

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 mineral 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.

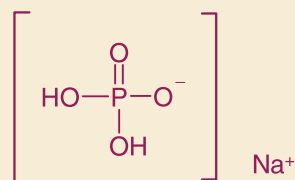
* U.S. Pharmacopoeia 29th
NF 24th Edition

Introducing...

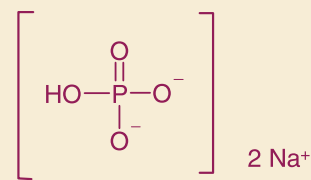
Sodium Phosphates

Jost Chemical Co is now manufacturing the following forms of Sodium Phosphate with differing levels of hydration. The products are produced under systems that comply with cGMPs and meet the USP monograph. These products are typically used as a buffering agent in pharmaceuticals and other high-purity specialty applications.

Product Code	Chemical Formula	Product Name
2766	$\text{NaH}_2\text{PO}_4 \cdot \text{H}_2\text{O}$	Sodium Phosphate Monobasic Monohydrate USP
2771	Na_2HPO_4	Sodium Phosphate Dibasic Anhydrous USP
2775	$\text{Na}_2\text{HPO}_4 \cdot 2\text{H}_2\text{O}$	Sodium Phosphate Dibasic Dihydrate USP



Sodium Phosphate Monobasic



Sodium Phosphate Dibasic

