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Explanation regarding the Manufacture of GMP 10N Sodium Hydroxide and why “true” GMP does not require it being made from a certified pellet.

“BioSpectra is not the only company in the world manufacturing true, full GMP Sodium Hydroxide Solutions, directly from raw material and not from a certified pellet. That company being BioMarin in Shanbally Ireland. They have a process that works directly with sea-water as starting material. Our process is similar in that we work with concentrated solutions and reduced it down through multiple steps of purification prior to manufacturing the final GMP NaOH solution (10M, 25%, 5M, 2M, 1M, 0.5M and 0.1M). The former is combined with WFI water at all strengths.

Where does a pellet come from in the first place? it’s a concentrate of a solution from a slurry that was itself, not created under GMP but like all GMP chemicals, the elements were brought together, reacted, reduced and purified under GMP to make a GMP final product. In that former situation, a Slurry to a pellet. The pellets are then used to make solutions around the world as this is the most economical way to ship material (without-water).

Unfortunately, countless generations of chemists have made NaOH solutions from pellets and because of that, most people simply believe it has to be done that way. GMP guidelines allow for purification of raw material and final product. All API’s are made this way as are all excipients. Just because many solutions are more easily made with compendial solids and compendial water, the alternative approach, though novel, perfectly conforms to all GMP standards in every way. Since the vast majority who make NaOH Solutions do so through the pellet route for NaOH, those CofA’s always make a statement such as “made from multicompendial pellets and USP Water” or made from USP NaOH Pellets and USP Water. The absence of that statement decries an alternate GMP path and is not a corruption of the concept. It should be noted however that there are no compendial certifications for any NaOH Solutions made from compendial certified pellets further combined with compendial grade water: no compendial monographs in the USP, EP, JP or CP.

Our unique, proprietary, fully GMP manufacturing system was created in the wake of a rather large disruption in the market in 2018 caused by a shift in the manufacturing processes by the old EK plant in Sweden as they finally moved away from the mercury cell process after many years of notification to the industry. They had to change the specification to increase impurity levels in all solutions made from those pellets and hence many end users were forced to recertify this very common product used in biomanufacturing. Our process was able to achieve purity levels for the final product that met and exceeded the original higher purity properties of the original pellets. Combined with our own WFI system, BioSpectra makes the highest purity, fully GMP Sodium Hydroxide solutions in the world.”

Respectfully submitted,



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