



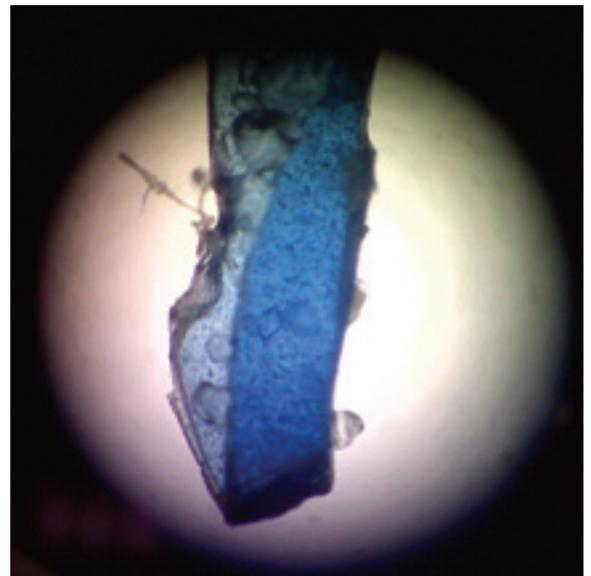
**THORNE RESEARCH**  
the original specialists in pure encapsulations™

## The Betaine Backorder Situation

Two years ago, the only manufacturer in the United States of betaine hydrochloride (betaine HCl) closed their manufacturing facility for a complete plant overhaul and refitting. Thorne Research purchased this manufacturer's entire remaining stock of betaine HCl (several thousand kilos) in anticipation of Thorne's future manufacturing needs. When this reserve began to run low, we attempted to find another quality manufacturer of betaine HCl; unfortunately, to no avail. There are no U.S. prime manufacturers, only brokers of this raw material that is manufactured in China. While many raw materials are manufactured in China in ISO level plants to high quality standards, many raw materials are not.

The following is what you, the practitioner, never sees.

We obtained a sample of betaine HCl from a potential supplier that easily passed our quality control for purity, identity, heavy metals, etc. It was beautiful crystalline powder. We therefore ordered 3,200 kilos from the supplier and received seven lots into our quarantine warehouse. You should know that the typical dietary supplement manufacturer in our industry would usually sample just one drum, test the material, and if the material passed, then the entire shipment would be approved. What we found, however, you can see in the pictures below. Mixed in with the product were a number of unknown contaminants, which would probably not be readily apparent in taking only a small sample from a single drum. Contaminants were found after screening several drums from each one of the seven lots of product – and contaminants were found in all seven lots. Some of the contaminants were even embedded in the betaine HCl crystals. The most interesting contaminant, seen under the microscope, is the blue crystalline sapphire-like structure.



But this was just the beginning of this saga, as you will see. We rejected the material and all 3,200 kilos were returned to the supplier. The supplier had already sold thousands of kilos of this material to other supplement manufacturers and informed us it had not received a single complaint. And it ostensibly had no problem selling this material to our competitors, who apparently were merely grinding up the contaminants, perhaps never seeing them. You see, 21 C.F.R Part 111, the FDA's newly implemented Good Manufacturing Practice guidelines for the dietary supplement industry has a major flaw – the FDA's new GMPs do not apply to raw material manufacturers. And neither are raw material manufacturers included in the FDA's new inspection protocol, these manufacturers only fall under food GMP. Therefore, the duty of assuring the quality and identity of ingredients falls squarely upon the manufacturer of the finished dietary supplement. "Know your supplier" really takes on meaning here.



Round two was to obtain a sample of raw material from every potential U.S. supplier, as well as a certificate of analysis (CofA). The first roadblock is the reluctance of many suppliers to provide the “original” CofA, so they are not circumvented in the purchasing process. Many times the original CofA document from the actual manufacturer is cut-and-pasted by the supplier onto the supplier’s letterhead. The next problem is that upon obtaining the CofA of the Chinese company from whom the supplier purchased the ingredient, you find that this company is not the actual manufacturer, but merely a Chinese broker for the ingredient. You have to move up the food chain to the next level, a more involved process.

The samples that came to us from the various potential suppliers were very similar in appearance to the initial material we analyzed – beautiful powder. Each supplier agreed to air-freight one drum of material from their respective Chinese broker. One supplier claimed to have 30,000 kilos available in Ontario, California. Each drum, upon subsequent screening by us, had the same type of contaminants – some of them also included the mysterious blue crystal. The CofA differed from supplier to supplier, but the supposedly different materials inexplicably contained the same contaminants.



We have a longstanding reputable supplier of Chinese raw materials who had a representative flying to China to source materials who agreed to look into this situation on our behalf. Upon actual inspection of the largest Chinese manufacturer, it was found that the mystery blue crystals are actually flakes of ceramic coating from a poorly maintained reactor, one of hundreds of “government-issued” reactors used in many Chinese manufacturing plants. This single large manufacturer makes thousands of kilos of betaine HCl and then down-chain distributors put their company’s name on the product and brokers sell the product with the multiple-distributor cut-and-pasted CofA representing the product as being from an individual manufacturer.

We now have a representative actually present at a high-quality Chinese manufacturing facility that is manufacturing product for our inspection. Thankfully, the U.S. plant who is our original supplier is now doing pilot batches and is close to re-opening and taking orders.

While Thorne Research obviously regrets our current backorder situation involving those products containing Betaine HCl, we want you to always know and be assured that we will never compromise quality.

Thorne Research strongly suggests that practitioners question those supplement manufacturers for any betaine HCl-containing products purchased during the past 18 months. It may be prudent to pursue obtaining a CofA for betaine HCl from your supplement manufacturer and request that the CofA be from the material’s primary manufacturer, along with an invoice showing your manufacturer’s purchase of the material within the past 18 months. If the CofA indicates a U.S. or Canadian company, call them yourself to find out whether or not they are an actual manufacturer. If they are not, demand to know where the betaine HCl was manufactured and request a CofA from the actual manufacturer. If you have any questions about a CofA you have received, or you need additional information, please contact Thorne Research.

Sincerely,  
Al Czap  
President & CEO



**THORNERESEARCH**  
the original specialists in pure encapsulations™