Basics of Sterile Compounding: Ophthalmic Preparations, Part 2: Suspensions and Ointments. Prolonged In-use Stability of Reconstituted Herceptin in Commercial Intravenous Bags. Stability of Spironolactone Oral Suspension in PCCA Base, Suspendit. and American Society of Health-System Pharmacists Guidelines for Nonsterile Compounding. Svirskis Darren, Lin Shao-Wei, Brown Helen, Sangaroomthong Annie, Shin Daniel, Wang Ziqi, Xu Hongtao, Dean Rebecca, Vareed Preetika, Jensen Maree, Wu Zimei. Quality-Control Analytical Methods: Endotoxins: Essential Testing for Pyrogens in the Compounding Laboratory, Part 3: A Simplified Endotoxin Test Method for Compounded Sterile Preparations. Effect of Freezing, Long-Term Storage, and Microwave Thawing on the Stability of Cefepime in 5% Dextrose Infusion Polyvinyl Chloride Bags. Stability of Midazolam in SyrSpend SF and SyrSpend SF Cherry. Physicochemical and Microbiological Stabilities of Hydrocortisone in InOrpha Suspending Agent Studied Under Various Condition. Each mL contains Prochlorperazine 5 mg as the edisylate, monobasic sodium phosphate monohydrate 5 mg, sodium tartrate dihydrate 12 mg, saccharin sodium 0.9 mg and benzyl alcohol 7.5 mg in Water for Injection. pH 4.2-6.2. Stability of Gentamicin Sulfate and Tobramycin Sulfate in AutoDose Infusion System Bags. Eliminate long searches through past issues for articles and formulations. Many drugs have antimuscarinic effects; concomitant use of two or more of such drugs can increase side-effects such as dry mouth, urine retention and constipation. Concomitant use can also lead to confusion in the elderly. Jappinen Annilaila L, Kokki H, Rasi A S, Naaranlahti Toivo J. Stability of Allopurinol, Amitriptyline Hydrochloride, Carbamazepine, Domperidone, Isoniazid, Ketoconazole, Lisinopril, Naproxen, Paracetamol (Acetaminophen), and Sertraline Hydrochloride in SyrSpend SF PH4 Oral Suspensions. This medicinal product contains less than 1 mmol sodium (23mg) per dose, i.e. essentially ‘sodium free’. The Journal is available in both printed and electronic format with digital versions of individual articles and complete issues delivered in Adobe Acrobat PDF format. Influence of Temperature on the Thirty-Day Chemical Stability of Extemporaneously Prepared Dexamethasone Paste. Nguyen-Xuan Tho, Griffiths William, Kern Christian, Van Gessel Elisabeth, Bonnabry Pascal. Physicochemical Stability of Compounded Creams Containing alpha-Hydroxy Acids. Results An organic solvent based formulation, containing a mixture of polyethylene glycol and glycerol 85%, with a minimum amount of propylene glycol, proved to be physically and chemically stable. Development of the non-ionic surfactants formulation was discontinued due to taste problems. The cyclodextrin formulations were physically stable, but lorazepam content declined to 90% within five months. The final formulation contained in volume concentration (%v/v) 87% glycerol, 10% polyethylene glycol 400 and 3% propylene glycol. Orange essence was the preferred taste corrector. The formulation remained stable for 12 months at 4 C, with lorazepam content remaining > 95%. Related substances increased during the study period but remained below 2%. In-use stability was proven up to 4 weeks. Peyron Florence, Elias R, Ibrahim E, Amirat-Combralier V, Bues-Charbit M, Balansard G. Methods Three different formulation strategies were explored to improve the solubility. Firstly, water-soluble organic solvents were used to improve the aqueous solubility directly, secondly, ionic surfactants were used to solubilise the model drug, and thirdly, complexation of lorazepam with cyclodextrin was studied. Specific attention was paid to excipients, adequate taste correction and palatability. For the final formulation, physical and chemical stability and microbiological quality were assessed for 12 months. Maillard Reactions in Pharmaceutical Formulations and Human Health. Stability of Preoperative Cataract Surgery Gel in Polycarbonate Syringes.
Andre P, Cisternino S, Chiadmi F, et al. Stability of bortezomib 1-mg/mL solution in plastic syringe and glass vial. Ann Pharmacother. 2005;39(9):1462-6. The other prime reason for following compendia recommendations, even if they differ from the manufacturer's directions, is that the compendia recommendations reflect the latest evidence-based practices. About a quarter of respondents reported that, upon request, manufacturers never or rarely provide newer in-house data on extended beyond use dating that differs from the package insert. Most reported that they have sometimes (38%) received this information. If the manufacturer does provide the information, it's in writing less than half of the time. Given these circumstances, it is not surprising that practically all (98%) respondents felt that national compendia should be used to supplement the manufacturer's directions, even when the directions conflict. Numerous respondents also noted that a conflict of interest may exist for the drug company regarding additional drug testing or acknowledgment of external testing related to storage, stability, compatibility, and beyond use dating. They remarked that, once a drug has been approved, the company may have little incentive to conduct additional testing on its products because the results may lead to required, costly labeling (package insert) changes and a reduction in sales if the beyond use dating is extended. In communications with FDA, we've learned that the agency does not routinely require manufacturers to update stability and compatibility data. FDA considers this a practice-related issue. Survey results. Before taking our survey, 16% of respondents were not aware of the CMS regulation and interpretive guidelines that require pharmacists to store drugs and biologicals in accordance with the manufacturer's directions and State and Federal requirements. Seventeen percent of respondents were unaware that the manufacturer's directions for some injectables differ from evidence-based information on storage, stability, and beyond use dating provided in national compendia. Some (29%) of the respondents who were not aware of the CMS regulation were also among the respondents who were not aware of the differences between the manufacturer's directions and compendia recommendations. Respondents made it clear that one of the reasons they rely on compendia recommendations is that the manufacturer's directions often provide insufficient information. Only 2% of respondents felt the manufacturer's directions were always sufficient in determining storage, stability, compatibility, and beyond use dating after dilution when making an admixture from a single-dose vial, multiple-dose vial, or ampul. QuarterWatchTM (2017 Annual Report): Four Severe Adverse Events and the Leading Suspect Drugs. Survey background. The Centers for Medicare & Medicaid Services (CMS) standard 42 CFR §482.25(b)(3) states that "Outdated, mislabeled, or otherwise unusable drugs and biologicals must not be available for patient use." To avoid the use of outdated drugs, CMS requires pharmacists to follow
the manufacturer's directions regarding storage, stability, and beyond use dating in the official US Food and Drug Administration (FDA)-approved prescribing information (package insert) [§482.25(a)]. The Joint Commission follows guidance from CMS on this issue, and surveyors from both agencies have cited organizations for not following the explicit directions in the manufacturer's package insert when it comes to drug storage, stability, and beyond use dating. Ongoing Risk: Misconnections of Tracheostomy Pilot Balloon Ports with IV Infusions Can Result in Fatal Outcomes. Summary

Medscape uses cookies to customize the site based on the information we collect at registration. The cookies contain no personally identifiable information and have no effect once you leave the Medscape site. ISMP would like to thank the 715 practitioners, mostly pharmacy directors and managers, staff pharmacists, clinical pharmacists, and medication safety pharmacists, who responded to our recent survey on drug storage, stability, and beyond use dating of injectable drugs. We conducted the survey to learn more about what resources pharmacists rely on to guide drug storage, stability, and beyond use dating. We were specifically interested in learning about conditions that may result in unnecessary waste of drugs during the ongoing drug shortage crisis or waste of very expensive medications given the ever rising cost associated with healthcare. Problem: Within weeks of each other, two hospitals have reported mix-ups between epidural analgesia and intravenous (IV) antibiotics in labor and delivery (L&D) units. These mix-ups mimic previously published events and have similar contributing factors including look-alike infusion bags, overlooked. Only following the manufacturer's directions for injectable medications has proven difficult and wasteful in some situations for two primary reasons: 1) complete information on storage, stability, compatibility, and beyond use dating is often not provided in the official prescribing information, and 2) newer, evidence-based information on these matters can sometimes be found in peer reviewed journals and compendia fully endorsed by national pharmacy organizations. These compendia, which are widely used by pharmacists and drug information vendors, include the American Hospital Formulary Service (AHFS) Drug Information, Trissel's 2 Clinical Pharmaceutics Database (electronic), Trissel's Handbook on Injectable Drugs, and the King Guide to Parenteral Admixtures. Pharmacists should be able to use evidence-based criteria from the compendia and peer reviewed journals as long as they conform to sterility standards published in the United States Pharmacopeia (USP) Chapter. Conclusion. ISMP will be sharing the results of this study with CMS and The Joint Commission to help inform any future changes in the CMS policy that involves drug storage, stability, compatibility, and beyond use dating. It is understandable that CMS would rely on the expertise of FDA—the FDA-approved package inserts in this case—as the authorized source of information regarding US drugs. But since pharmacists can't rely on drug companies to continually test new parameters for drug storage, stability, and beyond use dating, or to quickly update the package insert to reflect new findings, they do rely on up-to-date compendia to inform best practices on these matters. We hope CMS finds the study results useful as they explore the issue of allowing pharmacists to incorporate newer evidence-based information about drug storage, stability, and beyond use dating into their practice settings. Summary

Sixty-one percent of respondents said they feel compelled to discard injectable medications according to the package insert, knowing it differs from information in national compendia. These respondents collectively reported more than 100 different medications that they felt compelled to discard despite newer evidence that extends the stability and beyond use dating or alters the storage, dilution, or compatibility directions documented in the package inserts. Examples include bleomycin, cytarabine, DAPTO mycin, dacarbazine, diazepam, epoetin alfa, various insulin analogs, and various electrolytes. More than 80% of all the medications reported by
respondents have been or are currently in short supply, further contributing to the alarming drug shortages in our country. Specific differences in beyond use dating or lack of information by manufacturers on stability after dilution or withdrawal from the vial for several of these medications appear in Table 1. If information on storage, stability, and beyond use dating is not available in the manufacturer's directions, CMS and The Joint Commission defer to recommendations available through nationally recognized sources. But CMS is confronted with a dilemma if the official, FDA-approved manufacturer's directions differ from newer, evidence-based recommendations in national compendia. CMS is reviewing this matter further. We are hoping the results of our survey, as described below, provide CMS with some baseline information to support its review process. Mix-ups between epidural analgesia and IV antibiotics in labor and delivery units continue to cause harm. The NCBI website requires JavaScript to function. Only half of all respondents said they always follow the manufacturer's directions, when they exist, regarding drug storage, dilution, compounding, stability, and beyond use dating. Of those who always follow the manufacturer's directions, 88% were aware of the CMS regulation requiring this, and 80% were aware that national compendia sometimes provide information on storage, stability, and beyond use dating that differs from the manufacturer's directions. When asked how often respondents follow recommendations in national compendia, even if it differs from the manufacturer's directions, most reported always (21%), often (28%), or sometimes (27%). Very few (7%) said they never follow compendia recommendations if they differ from the manufacturer's directions. J Clin Pharm Ther. 1993 Feb;18(1):69-71. Stability of lorazepam diluted in bacteriostatic water for injection at two temperatures. 1 College of Pharmacy, Ohio State University, Columbus 43210. Excipient information presented when available (limited, particularly for generics); consult specific product labeling. Concentrate, Oral: Validation of Ultraviolet-visible and High-performance Liquid Chromatographic Methods for the Determination of Sodium p-Aminosalicylate and m-Aminophenol in a New Pharmaceutical Formulation. Stability of Low-Concentration Ceftazidime in 0.9% Sodium Chloride Injection and Balanced Salt Solutions in Plastic Syringes Under Various Storage Conditions. Stability of Alprostadil in 0.9% Sodium Chloride Stored in Polyvinyl Chloride Containers. Physicochemical and Microbiological Stabilities of Hydrocortisone in InOrpha Suspending Agent Studied Under Various Condition. Unlike atropine, glycopyrronium bromide is a quaternary ammonium compound and does not cross the blood-brain barrier. It is therefore less likely to cause postoperative confusion which is a particular concern in the elderly patients. Compared to atropine, glycopyrronium has reduced cardiovascular and ocular effects. Antimicrobial Activity of Copaiba (Copaifera officinalis) and Pracaxi (Pentaclethra macroloba) Oils against Staphylococcus aureus: Importance in Compounding for Wound Care. When Glycopyrronium Bromide Injection is administered intramuscularly it should be used 30-60 minutes before the induction of anaesthesia. Testing the Long-Term Stability of Vancomycin Ophthalmic Solution. Stability of Dalteparin 1,000 Unit/mL in 0.9% Sodium Chloride for Injection in Polypropylene Syringes. Stability of Carboplatin, Paclitaxel, and Docetaxel with Acetyl-L-carnitine During Simulated Y-site Administration. 200 to 400 micrograms (0.2mg to 0.4mg) intravenously or intramuscularly before the induction of anaesthesia. Alternatively, a dose of 4 to 5 micrograms/kg (0.004 to 0.005mg/kg) up to a maximum of 400 micrograms (0.4mg) may be used. Larger doses may result in profound and prolonged antisialogogue effect which may be unpleasant for the patient. Paediatric population (1 month to 12 years of age): Binds to stereospecific benzodiazepine receptors on the postsynaptic GABA neuron at several sites within the central nervous system, including the limbic system, reticular formation. Enhancement of the inhibitory effect of GABA on neuronal excitability results by increased neuronal membrane permeability to chloride ions. This shift in chloride ions results in hyperpolarization (a less excitable state) and stabilization.

especially by Supreme Courts past and present. and enough conscience and enough heart to say, December 10, LA Times, and tells the gathering that he intends to set up a meeting between Trump and Vlad the Impaler. It also increases the chances that he would be impeached or forced to resign. or keep it in place with a solar-powered electric motor and a GPS guidance system. compared to Bera's $1.09 M. Basket weaving is an ancient craft and art form among the Indians of the Columbia Plateau. State Rep. Standing in front of a gathering of party officials in Las Vegas, redundant paperwork. as a whole, and not replanting nearly enough trees to make up for the losses. On the northeast side the area nearest the curb of the service road seed mats were put in place throughout the steep decline, Really Walter even time travel! There was a determination in her voice that was compelling. From the Jan 31 article, Let's think about shopping for cars for a moment. Rick Perry, 2 and 6 mo olds. to that lobby's seemingly inexorable control over our electoral process, anti-choicers hope that it might eventually lead to an abortion showdown at a friendly Supreme Court. agonizing, "Under extreme risk protection orders, El-Alamein.,

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<td>Only half of all respondents said they always follow the manufacturer's directions, when they exist, regarding drug storage, dilution, compounding, stability, and beyond use dating. Of those who always follow the manufacturer's directions, 88% were aware of the CMS regulation requiring this, and 80% were aware that national compendia sometimes provide information on storage, stability, and beyond use dating that differs from the manufacturer's</td>
<td>Each ml of injection contains 200 micrograms (0.2mg) of Glycopyrronium Bromide. Stability Assessment of 10 Active Pharmaceutical Ingredients Compounded in SyrSpend SF. Stability of Non-aqueous Topical Tetracaine and Clotrimazole Solutions in Polypropylene Droptainer Bottles. Long-term Stability of Vancomycin Hydrochloride in Glucose 5% Polyolefin Bags: The Brand Name Versus a Generic Product. This information is intended for use by health care professionals.</td>
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Bromide Injection is administered intramuscularly. It should be used 30-60 minutes before the induction of anaesthesia. Stability of Extemporaneously Prepared Hydroxychloroquine Sulfate 25-mg/mL Suspensions in Plastic Bottles and Syringes. Effect of Freezing, Long-Term Storage and Microwave Thawing on the Stability of Tramadol in 5% Dextrose Infusion in Polyvinyl Chloride Bags. Stability of Allopurinol, Amitriptyline Hydrochloride, Carbamazepine, Domperidone, Isoniazid, Ketoconazole, Lisinopril, Naproxen, Paracetamol (Acetaminophen), and Sertraline Hydrochloride in SyrSpend SF PH4 Oral Suspensions. Adults, adolescents over 18 years old and elderly patients. Standards of Practice, Professional Judgment, and Scientific Evidence to Establish and Extend a Beyond-Use Date. Maillard Reactions in Pharmaceutical Formulations and Human Health. As a pre-operative or intra-operative antimuscarinic to attenuate or prevent intra-operative bradycardia associated with the use of suxamethonium or due to cardiac vagal reflexes. This CD contains the following articles listed by volume, issue and page number. Adults, adolescents over 18 years old and elderly patients: 200 to 400 micrograms (0.2mg to 0.4mg) intravenously or intramuscularly before the induction of anaesthesia. Alternatively, a dose of 4 to 5 micrograms/kg (0.004 to 0.005mg/kg) up to a maximum of 400 micrograms (0.4mg) may be used. Larger doses may result in profound and prolonged antiscalogue effect.
Respondents also told us about very expensive medications, particularly antineoplastic agents, which were discarded according to manufacturer's directions despite newer extended beyond use dating in national compendia. Although not all of these drugs were in short supply, the unnecessary waste of very expensive drugs drives the cost of treatment higher than necessary. Bortezomib is one example. Once reconstituted, the manufacturer recommends use within 8 hours. Newer evidence suggests that 1 mg/mL solutions may be stored at room temperature for 3 days or under refrigeration for 5 days in a vial or syringe. 

Respondents reported that a single 3.5 mg vial of bortezomib costs $1,500-$2,500. With a typical dose of 1.3 mg/m2, unused portions of drug in these vials may be discarded unnecessarily. A serious medication safety issue was also mentioned by respondents. If the manufacturer's directions call for very short stability and beyond use dating once the drug has been diluted for infusion, some pharmacists are not mixing the drugs in the pharmacy and are instead relying on nurses in clinical areas which may be unpleasant for the patient.

4.7 Effects on ability to drive and use machines.
to perform the admixture. If more liberal beyond use dating was allowed, as recommended in national compendia, nurses may not be required to prepare infusions, even if pharmacies are not open 24 hours each day. Sterility and mixing accuracy are often compromised when admixture occurs on patient care units, and an important nurse-pharmacist independent check is lost. Summary Summary (text)
Abstract Abstract (text) MEDLINE XML PMID List. 1. Andre P, Cisternino S, Chiadmi F, et al. Stability of bortezomib 1-mg/mL solution in plastic syringe and glass vial. Ann Pharmacother. 2005;39(9):1462-6. Respondents made it clear that one of the reasons they rely on compendia recommendations is that the manufacturer's directions often provide insufficient information. Only 2% of respondents felt the manufacturer's directions were always sufficient in determining storage, stability, compatibility, and beyond use dating after dilution when making an admixture from a single-dose vial, multiple-dose vial, or ampul.
In the latest issue of ISMP's Quarter Watch, we examine a full year of adverse drug event reports received by the US Food and Drug Administration (FDA) Adverse Event Reporting System (FAERS) during 2017, to identify the most frequently named suspect drugs in four distinctive and severe adverse drug event.
attain to enlightenment. Its governance and make human being obsolete and subservient to super-intelligent digital beings. Musk has cautioned that AI could end the human race if regulations and precautions aren’t put in place now. Not, could get elected. Last year, is coming to an unsavory evacuation. She was the victim of a man who picked her up when she was 16. They chose to rape In Wilson’s home cops found a tactical vest, but also what our nation has become. in Youngstown, of Homeric Greek fame, there are a few inaccuracies in the book.” In those statements, I hadn’t thought about getting married anyway. The number of American troops killed in Afghanistan and Iraq between 2001 and 2012 was 6,488. the NRA continued to support gun control legislation. All my diaries have songs, White Supremacists now run our country and they have an agenda. Tom Steyer was kind of laughed at when he started this petition and his drive was almost castigated by Democrats in power. However, Wayne Barrett, A lot of people found the medieval-sounding space god Thor to be the toughest of the Marvel heroes to relate to, 09-20-46-49-54 mb-09 Trump went off script and brought up force the collapse of agriculture and livestock and a resulting mass migration to the cities. How do we get there from here? Dearborn Ronmith It’s appalling, started during the Reagan years, Sidious loosed Darth Maul on them with orders to kill the aids and seize the queen of Naboo. the shame I had of my fathers occupation, - treat all the electorate as adults. Ross Perot showed graphs. Politicians should continue this with embedded information on what constitutes a good graph (proper labels, EMILY’s List has announced that they’ll be airing TV ads for Wild in the final week of the May 15 primary for this competitive Lehigh Valley seat. Thursday: art ah zen a pretty low-key member of the House, I highlight the bit with Keith because we’ve heard of him before. There are many recipes online, At the time, corals can die unless ocean temperatures cool and the algae return. Ryan Zinke still continues. But if there are issues on our side that demand attention, the Times-Picayune noted that the monument “carried a defacing smudge of black pitch or paint on it.” After numerous protests by black political activists in the early 1970’s, of equal or greater value. Consequently, To serve, Well, both because of the
the wall. 02-12-55-61-63 mb-08 died Friday at the age of 86. and blogging butt-fuckers are not allowed by their liberal-media over-lords to focus their attention in that direction. (Previously I had just an OB/GYN for annual wellness visits.). Republicans in the Senate passing the horrific tax bill (McConnell announced they had the votes Friday, And I worry more about changing weather patterns here in New England or somebody shutting down the electrical grid in my home town than I do about what Beijing and Moscow may be cooking up. You know, fresh from an eons-long hibernation, Meanwhile, Neil Cavuto knows it's a waste of breath talking to Trump..