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Why are compounders looking to compound amoxicillin?

Amoxicillin (a beta-lactam antibiotic) for oral suspension is currently on acute shortage. A comprehensive list of products on shortage can be found at the FDA's site here: [FDA Drug Shortages](#).

Why the specific concern regarding beta-lactam antibiotics?

Beta-lactam antibiotics are considered to represent a significant allergenic risk and cross-contamination between beta-lactam antibiotics and other drugs could potentially result in life-threatening allergic reactions. The FDA has previously stated on their Insanitary Conditions at Compounding Facilities guidance for industry (GFI) that the processing of beta-lactams without complete and comprehensive separation from non-beta-lactam products is considered to be insanitary.

May 503a compounding pharmacies compound amoxicillin oral suspension during the shortage?

The recent GFI from the FDA, Compounding Certain Beta-Lactam Products in Shortage Under Section 503A of the Federal Food, Drug, and Cosmetic Act, clarifies that enforcement and regulatory actions will be prioritized if the below steps are not followed when working with beta-lactam antibiotics:

1. Use of FDA-approved beta-lactam tablets and capsules instead of bulk drug substances to compound the beta-lactam oral antibiotic suspension product

2. Temporal segregation of the compounding of these oral suspensions from non-beta-lactam products
3. Use of dedicated or disposable equipment, utensils, and personal protective equipment (e.g., gowns, gloves)
4. Segregation and storage in a separate area of any equipment, utensils, and personal protective equipment used in the compounding of these oral suspensions (e.g., glassware, mortar and pestle) from equipment, utensils, and personal protective equipment not used in beta-lactam compounding
5. Trituration of the FDA-approved product after wetting it with a quantity of the suspension vehicle sufficient to eliminate formation of product dust
6. Use of proper cleaning procedures after completing compounding, including use of peroxide or bleach solutions to deactivate the beta-lactam ring of any drug residue on surfaces. The use of strong oxidizers should be followed by neutralizers and volatile cleaning agents (e.g., purified water, isopropanol) to minimize damage to these surfaces
7. Containment and remediation of spills
8. The beyond-use-date assigned to the compounded oral suspension does not exceed the beyond-use-date of the related reconstituted FDA-approved beta-lactam antibiotic powder for oral suspension product that is on FDA's drug shortage list, as found on the approved labeling; and
9. Storage conditions used for the compounded oral suspension are consistent with those for the related reconstituted FDA-approved beta-lactam antibiotic powder for oral suspension product that is on FDA's drug shortage list, as found on the approved labeling.

For more information, read the complete GFI here: [Compounding Certain Beta-Lactam Products in Shortage Under Section 503A of the Federal Food Drug and Cosmetic Act | FDA](#)

Sources:

Compounding Certain Beta-Lactam Products in Shortage Under Section 503A of the Federal Food, Drug, and Cosmetic Act Immediately in Effect Guidance for Industry. U.S. Food and Drug Administration. November 18, 2022. Accessed November 18, 2022. [Compounding Certain Beta-Lactam Products in Shortage Under Section 503A of the Federal Food Drug and Cosmetic Act | FDA](#)

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