SterRx®

STERILE MANUFACTURER OF 503B COMPOUNDED DRUGS

Polyethylene and PVC Plastics: Effects on Drug Stability Due to Leaching and Component Extractability

Purpose: SterRx customers have inquired about the leachable and extractible nature of our containers in relation to medications they may add to our product. Chemical properties will be used to compare typical market product containers to our product container.

Background: Low-density polyethylene (LDPE), or polyethylene (PE), is a polyolefin used for making various plastic products such as intravenous (IV) tubing, bottles, and laboratory equipment. SterRx, LLC uses vendor qualified LDPE plastics to create a sterile container enclosure that is representative of an IV bag. SterRx bags are manufactured using Blow-Fill-Seal technology and are created at the time of filling by machinery and closed immediately after filling before leaving the sterile area of the machine. These bags are different in composition from commonly studied bags that many hospital staff are familiar with; generally, those heavily studied bags are made of Polyvinylchloride (PVC) and mixed with Di-2ethylhexylphthalate (DEHP), a plasticizer, to form a soft, flexible bag.[1]

Scope: Assessment of the "typical" IV bag compared to SterRx IV bags in terms of leachable and extractible capabilities using studies and characteristics of the materials used to create the bags.

Assessment: Contact with the inside of a container has the ability to affect the pharmaceuticals in a preparation intended for IV administration. B. Braun has a line of products that utilize PE plastics, to create containers for holding medications for IV administration. They state that the PE plastic is "chemically inert, toxicologically safe, free from plasticizers, additives and other compounds that may potentially migrate into the finished preparation."[2]

Zeidler et al performed comparisons of drug stability in various containers using PE bags (manufactured by B. Braun®), PVC bags (manufactured by Baxter®), and glass containers (manufactured by B.Braun®); this showed beneficial characteristics to the pure PE container over the PVC container. Looking at common intensive care medications, the inert nature of PE is shown in comparisons between glass, PE, and PVC. Diazepam, isosorbide dinitrate, miconazole, and nitroglycerin all showed marked difficulties with 24 hour stability in PVC with initial concentration decreases to 33.7%, 56.8%, 71,4%, and 33.8%, respectively. The same drugs in PE demonstrated fair stability with 24 hour concentration of 96.0%, 98.8%, 98.6%, and 99.3%, respectively. Glass containers were similar to PE with decreases after 24 hours to 94.5%, 97.5%, 98.3%, and 99.6%, respectively. The study demonstrated PE has a profile comparable to glass containers within the studied drugs[3].

IV tubing is another source of leaching in the administration process and provides data on plastic characteristics that are applicable to IV bags. Data supporting PE's inert characteristics is available in a study concerning different tubing and the reactivity of the tubes to different drugs at room temperature. Specific drugs observed were chlormethiazole hydrochloride, isosorbide dinitrate, and nitroglycerin; PVC showed high leaching of all 3 examples, whereas PE showed greatly reduced leaching of chlormethiazole hydrochloride and minimal to no leaching of the other drugs. This study adds more supportive data to the inert nature of PE plastics compared to PVC[4].

Conclusion: The data supports the use of LDPE/PE bags over PVC bags. The LDPE plastic is inert in nature and shows reduced leaching compared to PVC. The absence of DEHP eliminates a major issue of extraction of plasticizer present in PVC bags compared to LDPE. LDPE has a profile that is similar to glass, enhancing the stability of drugs that would otherwise be unstable in the highly studied PVC bags.

References

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