DOWNLOAD PDF PROPER STORAGE AND DELIVERY OF DRUG PRODUCTS

Chapter 1 : Drug stability: How storage conditions affect their performance - Vital Record

Drug products such as biologics, vaccines and products whose chemical and physio-chemical stability depends on temperature put an added emphasis on pharmaceutical manufacturers to ensure proper handling, storage, transportation and dispensing.

Proper Storage of Veterinary Medicines Organization s: More Like This Correct storage and handling of livestock medicines helps prevent contamination of meat and milk with drug residues. Proper storage facilities improve medication effectiveness and reduce treatment errors. The ideal location for a storage unit is a clean, dry, frost-free area, such as a farm office or utility room. Animal health products should be protected from changes in temperature, sunlight, dust, moisture, animals, and insects. A clean, organized refrigerator makes an ideal drug storage unit. An example of products affected by incorrect storage temperature are teat dips containing the disinfectant chlorhexidine. These may irritate skin if used after freezing and thawing has occurred. Vaccines containing modified live organisms will have markedly reduced effectiveness if stored at room temperature. Most antibiotics are heat sensitive. Check product labels for information on acceptable storage temperature. Product decomposition may result from exposure to light. Manufacturers package light-sensitive products e. These should be kept in a light-proof storage unit. Different classes of products e. This will further reduce the potential for error in product selection. Label shelves to maintain an organized storage unit. Lock storage units to prevent access by children or unauthorized individuals. Inventory management The on-farm veterinary medicine inventory should be managed according to the following procedures: Purchase drugs in quantities which will be used in a reasonable amount of time. Check product expiry dates before purchase. Clean and reorganize the drug cabinet on a regular schedule. Use products with older expiry dates first. Discard all expired products. Proper disposal Safe disposal of livestock medicines is essential to protect farm employees, family members, untreated livestock, and the environment from accidental exposure to potentially hazardous chemicals. Many veterinarians and manufacturers will accept returns of products at the location of purchase. In some municipalities, medicines can be disposed of on "Household Hazardous Waste Days. Never reuse livestock medicine containers. Store containers for discarding in a way which prevents access by children, livestock and pets. Most washed containers with the exception of pesticide containers may be disposed of in landfill sites. Check with your municipality. More information available Proper storage and handling of veterinary medicines ensures drug effectiveness and reduces potential for treatment error. Consult your veterinarian about preventive animal health management and proper use of livestock medicines. Other excellent sources of information on these subjects include local offices of the Ontario Ministry of Agriculture and Food, and the Canadian Animal Health Institute in Guelph. A clean, organized refrigerator in a frost-free location makes an excellent storage unit for livestock medicines.

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Chapter 2 : Lactated Ringers - FDA prescribing information, side effects and uses

Drug products:Medicines, including marketed human Storage Management System:A program that is used and veterinary prescription finished dosage medications, to control the storage of drug products. in-process/intermediate/bulk materials, drug product Supply chain:The continuum of entities spanning the.

Did you know that mail order pharmacies routinely violate USP guidelines for shipping prescription medicines? What about generic drug shipments from abroad? In an attempt to save moneyâ€”lots of moneyâ€”insurance companies and other payers have turned to large mail order pharmacy services. These organizations usually charge less than chain pharmacies or mom and pop drugstores because their overhead is lower. How do you think the majority of medications are delivered to the pharmacy? You raise a fascinating question that neither the FDA nor the pharmacy industry likes to address. Many yeas ago we met with quality control experts who worked for big brand name drug companies. They were passionate about maintaining and shipping medicine under ideal conditions. They have strict procedures for the proper storage of medicine based on rigorous stability testing. That meant storage at the plant under both temperature and humidity control within narrow parameters. When they shipped to large pharmacy chain warehouses or drug wholesalers they relied upon trucks that were also temperature and humidity controlled. In addition, the manufacturers frequently inserted their own monitoring systems into the packaging so they could verify that the truckers followed the rules. The quality control experts admitted to us that once their products were delivered to warehouses, the responsibility for proper storage reverted to the wholesalers and pharmacy chains. The delivery vehicles from warehouses to individual pharmacies are probably not carefully monitored for temperature or humidity. Instead, it goes onto shelves that are room temperature. Every medication comes with specific guidelines for proper storage. Here are just a few examples: Store at controlled room temperature 68 degrees to 77 degrees with excursions permitted between 59 degrees and 86 degrees. Store at 77 degrees Fahrenheit. Excursions permitted to 59 degrees to 86 degrees Fahrenheit. The Loophole Called Excursions: Companies are allowed short-term violations of the specified storage temperature during shipping and distribution. In most cases the time limit is 24 hours and the deviations excursions from the standard temperature are specified. For another, medications are likely to sit for hours in mailboxes that are below freezing in the winter or above degrees F in the summer. What About Drugs Imported from Abroad? As far as we can tell, the FDA does not involve itself in issues of shipping and distribution. A generic manufacturer in India, China, Brazil or Thailand might well store and transport medications in violation of USP guidelines and no one would be the wiser. Because it can take many days to get packages from the manufacturing plant abroad to the U. Finally, letting the bottles sit for hours in a freezing delivery vehicle and a mail box does not add to our confidence. Imagine shipping fish, chocolate or milk under such uncontrolled conditions! We think that generic drug companies and mail order pharmacies should be required to follow USP recommendations for storage and shipment. So should pharmacy chains and mom and pop pharmacies. What do you think? Please comment on this article below, share your own story and vote on this article at the top of the page.

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Chapter 3 : National Ag Safety Database - National Ag Safety Database

Good storage and distribution practices apply to all organizations and individuals involved in any aspect of the storage and distribution of all drug products, including but not limited to the.

The amount of water that can permeate from inside the container into the overwrap is insufficient to affect the solution significantly. Solutions in contact with the plastic container can leach out certain of its chemical components in very small amounts within the expiration period, e. However, the safety of the plastic has been confirmed in tests in animals according to USP biological tests for plastic containers as well as by tissue culture toxicity studies. It is capable of inducing diuresis depending on the clinical condition of the patient. Lactate ions are metabolized ultimately to carbon dioxide and water, which requires the consumption of hydrogen cations. If the same infusion line is used for sequential administration, the line must be thoroughly flushed between infusions with a compatible fluid. The infusion must be stopped immediately if any signs or symptoms of a suspected hypersensitivity reaction develop. Appropriate therapeutic countermeasures must be instituted as clinically indicated. Hypersensitivity reactions are reported more frequently during pregnancy. The risk of dilutional states is inversely proportional to the electrolyte concentrations of the injections. The risk of solute overload causing congested states with peripheral and pulmonary edema is directly proportional to the electrolyte concentrations of the injections. Clinical evaluation and periodic laboratory determinations may be necessary to monitor changes in fluid balance, electrolyte concentrations, and acid base balance during prolonged parenteral therapy or whenever the condition of the patient or the rate of administration warrants such evaluation. Because lactate is metabolized to bicarbonate, administration may result in, or worsen, metabolic alkalosis. Precautions Do not connect flexible plastic containers in series in order to avoid air embolism due to possible residual air contained in the primary container. Pressurizing intravenous solutions contained in flexible plastic containers to increase flow rates can result in air embolism if the residual air in the container is not fully evacuated prior to administration. Use of a vented intravenous administration set with the vent in the open position could result in air embolism. Vented intravenous administration sets with the vent in the open position should not be used with flexible plastic containers. Hyperlactatemia can develop in patients with severe hepatic insufficiency, since lactate metabolism may be impaired. Solutions containing calcium salts should be used with caution in patients with hypercalcemia or conditions predisposing to hypercalemia, such as patients with severe renal impairment and granulomatous diseases associated with increased calcitriol synthesis such as sarcoidosis, calcium renal calculi or history of such calculi. Lactate is a substrate for gluconeogenesis. The warnings, precautions and adverse reactions identified in the label copy should be observed in the pediatric population. Lactate-containing solutions should be administered with particular caution to neonates and infants less than 6 months of age. Other reported clinical experience has not identified differences in responses between the elderly and younger patients. In general, dose selection for an elderly patient should be cautious, usually starting at the low end of the dosing range, reflecting the greater frequency of decreased hepatic, renal, or cardiac function, and of concomitant disease or other drug therapy. Renal clearance of lithium may also be increased. Studies to evaluate the possible impairment of fertility have not been performed. Caution should be exercised when administering this drug during labor and delivery. Nursing Mothers It is not known whether this drug is excreted in human milk. Excessive administration of lactate may lead to metabolic alkalosis. Metabolic alkalosis may be accompanied by hypokalemia. Excessive administration of potassium may lead to the development of hyperkalemia, especially in patients with severe renal impairment. Excessive administration of calcium salts may lead to hypercalcemia. When assessing an overdose, any additives in the solution must also be considered. The effects of an overdose may require immediate medical attention and treatment. Lactated Ringers Dosage and Administration As directed by a physician. After opening the container, the contents should be used immediately and should not be stored for a subsequent infusion. Do not reconnect any partially used containers. Parenteral drug products should be

inspected visually for particulate matter and discoloration prior to administration whenever solution and container permit. Do not administer unless the solution is clear and seal is intact. Mix the solution thoroughly when additives have been introduced. Do not store solutions containing additives. The instructions for use of the medication to be added and other relevant literature must be consulted. Additives known or determined to be incompatible should not be used.

Chapter 4 : How Was Your Medicine Stored, Shipped and Delivered? - The People's Pharmacy

(2) Each outgoing shipment shall be carefully inspected for identity of the prescription drug products and to ensure that there is no delivery of prescription drugs that have been damaged in storage or held under improper conditions.

Such rules shall include, but not be limited to, requirements for the storage and handling of prescription drugs and for the establishment and maintenance of prescription drug distribution records. Access from outside the premises must be kept to a minimum and be well controlled. The outside perimeter of the premises must be well lighted. Entry into areas where prescription drugs are held must be limited to authorized personnel. An alarm system to detect entry after hours; however, the department may exempt by rule establishments that only hold a permit as prescription drug wholesale distributor-brokers; and 2. A security system that will provide suitable protection against theft and diversion. When appropriate, the security system must provide protection against theft or diversion that is facilitated or hidden by tampering with computers or electronic records. This examination must be adequate to reveal container damage that would suggest possible contamination or other damage to the contents. Prescription drugs that are outdated, damaged, deteriorated, misbranded, or adulterated must be quarantined and physically separated from other prescription drugs until they are destroyed or returned to their supplier. A quarantine section must be separate and apart from other sections where prescription drugs are stored so that prescription drugs in this section are not confused with usable prescription drugs. Prescription drugs must be examined at least every 12 months, and drugs for which the expiration date has passed must be removed and quarantined. Persons permitted or required to be permitted under this chapter to engage in the manufacture, repackaging, or distribution of active pharmaceutical ingredients or prescription drugs. Persons other than those set forth in subparagraph 1. The name and address of the seller, and the Florida permit number of the seller if such seller is not exempt from Florida permitting requirements, of the active pharmaceutical ingredient or prescription drug. The address of the location the active pharmaceutical ingredient or prescription drug was shipped from. The distribution date of the active pharmaceutical ingredient or prescription drug. The name, strength, and quantity, and the National Drug Code if such code has been assigned, of the distributed active pharmaceutical ingredient or prescription drug. The name and Florida permit number of the person that purchased the active pharmaceutical ingredient or prescription drug. The financial data, including the unit type and unit price, for the distributions involving active pharmaceutical ingredients or prescription drugs. The date and method of disposition of the active pharmaceutical ingredient or prescription drug. The name and address of the seller or transferor of the product. The address of the location the product was shipped from. The date of the sale or distribution of the product. The name and quantity of the product involved. The name and address of the person who purchased the product. Records kept at a central location outside of this state which are not electronically retrievable must be made available for inspection within 2 working days after a request by an authorized official of a federal, state, or local law enforcement agency. Records maintained at a central location within this state must be maintained at an establishment that is permitted pursuant to this part, and such records must be readily available for inspection. A wholesale distributor, except a manufacturer, shall notify the department not later than 10 days after any change to either list. Wholesale distributors must include in their written policies and procedures: The procedure may permit deviation from this requirement, if the deviation is temporary and appropriate. Such procedure must be adequate to deal with recalls and withdrawals due to: Any action initiated at the request of the Food and Drug Administration or any other federal, state, or local law enforcement or other government agency, including the department. Any voluntary action by the manufacturer or repackager to remove defective or potentially defective drugs from the market; or 3. Any action undertaken to promote public health and safety by replacing existing merchandise with an improved product or new package design. This procedure must provide for written documentation of the disposition of outdated prescription drugs. This documentation must be maintained for 2 years after disposition of the outdated drugs. A wholesale distributor

that distributes any substance controlled under chapter must notify the department when registering with the Drug Enforcement Administration pursuant to that chapter and must provide the department with its DEA number. A person selling a prescription drug for export must obtain documentation, such as a validated airway bill, bill of lading, or other appropriate documentation that the prescription drug was exported. A person responsible for shipping or transporting prescription drugs is not required to maintain documentation from a common carrier that the designated recipient received the prescription drugs; however, the person must obtain such documentation from the common carrier and make it available to the department upon request of the department. Before purchasing any drug from the wholesale distributor, and at least once each subsequent year; or 2. Before purchasing any drug from the wholesale distributor, and each subsequent year obtain a complete copy of the most recent inspection report for the establishment which was prepared by the department or the regulatory authority responsible for wholesale distributors in the state in which the establishment is located. Wholesale distributor facilities located within this state shall report all transactions involving controlled substances, and wholesale distributor facilities located outside this state shall report all distributions to entities located in this state. If the prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, retail pharmacy drug wholesale distributor, manufacturer, or repackager does not have any controlled substance distributions for the month, a report shall be sent indicating that no distributions occurred in the period. The report shall be submitted monthly by the 20th of the next month, in the electronic format used for controlled substance reporting to the Automation of Reports and Consolidated Orders System division of the federal Drug Enforcement Administration. Submission of electronic data must be made in a secured Internet environment that allows for manual or automated transmission. Upon successful transmission, an acknowledgment page must be displayed to confirm receipt. The report must contain the following information: The prescription drug wholesale distributor, out-of-state prescription drug wholesale distributor, or retail pharmacy drug wholesale distributor shall maintain records of such credentialing and make the records available to the department upon request. Such credentialing must, at a minimum, include: A determination of the clinical nature of the receiving entity, including any specialty practice area. A wholesale distributor must establish internal policies and procedures for identifying suspicious orders and preventing suspicious transactions. A wholesale distributor must assess orders for more than 7, unit doses of any one controlled substance in any one month to determine whether the purchase is reasonable. A wholesale distributor must report to the department any regulated transaction involving an extraordinary quantity of a listed chemical, an uncommon method of payment or delivery, or any other circumstance that the regulated person believes may indicate that the listed chemical will be used in violation of the law. The wholesale distributor shall maintain records that document the report submitted to the department in compliance with this paragraph.

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Chapter 5 : Proper Storage for Temperature-Sensitive Drug Products - West Pharma

Drug products must be transported, handled and stored in a manner that mitigates the risk of exposure to temperatures outside labelled storage conditions; potentially impacting the safety, quality and effectiveness of the drug product.

Drug products must be transported, handled and stored in a manner that mitigates the risk of exposure to temperatures outside labelled storage conditions; potentially impacting the safety, quality and effectiveness of the drug product. Section 11 of the Food and Drugs Act , read together with the definition "unsanitary conditions" in Section 2 of the Food and Drugs Act, prohibits any person from: These requirements are in place to maintain the safety, quality and efficacy of the drugs. Every activity in the distribution of drugs should be carried out according to requirements of the Food and Drugs Act, the principles of Good Manufacturing Practices GMP , as well as appropriate storage and transportation practices. Environmental controls play a key role in maintaining drug safety, quality and efficacy. Temperature is one of the most important parameters to control. Drugs must be stored, and transported according to predetermined conditions for example, temperature, etc. This guidance is not intended to cover every conceivable case. Alternative means of complying with the intent will be considered with appropriate scientific justification. Different approaches may be called for as new technologies emerge. This document builds on other pre-existing international guidance see List of References. The maintenance of the chain of storage and transportation conditions should be supported by written agreements among the distributor, the importer, the wholesaler, and the transportation provider in order to preserve drug safety, quality and efficacy. The responsibility of each party, is to ensure that the required storage and transportation conditions are met through their respective GMP activities. These guidelines apply equally to drugs for human and veterinary use and to clinical trial drugs for human use as required under C. Semen is excluded from the scope of this guide. All drugs should be stored according to the conditions described on the label. When specified on the label, controls for humidity, light, etc. Storage areas should be designed or adapted to ensure good storage conditions. In particular, they should be clean, dry, have adequate circulation and maintained within acceptable temperature limits. To reduce human error, general storage areas are well lit. The label should specify any special storage conditions required for the product. Adherence to these conditions should be checked, monitored and recorded. Temperatures should be controlled and monitored using calibrated monitoring devices and records of temperature and alarms, where applicable, should be maintained. Monitoring of storage facilities is conducted at points representing the worst case scenarios of the temperature range based on temperature mapping. Refrigerators and freezers used to store drugs should: The use of household type refrigerators and freezers is discouraged. Written procedures should be available describing the actions to be taken in the event of temperature excursions outside the labelled storage conditions. All excursions outside the labelled storage conditions must be appropriately investigated and the disposition of the stock in question must be evidence-based for example, stability data and technical justification. Appropriate training, as determined by the company, should be provided for personnel involved in warehousing and storage to ensure appropriate handling of temperature sensitive material. Records of this training should be maintained. The transport process and containers should be designed to prevent damage and maintain the integrity and quality of the drug products. For example, transport conditions for ampoules should limit their exposure to physical stress to avoid the development of hairline cracks. Written procedures for the shipping of drug products should be established. Such procedures should take into account the nature of the drug products, local conditions, modes of transport and any seasonal variations experienced, as well as describe any special handling precautions. Where controlled storage conditions for example, temperature, relative humidity, light, etc. Within a transportation container, the packaging configuration, which provides the primary means of environmental control for the drug product, should ensure that the drug product remains within the acceptable temperature range. Temperature and humidity monitoring devices, such as data loggers, should be calibrated at

predetermined intervals. Single use monitoring devices should be qualified for example, verification of performance for indicator strips or freeze indicator units. A record of the review should be kept and any discrepancies should have a follow up. Vehicles and equipment used to distribute, store, or handle drugs should be suitable for their use and appropriately protective of the products to prevent exposure to conditions that could affect their stability and packaging integrity, as well as prevent contamination of any kind. Loading activities loading and unloading should be done in a manner that preserves the quality of the drugs. This label should be securely affixed and indelible. The label and shipping documents should clearly state that these products should be transferred without delay to the specified storage temperature upon receipt. Shipping containers should be qualified to meet the expected extremes of ambient temperature within the distribution environment, if they provide the primary means of environmental control for the drug product. The use of dry ice in the transportation of drugs must not adversely affect the drug product or the primary package and must be handled in accordance with the Transportation of Dangerous Goods Act. Temperature monitoring devices or temperature indicators should be used when appropriate. If temperature excursions outside predetermined temperature conditions, as per the labelled storage conditions occur, these excursions must be assessed and documented to determine product disposition. Corrective action should be implemented where necessary and documented. The reception area should be separate from storage area. Deliveries should be examined at receipt in order to check that containers are not damaged and that the consignment corresponds to the order. Where controlled conditions for example, temperature, relative humidity, light, etc. Products should be promptly transferred to the appropriate, environmentally controlled storage area. Controlled drugs and substances subject to specific security requirements should be immediately identified and stored in accordance with written instructions and with relevant legislative requirements. Security on these products is monitored and maintained at the legally required level. The contractors should comply with the written agreement. Distributors, importers and wholesalers should maintain transportation records of inbound and outbound shipments, including monitoring records where applicable, for a period of one year after expiry date of the product. Records of investigations and actions taken in the event of excursions outside predetermined temperature conditions, as per labelled storage conditions are kept for a minimum of one year after the expiration date of the product. Recorded temperature monitoring data and alarm records should be available for review. The maintenance and calibration records of the equipment used for monitoring should be maintained. Final Distribution Point - The final destination where the drug will be used or sold for example, pharmacy, hospitals, clinics, retail stores, etc. Such samples should be based on seasonal extremes. Stability Data - Data from the accelerated storage condition stability study and, if appropriate, from the intermediate storage condition stability study can be used to evaluate the effect of short term excursions outside the labelled storage conditions such as might occur during shipping. Temperature excursion - A temperature excursion is a variance outside of the labelled storage conditions. PDF version - K.

Chapter 6 : Statutes & Constitution :View Statutes : Online Sunshine

The quality control experts admitted to us that once their products were delivered to warehouses, the responsibility for proper storage reverted to the wholesalers and pharmacy chains. The delivery vehicles from warehouses to individual pharmacies are probably not carefully monitored for temperature or humidity.