

The Beyond-Use-Date of Dextrose Syringes from a Sterile Stock Solution

The goal of OPA's Drug Information Challenge is to highlight quality drug information responses solicited from students across the state, who submitted questions from physicians, educators, patients and preceptors. Submissions were encouraged to be innovative and unique. Judges scored responses on grammar, punctuation, completeness of response, strength of references, and clarity of recommendation.

This year's winner was Sarah Turley, PharmD candidate 2015 from Ohio Northern University. Her article, *Guaifenesin in Fertility*, was published in the April 2014 issue of the *Ohio Pharmacist*.

The following article, *Beyond-Use-Date of Dextrose Syringes from a Sterile Stock Solution*, was submitted by Brandon Bourgeois, PharmD candidate 2016 Ohio Northern University and received honorable mention.

What is the beyond-use-date (BUD) of individually compounded dextrose syringes?

Background:

Code trays contain life-saving medications that can be used in emergent medical conditions and are stocked in crash carts in hospitals. Although the medications, their strengths, and formulations found in each hospital's code trays will vary depending on the formulary, preferences, and the availability of each medication, one universal item is a dextrose syringe for IV push during a hypoglycemic crisis. Memorial Hospital of South Bend (MHSB) (South Bend, Indiana) uses prefilled Abboject sterile dextrose 50% syringes for IV push (25g/50mL) for this purpose.

Due to drug shortages and availability issues with medications, this sterile prefilled dextrose syringe has been on back order. However, an equivalent dextrose syringe or a therapeutic alternative must be available in the case of hypoglycemic emergency.

The easiest alternative would be for the pharmacy to prepare 50mL syringes of sterile dextrose from a large stock bag. MHSB uses sterile dextrose 70% as a stock solution for the preparation of bulk preparations and total parental nutrition (TPN) formulations. By using 35.71 mL of the dextrose 70% solution and diluting it with 14.29 mL of sterile water in a syringe an approximate 25g/50mL of sterile dextrose in a syringe could be made to replace the unavailable prefilled syringes.

However, stability data of the compounded syringes was unknown. This was vital to know before the product could be used for two reasons: the product must remain chemically stable so that it will be biologically active, and because the dextrose solution is to be used parenterally it must remain free from microbiological contamination. The second factor is an issue whenever a product is manually prepared; generally the beyond-use-date (BUD) is shorter to prevent contamination of the product.

Response:

The United States Pharmacopeial Convention (USP) provides general BUD guidelines in the absence of other data.¹ Based on the number of products going into the sterile preparation (stock dextrose 70% solution and sterile water for dilution), the cleanroom environment, limited manipulations, and lack of sterility testing the longest BUD that can be given to the sterile syringes is 14 days at a cold temperature based on USP guidelines. Dextrose may not be autoclaved due to chemical degradation.² 5-hydroxymethylfurfural (5-HMF) is the primary degradation product of aqueous dextrose solutions, though at a refrigerated temperature this process occurs very slowly, and over a longer period than the preparation may remain sterile.^{1,3}

Final Recommendation:

The manually compounded dextrose 50% syringes may be drawn up by the MHSB pharmacy and stored in the local refrigerator at each place there is a crash code. Although the solution may remain chemically stable for months, sterility is key due to IV administration and the fact that dextrose cannot be autoclaved, and therefore the shorter BUD that will be used is the 14 days based on USP sterility recommendations. A note should be placed in the appropriate spot in the code tray to notify the responding staff that if the dextrose 50% syringe is needed it can be found in the refrigerator on the unit and is ready to use. Pharmacy staff will keep track of the outdated syringes through the automated dispensing cabinet system and will replace outdated syringes as needed until the premade solution is available.

References:

1. USP 36-NF 31. United States Pharmacopial Convention and National Formulary (USP-NF). Rockville, MD, 2013. p. 366.
2. Durham DG, Hung CT, Taylor RB. Identification of some acids produced during autoclaving of D-glucose solutions using HPLC. *Int J Pharm.* 1982 Mar 3;11:31-40.
3. Xu H, Templeton AC, Reed RA. Quantification of 5-HMF and dextrose in commercial aqueous dextrose solutions. *J Pharmaceut Biomed.* 2003 Feb 23;32:451-9.