: 15-3334-1

Test Method: See Below

Project: Maxon Industries - 2015 Lab Testing. Report Date: 07/02/2015
Location: Date Sampled: 05/05/2015
Client: Maxon Industries Incorporated Sampled By: Client

Client: Maxon Industries Incorporated Sampled By: Client
Acct. No: MAXON By Order Of: Client
Client PO: Order Number:

Report No: 15-3334-1 Project No: 4667

Field Results

Lot/Test No.: 101 Mix ID:

Location:

Curing Method: Field Transported By: Client Date Received: 07/01/2015

Time Sampled: Producer:
Temp.: Ambient: Plant:
 Mix: Sampled At:
 Slump: Truck No:
 Air Content: NA Ticket No:

Lab Results

Spec Nbr	Age Tested (date : days)	Diameter (in)	Area (in²)	Maximum Load (lbs)	Break Type	Cure	 Compressive Strength (PSI)	Tested By
1	07/01/15 : 57	4.00	12.566	2,080	Type 2	Fld	170	Ryan Jennaro
2	HOLD							
	Comments: Una	ble to test						
		()))						

Type 6

Type 1 Type 2 Quantity Represented:

Remarks: if material reference value achieved, "hold" specimens automatically discarded at 28 days (unless advised otherwise in advance by client).

Type 5

Test Method (As Applicable): ASTM C31, C39, C138, C143, C172, C231, C1064, C1231; AASHTO T22, T23, T119, T121, R60, T152, T309

Orig: Maxon Industries Incorporated (Milwaukee, WI) Attn: Bill Maxon (1-ec copy)

Respectfully Submitted, GeoTest, Inc.

Andrew Davis, Field Manager

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Type 3 Type 4



2135 South 116th Street West Allis, WI 53227 414-321-8378

Page 1 of 1

LAB NO: 15-3334-2 REPORT: **Concrete Compression - Contractor Made** Test Method: See Below Project: Maxon Industries - 2015 Lab Testing. Report Date: 07/02/2015 Location: Date Sampled: 05/14/2015 Sampled By: Client: Maxon Industries Incorporated Client By Order Of: Client Acct. No: **MAXON** Order Number: Client PO: Report No: 15-3334-2 Project No: 4667

Field Results

Lot/Test No.: Mix ID:

Location:

Transported By: Client Curing Method: Field Date Received: 07/01/2015

Producer: Time Sampled: Temp.: Ambient: Plant: Mix: Sampled At: Slump: Truck No: Air Content: NA Ticket No:

Lab Results

Maximum Rate of Compressive Load Strength Spec Age Tested Diameter Area Load Cure Tested (lbs) (lbs/min) (PSI) Nbr (date: days) (in) (in²) Ву Break Type

Comments: Unable to test

2 **HOLD**

Comments: Unable to test - too soft

3 07/01/15:48 4.00 12.566 1,200 Type 2 Fld 100 Ryan Jennaro

Type 1 Type 2 Type 3 Type 4 Type 5 Type 6

Quantity Represented:

Remarks: if material reference value achieved, "hold" specimens automatically discarded at 28 days (unless advised otherwise in advance by client).

Test Method (As Applicable): ASTM C31, C39, C138, C143, C172, C231, C1064, C1231; AASHTO T22, T23, T119, T121, R60, T152, T309

Orig: Maxon Industries Incorporated (Milwaukee, WI) Attn: Bill Maxon (1-ec copy)

Respectfully Submitted, GeoTest, Inc.

Andrew Davis, Field Manager

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2135 South 116th Street West Allis, WI 53227 414-321-8378 Page 1 of 2

REPORT: Concrete Compression - Contractor Made LAB NO: 15-3334-3 Test Method: See Below

Project: Maxon Industries - 2015 Lab Testing. Report Date: 07/02/2015

Location:

Date Sampled: 06/02/2015 Sampled By: Client Client: Maxon Industries Incorporated

By Order Of: Client Acct. No: **MAXON** Order Number: Client PO:

Report No: 15-3334-3 Project No: 4667

Field Results Lot/Test No.: Mix ID:

Location:

Curing Method: Field Transported By: Client Date Received: 07/01/2015

Time Sampled: Producer: Temp.: Ambient: Plant: Sampled At: Slump: Truck No: Air Content: NA Ticket No:

					Lab Results	8			
				Maximum			Rate of (Compressive	!
Spec	Age Tested	Diameter	Area	Load		Cure	Load	Strength	Tested
Nbr	(date : days)	(in)	(in²)	(lbs)	Break Type		(lbs/min)	(PSI)	Ву
1	07/01/15 : 29	4.00	12.566	4,430	Type 2	Fld		350	Ryan Jennaro
2	07/01/15 : 29	4.00	12.566	3,300	Type 2	Fld		260	Ryan Jennaro
3	07/01/15 : 29	4.00	12.566	2,940	Type 2	Fld		230	Ryan Jennaro
4	07/02/15 : 30	4.00	12.566	4,140	Type 5	Fld		330	Ryan Jennaro
5	HOLD								
	Comments: Una	able to test							
6	07/02/15 : 30	4.00	12.566	2,720	Type 3	Fld		220	Ryan Jennaro
	\times	八八							
	Type 1	Type 2	Type 3 T	ype 4 Typ	pe 5 Type 6				

Orig: Maxon Industries Incorporated (Milwaukee, WI) Attn: Bill Maxon (1-ec copy)

Respectfully Submitted, GeoTest, Inc.

Andrew Davis, Field Manager

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REPORT:	Concrete Compression - Contractor Made	LAB NO: 15-3334-3 Test Method: See Below
Project: Location:	Maxon Industries - 2015 Lab Testing.	Report Date: 07/02/2015 Date Sampled: 06/02/2015
Client: Acct. No: Client PO:	Maxon Industries Incorporated MAXON	Sampled By: Client By Order Of: Client Order Number: Report No: 15-3334-3 Project No: 4667

Quantity Represented:

Remarks: if material reference value achieved, "hold" specimens automatically discarded at 28 days (unless advised otherwise in advance by client).

Test Method (As Applicable): ASTM C31, C39, C138, C143, C172, C231, C1064, C1231; AASHTO T22, T23, T119, T121, R60, T152, T309

Orig: Maxon Industries Incorporated (Milwaukee, WI) Attn: Bill Maxon (1-ec copy)

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Date Received: 07/01/2015

REPORT: **Concrete Compression - Contractor Made** LAB NO: 15-3334-4 Test Method: See Below Project: Maxon Industries - 2015 Lab Testing. Report Date: 07/16/2015 Location: Date Sampled: 06/18/2015 Client: Sampled By: Client Maxon Industries Incorporated By Order Of: Client MAXON Acct. No: Order Number: Client PO: Report No: 15-3334-4 Project No: 4667

> Field Results Mix ID:

Lot/Test No.:

Location:

Curing Method: Field

Time Sampled: Temp.: Ambient: Mix:

> Slump: Air Content: NA

Transported By: Client

Producer:
Plant:
Sampled At:

Truck No: Ticket No:

Lab Results

Maximum Rate of Compressive Spec Age Tested Diameter Area Load Cure Load Strength Tested (lbs/min) (lbs) (PSI) Nbr (date : days) (in) (in²) Break Type Ву

1 HOLD

Comments: Cylinder is unable to be tested

2 HOLD

Comments: Cylinder is unable to be tested

3 HOLD

Comments: Cylinder is unable to be tested

4 HOLD

Comments: Cylinder is unable to be tested

Type 1 Type 2 Type 3 Type 4 Type 5 Type 6

Orig: Maxon Industries Incorporated (Milwaukee, WI) Attn: Bill Maxon (1-ec copy)

1-ec Maxon Industries Incorporated Attn: Tuck Maxon

Respectfully Submitted, GeoTest, Inc.

Andrew Davis, Field Manager

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2135 South 116th Street West Allis, WI 53227 414-321-8378 Page 2 of 2

REPORT:	Concrete Compression - Contractor Made	LAB NO: 15-3334-4 Test Method: See Below
		Test Method. See Below
Project:	Maxon Industries - 2015 Lab Testing.	Report Date: 07/16/2015
Location:		Date Sampled: 06/18/2015
Client:	Maxon Industries Incorporated	Sampled By: Client
Acct. No:	MAXON	By Order Of: Client
Client PO:		Order Number:
		Report No: 15-3334-4
		Project No: 4667

Quantity Represented:

Remarks: if material reference value achieved, "hold" specimens automatically discarded at 28 days (unless advised otherwise in advance by client).

Test Method (As Applicable): ASTM C31, C39, C138, C143, C172, C231, C1064, C1231; AASHTO T22, T23, T119, T121, R60, T152, T309

Orig: Maxon Industries Incorporated (Milwaukee, WI)
Attn: Bill Maxon (1-ec copy)
1-ec Maxon Industries Incorporated Attn: Tuck Maxon

Respectfully Submitted, GeoTest, Inc.

Andrew Davis, Field Manager

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Giles Engineering Associates, Inc.

GEOTECHNICAL, ENVIRONMENTAL AND CONSTRUCTION MATERIALS CONSULTANTS
N8 W22350 JOHNSON DRIVE, SUITE A1 / WAUKESHA, WI 53186 / (262) 544-0118 / FAX: (262) 549-5868

Report of Concrete Compression Test

CLIENT: Midwest Manufacturing

PROJECT: Midwest Materials Lab Testing

W3247 County Road S Iron Ridge, WI 53035

Waukesha, WI

DATE: March 07, 2014

PROJECT NO.: 1M-1402004 -C-3

FIELD TEST DATA

LOCATION OF POUR: 4000 psi mix

DATE CAST: 2/7/14
WEATHER: indoors
TIME: 1:00pm
NO. OF CYLINDERS: 3
CLIENT SAMPLE NO.: 4000 psi

SUPPLIER: Mastercraft
TICKET NO.: *
TRUCK NO.: *
MIX NO.: 4000 psi
CONTRACTOR: *
CEMENT: *
CEMENT TYPE: *

PORTION OF LOAD SAMPLED:

SAMPLE TAKEN FROM:

TYPE OF BATCHING: on-site batch
BATCH SIZE: 2 bags

CEMENT BRAND: *
FLY ASH: *
SLAG: *

SLUMP: 6 inches
AIR CONTENT: 3.5 %
UNIT WEIGHT: 143.66 pcf
TEMPERATURE CONCRETE: 66 F

WATER: *
FINE AGG. SOURCE: *
FINE AGGREGATE: *
COARSE AGG. SOURCE: *

AIR: 65 F
WATER ADDED ON SITE: 1.5 gallons
BATCH TO PLACEMENT TIME: *
FIELD DATA SUBMITTED BY: Mark Statz

COARSE AGGREGATE: *
#2 C. AGG. SOURCE: *
#2 COARSE AGGREGATE: *
ADMIXTURE: *

FIELD DATA SUBMITTED BY: Mark Statz
LABORATORY TECHNICIAN: Mark Statz
FINE AGG. MOISTURE (%): *

ADMIXTURE: *
ADMIXTURE: *

#1 COARSE AGG. MOISTURE (%): *
#2 COARSE AGG. MOISTURE (%): *

[X1 CYLINDER MADE BY GILES

[X]

WATER/CEMENT RATIO: *

CYLINDER MADE BY OTHER
CYLINDER DELIVERED TO LAB

LAB NUMBER:

C-140112

CYLINDER PICKED UP BY GILES

DATE RECEIVED:

2/7/14

ij	CYL	TYPE OF	AGE	TEST	CYLINDER	TOTAL L	OAD	DIAMETER	CYLINDI	ER AREA	FRACTURE	COMPRESS	IVE STRENGTH
i	ID	CURING	(days)	DATE	CONDITION	(lb-f)	(kN)	(in.)	(sq. in.)	(sq. cm)	& CAPPING	(psi)	(MPa)
	Α	0F/3L	3	2/10/14	good	55700	248	6.003	28.30	182.6	D & N	1968	13.6
	В	0F/7L	7	2/14/14	good	94680	421	5.996	28.24	182.2	B & N	3353	23.1
	С	0F/28L	28	3/7/14	good	131540	585	6.002	28.29	182.5	D & N	4649	32.1

SPECIFIED COMPRESSIVE STRENGTH AT 28 DAYS

4000

27.6

TEST RESULTS COMPLY WITH SPECIFICATION

1) Laboratory ASTM test methods used: C 39, C 617 or 1231, C 511.

2) Field ASTM test methods used: C 31, C 173 or 231, C 138, C 143, C 172, C 1064.

3) 58.61 lb/bag

4)

FRACTURE TYPES

REMARKS:













* INFORMATION NOT SUPPLIED

CAPPING METHODS

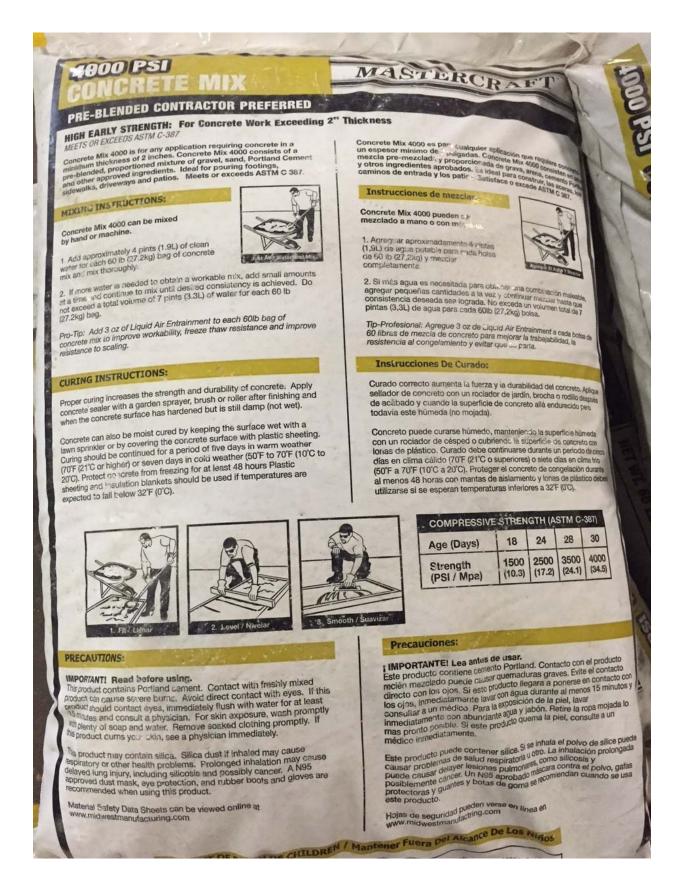
N = neoprene pads

S = sulfur capping compound

P = plaster capping compound

Laboratory testing was performed by an AASHTO accredited laboratory.

Reviewing Engineer: Steven P. Homar, P.E.





PREMIUM CONCRETE/MASO ET ACCELER

Product Description

Akona® Premium Concrete/Masonry Set Accelerator is a ASTM C494, Type C, non-chloride, non-corrosive, liquid that improves workability and initial strength while it reduces the hydration time of cement. The product is recommended for use during cooler weather to accelerate set time and reduce the risk of frozen mortar and concrete mixes. It is also recommended for use when early strength gain is desired to speed up construction. Akona® Premium Concrete/Masonry Set Accelerator provides a reduced curing time, faster set time and increased early strength. The product speeds finishing operations in any weather condition without any corrosive effects.

When/Where to Use

- G Interior / exterior
- G Concrete & masonry projects
- · G To accelerate cement set time to decrease project time
- · G Freeze thaw conditions

Advantages

- G Non-Chloride Accelerator
- G Non-Corrosive
- G Meets ASTM C494 Standard Specification for Chemical Admixtures for Concrete
- G Increases early compressive strengths of concrete or mortar
- G Increases workability of concrete or mortar
- · G Accelerates initial/final set and curing time for concrete and mortar
- G Allows earlier finishing of concrete and removal of concrete forms

Package

1 Quart (32 ounces) / (.946 liters)



Mixina

Slowly stir product before use. Do not create bubbles or foaming by shaking the product. In most cases, substitute recommended "water addition" with equal amount of Akona® Premium Concrete/Masonry Set Accelerator or follow packaged product manufacturer instructions for proper

Application

Stir product before using. Intended for use when temperature is 20°F (-7°C) or higher and a faster set is desired. Follow typical water addition mixing instructions on the applicable cement, concrete or mortar bag. Combine the recommended amount of Akona® Premium Concrete/Masonry Set Accelerator with sufficient water to provide the desired consistency of the mix. Set Accelerator is added directly to the mix water. Reduce the amount of water proportionally to compensate for the liquid addition. This product affects only the portland cement portion of the mix and is not antifreeze for the water portion. Protect set accelerator from freezing.

Table I: Typical Addition Ratio

rubic ii Typicui Addition Rutio					
Product:	Suggested Rate*:				
94 lbs. (42.6 kg) Portland Cement	64 ounces (2 quarts)				
70-75lbs. (32-34 kg) Masonry Cement	32 ounces (1 quart)				
80 lbs. (36.6 kg) Pre-blended Mortar	16 ounces (½ quart)				
60 lbs. (27.2 kg) Pre-blended Concrete	8 ounces (¼ quart)				

^{*} Typical addition ratio can be adjusted to achieve desired results



Warranty:

Seller warrants that its product will conform to and perform in accordance with the product specifications. The foregoing warranty is in lieu of all other warranties, express or implied, including, but not limited to, those including merchantability and fitness for a particular purpose. Because of the difficulty in ascertaining and measuring damages hereunder, it is agreed that, seller's liability to the buyer at no point for any particular project shall exceed the total purchase price of said product.

WARNING: PROTECT FROM FREEZING

KEEP OUT OF REACH OF CHILDREN!

Precautions:

Avoid contact with eves and skin. If contact with eyes occurs, flood eyes repeatedly with clean water and see a physician immediately. Do not rub eyes. Wash hands thoroughly after handling or before eating with warm, soapy water. Do not take internally. Keep out of reach of children.

Table II: Typical Set Time Properties:

	60 lbs. C	oncrete Mix	Masonry Mo	ortar—Type S	Masonry Mortar—Type N		
Set Time	Control:	Akona Set Accelerator:	Control:	Akona Set Accelerator:	Control:	Akona Set Accelerator:	
Initial Set (hr:min)	3:30	2:35	2:50	1:45	3:45	2:10	
Final Set (hr:min)	5:10	4:10	5:00	3:20	7:00	5:00	

2025 Centre Pointe Blvd, Suite 300, Mendota Heights, MN 55120 | P 651.905.8137 | F 651.688.9164 | www.akonallc.com



Pharmaceutical Waste Processing Systems

oduct Informati



MAXPRO SPU 4.5 Pharmaceutical Waste processing system. In plant installation complete with elevated platform for direct discharge to 55 gallon barrels. System also included a cement silo (located outside the building) with screw auger feed for dustless charging of MAXPRO with solidification agents.

The MAXPRO SPU is uniquely designed to process and solidify unusable pharmaceutical products for safe disposal. There is no other system like it in the world.

The MAXPRO SPU combines granulation and solidification within an integrated system. Disposed pills, tablets and capsules are rendered unusable, reduced to grain size, and then encapsulated into a solid inert form that can be landfilled without posing any risks to the environment or public health.

The MAXPRO SPU is simple to operate, easy to maintain, and has the lowest costs when compared to any other pharmaceutical product disposal option.



MAXPRO SPU 2.0 Pharmaceutical Waste processing system. Portable unit, trailer mounted for easy towing behind one ton pickup truck. MAXPRO includes hydraulic barrel loader, that will grab, lift, swing and rotate drums up to 55 gallon or 800 lbs capacity.

Maxon Industries Inc. ■ 3204 W. Mill Road ■ Milwaukee, WI 53209 ■ Phone: (414) 351-4000 Fax: (414) 351-9057 ■ Website: www.maxon.com ■ E-mail: sales@maxon.com

MAXPRO SPU - Solidification Processing Unit

Pharmaceutical waste management and disposal are issues of great international concern because of their threats to the environment leading to potentially serious impacts on humans and wildlife. In addition, the improper disposal of expired and unusable drugs and pharmaceutical product could result in pilfering and diversions to markets for misuse and resale. Accordingly, the U.S. Environmental Protection Agency and similar agencies worldwide are aggressively enacting regulations, standards and enforcement policies to minimize and eliminate such concerns and impacts.

Encapsulation, or solidification, including cement-based solidification, is internationally-recognized and endorsed as a preferred option for the safe disposal of pharmaceutical waste and unusable pharmaceutical products. In comparison to other disposal options, cement-based solidification technologies have very low capital and operating costs, are simple and easy to operate and maintain, and they have far less environmental impacts and restrictions when compared to incineration.



Discharge options include hydraulic gate for controlled discharge of processed pharmaceutical waste. Processed waste can be discharged direct back into original storage container for final disposal.



MAXPRO SPU 1.0 Pharmaceutical Waste processing system. Unit shown in electrical power configuration. Cementitious material is fed into the processor by screw auger from a silo located outside the building. The MAXPRO is equipped with optional discharge swivel chutes to allow for direct charging to 20yd³ rolloff box located in a pit behind the unit.

Maxon Industries is the world-leader in providing systems for the solidification and stabilization of pharmaceutical waste and unusable products, hazardous waste, and other special wastes. Maxon Industries offers complete, turn-key cement-based solidification systems and equipment, both nationally and internationally, with services ranging from treatability studies and design through installation, start-up and commissioning.

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Waste Encapsulation Systems

MAXON PHARMACEUTICAL WASTE PROCESSING SYSTEMS

Maxon provides complete, turn-key, design-build pharmaceutical waste solidification systems that include the following:

Pre-Processing Systems & Equipment

- Product & Waste Unloading & Handling
- Interim Storage, Inventory Control & Security

Processing Systems & Equipment

- Product Preparation: Shredding, Crushing Or Granulation
- Product Loading Or Charging
- Reactant Handling & Feed: Cement, Water & Additives
- Processing: Blending & Mechanical Mixing
- Treated Residue Discharge

Residue Handling Systems & Equipment

- Discharge Handling & Conveying
- Residue Containment & Solidification
- Container Handling & Disposal Equipment



A cross section of a test cylinder is shown with pharmaceutical waste 24 hours after processing.

OTHER RELATED MAXON SERVICES & OFFERINGS

Technical Support Services

- Bench-Top & Full-Scale Treatability Studies
- Engineering & Design Support
- Architectural & Engineering Drawings

Facility & Infrastructure Components

- Shelving & Rack Storage Systems
- Emergency & Back-up Generators
- Quality Control Analysis Equipment

Installation & Related Support

- Field Supervision & Oversight
- Start-up & Commissioning
- Performance Testing
- Operator Training



MAXPRO SPU 7.0 Pharmaceutical Waste Processing System. Unit shown discharging processed waste into a plastic lined form box, handled by a fork lift truck. Once the encapsulated pharmaceutical waste solidifies (approximately 4 hours) the form box is stripped and reused, and the block of encapsulated pharma waste is hauled to the local landfill.

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Pharmaceutical Waste Processing Systems

MAXON INDUSTRIE	S PHARMACEUTICAL WASTE P	ROCESSING SYSTEMS			
PRIMARY CEMENT-BASED SYSTEM OPERATIONS & PROCESSESS					
SOLIDIFICATION SYSTEM OPERATIONS	SOLIDIFICATION SYSTEM PROCESSES	SOLIDIFICATION SYSTEM OPTIONS			
	1. Product Container Unloading & Handling				
Pre-Processing	2. Product Container Storage & staging				
1 10-1 100033mg	3. Product Preparation	Shredding			
		Crushing or Granulation			
	1. Product Loading or Charging				
	2. Reactant Handling & Feeding				
Processing	Portland Cement	Silos or Super Sacks			
	Water				
	Additives	Aggregate, Sand, Other			
	3. Treated Residue Discharge				
		•			
	1. Residue Conveying & Handling				
	2. Containment & Solidification	Fiber Drums or Boxes			
Treated Residue Disposal		Metal Drums or Bins			
		Wooden Forms			
	3. Container Handling & Disposal				



MAXPRO SPU 2.0 Pharmaceutical Waste processing system. Cementitious material for encapsulation is charged manually by 90 lbs. sack. After material is processed, it is discharged into a fiber reinforced, plastic lined cardboard box, allowed to solidify and hauled to a local landfill.

To learn more about Maxon's complete line of waste encapsulation and solidification equipment, please visit our website at www.maxon.com or contact us directly at the numbers provided below.

BUL.709 printed in the U.S.A c.c.

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CLINTON 106 CORN STARCH

Clinton 106 is one of a series of unmodified starches manufactured by ADM. It displays the properties typical of unmodified (thick boiling) starches. Clinton 106 is also extremely well suited for use in corrugating adhesives. It develops an outstandingly uniform, stable viscosity that is highly resistant to breakdown, which makes it an ideal adhesive for high-speed corrugating operations.

Benefits

- High in viscosity with good body at both high and low solids.
- Properties also allow it to be an exceptionally versatile starch with a number of industrial applications.
- Well suited for use in chemical conversion processes.
- Converted starch pastes have strong adhesive properties and can be utilized to great advantage in the surface sizing of paper.
- May be used in both the primary (carrier) and the secondary (raw) portions of adhesive formulations.
- Versatility promotes increased economy as initial cost inventory requirements and storage areas
 are appreciably reduced. Because of the high versatility, operation with automated systems for
 the continuous preparation or adhesive pastes is vastly simplified.

Typical Chemical and Physical Properties

Characteristics:

Appearance White, free flowing

Typical Properties:

Moisture 11.0% pH 5.75

Protein 0.40% maximum

Availability

Clinton 106 Corn Starch is available in 50-pound bags, totes, bulk truck and rail car quantities.

For more information, samples or assistance, please contact our Technical Center at 888/371-4408 or our Sales Department in Decatur at 800/877-7205.

The information contained herein is correct as of the date of this document to the best of our knowledge. Any recommendations or suggestions are made without guarantee or representation as to results and are subject to change without notice. We suggest you evaluate any recommendations and suggestions independently. We disclaim any and all warranties, whether express or implied, and specifically disclaim the implied warranties of merchantability, fitness for a particular purpose and non-infringement. Our responsibility for claims arising from any claim for breach of warranty, negligence or otherwise shall not include consequential, special or incidental damages, and is limited to the purchase price of material purchased from us. None of the statements made here shall be construed as a grant, either express or implied, of any license under any patent held by ADM or other parties. Customers are responsible for obtaining any licenses or other rights that may be necessary to make, use or sell products containing ADM ingredients.



SLUMP TEST PROCEDURE (FIELD TESTING)

samples from two or more regular intervals To obtain a representative sample, take truck. DO NOT take samples at the beginthroughout the discharge of the mixer or ning or the end of the discharge.

smooth, moist, non-absorbent, level surface 2 Dampen inside of cone and place it on a procedure to hold the cone firmly in place. Stand or, foot pieces throughout the test large enough to accommodate both the slumped concrete and the slump cone.

Fill cone 1/3 full by volume and specification requirement which will produce nonstandard results unless followed exactly.) Distribute rodding evenly over the entire rod 25 times with 5/8-inchdiameter x 24-inch-long tamping rod. (This is a hemispherical tip steel 3

cross section of the sample.

rodding evenly over the entire Fill cone to overflowing. Rod this cross section of this layer. etrating into but not through, layer 25 times with rod pensecond layer. Distribute 5

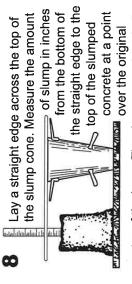
cone, using tamping rod as Remove the excess concrete from the top of the a screed. Clean overflow from base of cone. 6

entire cross section of the hrough first layer. Distribute Fill cone 2/3 full by volume. Rod this layer 25 times with rod rodding evenly over the penetrating into, but not layer.

withdrawn cone, and not jar the concrete or slow, even motion. Do cone vertically with his process. Invert the tilt the cone during Immediately lift

0

place next to, but not touching the slumped concrete. (Perform in 5-10 seconds with no lateral or torsional motion.)



be completed in a maximum elapsed time of 2 1/2 minutes. Discard concrete. DO NOT use in center of the base. The slump operation shall any other tests.



NATIONAL® Standard Bentonite 200 Mesh

Revised: June 30, 2008 Category: Product Data Sheet

SCREEN ANALYSIS

NATIONAL® Standard Bentonite 200 mesh is a Wyoming sodium bentonite that is used as a binder, a stabilizer, and a suspension agent to impart theological properties to aqueous systems. NATIONAL Standard Bentonite 200 mesh imparts the highest degree of instantaneous hydration over other Wyoming sodium bentonites, ideal as an additive for industrial coatings, IOP, detergents, paper, ceramics and household products.

Typical Physical Properties*

TYPICAL

SPECIFICATION

Dry Screen, percent minus 200 mesh	75	67.5 min
Wet Screen, percent plus 200 mesh	1.2	
SLURRY PROPERTIES		
Viscosity, FANN® Viscometer 600 rpm	19	

Viscosity, FANN® Viscometer 600 rpm	19	
Apparent Viscosity, cps	9.5	
Yield - 42 gal bbl of 15 cps slurry/ton	82	
Plastic Viscosity (PV)	9	
Yield Point, lb./100 ft ²	10	·
Filtrate, 30 minutes @ 100 psi, ml	15	
Methylene Blue Capacity, Meg/100 gms	120	
pH of 6 percent suspension	9.3	8.2 min
Moisture, percent	9	12 max
Base exchange capacity me/100g	92	

MISCELLANEOUS PROPERTIES

Swell Index (ml)	30	100
Plate Water Absorption, wt % @ 20° C/18 hr	1000	
Oil absorption, ASTM D 281-31	41.3 lb/100lb clay	
Surface area (N ₂ absorption)	20m²/gram	
Specific Gravity	2.7	
pH of 6 percent suspension	9.5	
Bulk Density (lbs per ft³) uncompacted	52	
Bulk Density (lbs per ft3) compacted	72	

^{*} The typical physical values listed are not to be construed as rigid specifications.

Bentonite Performance Minerals LLC

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Because the conditions of use of this product are beyond the seller's control, the product is sold without warranty either express or implied and upon condition that purchaser make its own test to determine the suitability for purchaser's application. Purchaser assumes all risk of use and handling of this product. This product will be replaced if defective in manufacture or packaging or if damaged. Except for such replacement, seller is not liable for any damages caused by this product or its use.

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Maxon PowerPoint presentation

FSCM Pharmaceutical Waste Processing System

June 18, 2015 Bench Scale Testing

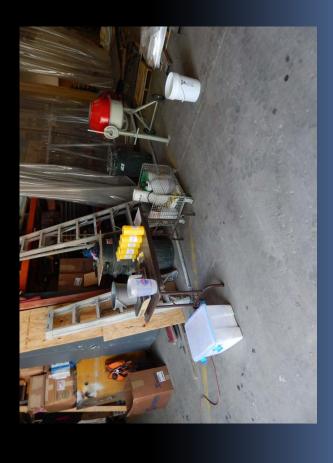


Milwaukee, WI 53209 USA Phone 414-351-4000 Fax 414-351-9057 www.maxon.com 3204 W. Mill Road

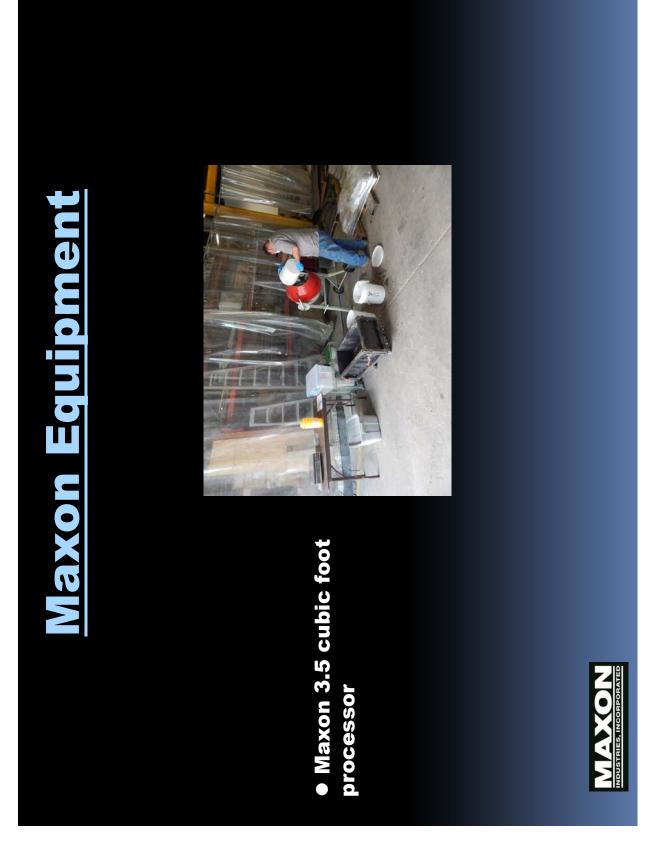
Maxon Industries Inc

Test Conducted on June 18th, 2015

- Location: Maxon Industries, Milwaukee, WI
- Objective: Small Scale Mixing of Pharma Waste
- Four test batches produced (Tests 104.1 thru 104.4)







Maxon Test

- Test 104.1
- One (1) bag of 60 lbs. dry concrete mix was added to mixer, along with 6.8 lbs of crushed Pharma waste, one gallon of water, and 1 quart of Set Accelerator
- One test cylinder was poured and the balance was formed in a cube in the form box.

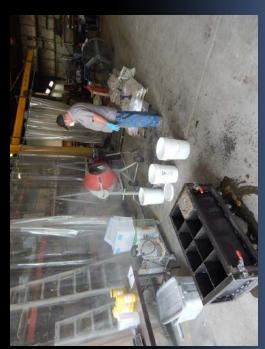


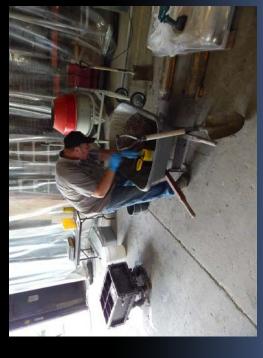




Maxon Test

- **Test 104.2**
- 30 lbs of dry concrete mix was added to mixer, along with 6.8 lbs of crushed Pharma waste, .5 gallon of water.
- One test cylinder was poured and the balance was formed in a cube in the form box.







- **Test 104.3**
- 30 lbs of sand was added to mixer Resulting mixture was discharged Water was added until we Pharma waste, and 5 lbs along with 30 lbs Betonite, 13.6 reached 3.5 gallon of water total material was still unworkable). cement. crushed

from mixer and disposed (no cylinders)









Maxon Test

- **Test 104.4**
- 30 lbs of sand is added to mixer, along with 20 lbs Betonite, 13.6 lbs of crushed Pharma waste, and 10 lbs cement. Water was added until we reached 1.75 gallon of water total.
- Two test cylinders were poured.









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