

Current Good Manufacturing Practices (cGMPs)

Jost Chemical Co. is registered with the Food & Drug Administration (FDA) as a “Drug Establishment” manufacturer of USP/NF high purity compounds. As such, Jost Chemical is audited by the FDA to ensure that its manufacturing systems comply with current Good Manufacturing Practices (cGMPs). The FDA conducts these audits in accordance with the guidance provided by ICH Q7A.

The current Good Manufacturing Practices formalize, through documented systems and procedures, the quality requirements and attributes of all systems, operations, equipment, and personnel. These procedures are often referred to as Standard Operating Procedures or SOPs. The term “manufacture” is very inclusive and refers not only to the actual production of a substance but also to all aspects of the manufacturing process including:

- **Organizational and Personnel Requirements**
- **Facilities/Equipment/Systems Qualification**
- **Receipt and Approval of Raw Materials**
- **Production and Processing Controls**
- **Packaging and Labeling Control**
- **Quality Control of Materials and Systems**
- **Systems and Process Validation**
- **Laboratory Controls and Release of Finished Products**
- **Product Stability Testing**
- **Storage and Distribution**



If a product is “not manufactured using good manufacturing practices,” the FDA can classify a product as adulterated even if it complies with all finished product specifications.*

Manufacturing practices that follow a rigorous cGMP system, designed to produce materials that meet all finished product specifications, is the only acceptable way to ensure consistent quality products. Finished product testing alone will not provide a sufficient level of quality. At best, only a very limited number of samples can be tested and this small sampling may or may not provide a true representation of the actual quality. In fact, if a product is “not manufactured using good manufacturing practices,”* the FDA can classify a product as adulterated even if it complies with all finished product specifications. Also, any product with USP/NF on the label can result in a mandate from the FDA for a formal audit.

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At Jost Chemical, all USP/NF products undergo extensive testing prior to release. While this is important, the ultimate assurance of quality comes from our all-inclusive system of cGMPs. This formalized system ensures that every aspect of our manufacturing process contributes to a final product that consistently and reproducibly satisfies all requirements for strength, identity, purity, potency, quality, and regulatory compliance.

By rigorously following cGMPs, Jost Chemical demonstrates a commitment to focusing on the details in the manufacture of high purity mineral salts.



The increased product cost associated with tighter regulations and quality assurance compliance is always a challenge for reputable manufacturers. One way to lessen this effect is to align with a supplier that can meet your requirements with a more consistent product, that rigorously adheres to cGMPs, and one that can verify its controlled manufacturing practices. By rigorously following cGMPs, Jost Chemical demonstrates a commitment to focusing on the details in the manufacture of high purity chemical salts. This includes the manufacture of a broad range of citrates, carbonates, fumarates, gluconates, lactates, phosphates, nitrates, and sulfates that meet the USP/NF monograph compendiums.

* U.S. Pharmacopoeia 38th
NF 33rd Edition



Introducing...

Free Flowing Ammonium Sulfate and Sodium Acetate

Jost Chemical Co. is now manufacturing Ammonium Sulfate and Sodium Acetate Trihydrate. The products are manufactured under cGMPs and meet the USP/EP/NF/ACS monographs. Both chemical salts are manufactured to be free-flowing without additives. They are typically used as buffering agents in the manufacturing of pharmaceuticals.

Product Code	Chemical Formula	Product Name
2032 2033	$(\text{NH}_4)_2\text{SO}_4$	Ammonium Sulfate NF/ACS Crystals or Granulated
2719	$\text{NaC}_2\text{H}_3\text{O}_2 \cdot 3\text{H}_2\text{O}$	Sodium Acetate Trihydrate USP/EP Granulated