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Cleaning in Place Solutions

Cleaning in place (CIP) is a mandatory requirement and critical in the pharmaceutical and biopharmaceutical markets due to the possibility of contamination and regulatory conformance. CIP solutions must always be validated to ensure proper cleaning. These solutions ensure safety, prevent toxic contamination of critical areas and products, as well as minimize the risk of recontamination. To achieve the highest cleaning efficiency and effectiveness, a composite blend of different chemicals is required during the decontamination process.

bio™ CERTIFIED

A critical area in any biopharmaceutical process is the purification/filtration processes. The devices, media and resins utilized during these processes are costly. For chromatography media, regeneration can be performed directly inside the column. This avoids unpacking and repacking of the media. CIP is critical to extend the life of costly chromatography media because it is used in multiple production runs. Spectrum Chemical can provide the CIP solutions you need to safeguard all of your chromatography and filtration devices.

The preservatives used for chromatography media solutions must meet a number of demands. Most importantly, they must be sufficiently effective at preventing growth of microorganisms during the entire shelf life, without affecting the functionality of the medium. In addition, the preservative should be non-toxic to humans, inexpensive and easy to dispose.

Spectrum Chemical's CIP solutions meet the highest demands for purity and reliability. They effectively prevent contamination of costly media and filtration equipment. These bioprocess-focused solutions are manufactured to meet and exceed the requirements of biopharmaceutical manufacturers. All of these solutions are manufactured under cGMP conditions and feature low bioburden levels with documentation and technical support provided.

CIP solutions generally include an acid, alkali and detergent, as well as a rinsing agent – preferably water for injection (WFI).

A CIP acidic solution based on nitric acid, phosphoric acid or sulfuric acid will eliminate inorganic sediment in tanks, tubes, fermentation or other similar equipment.

Acidic solutions containing 1% - 2% benzyl alcohol sanitize and clean affinity media efficiently.

A CIP alkali solution based on sodium hydroxide (NaOH) down to 0.01N and surfactants will eliminate organic and fatty contamination, gels and emulsions. Sodium hypochlorite can also be used.

Sodium hydroxide is the most common CIP solution. It is effective in removing proteins and nucleic acid impurities from chromatography media and filtration equipment. It saponifies fats and inactivates most proteins, viruses, bacteria, yeasts, fungi and endotoxins.

One particular time-saving technique is to add sodium chloride in combination with the sodium hydroxide solution to combine cleaning and sanitization. The sodium hydroxide solution has the ability to solubilize precipitated proteins and its hydrolyzing power is enhanced in the presence of chlorine.

Our membrane cell electrolysis plant where high purity brine (NaCl + purified water) is transformed to chlorine and sodium hydroxide.

This process feeds directly into our final finish room where we perform final polish, dilutions and fill containers in our cleanroom. We fill bulk ISO tankers through a MannTek dry lock system, under nitrogen blanket.

Sodium hydroxide solutions are also effective in inactivating endotoxins in solution. Higher sodium hydroxide solution concentrations (0.5N or 1.0N) require less contact time for inactivation versus lower concentrations (0.1N).

Since sodium hydroxide is inexpensive and bacteriostatic, it can also be used for storage. Concentrations from 0.1N to 1.0N can be used for storing packed chromatography columns.

Sodium hydroxide can be corrosive to skin and metal. Be sure that your chromatography media and equipment are compatible with the concentration, temperature and time exposed to the solutions.

A CIP solution of 20% ethanol protects costly chromatography resins from contamination during temporary storage between production runs until they are required again for future production runs. A 20% ethanol solution along with 150mMol/sodium chloride are used for resin storage. Combinations of ethanol and sodium hydroxide (0.1N NaOH in 10% ethanol) are also effective for resin storage.

Once the contaminations have been removed, it is critical to eliminate any traces of the CIP solutions. A highly purified water, such as WFI water, is generally used. This water must also be free from any conductivity. Only then will the cleaning process be complete.

Left: Large-scale sodium hydroxide dilutions occur in these tanks
Right: ISO class 8 cleanroom where all solutions are filled

Quality Management System & Chemicals

100% Tested. 100% Transparent. 100% Trusted.

The bioCERTIFIED™ quality program covers an expanded menu of analytical tests and certifications required by biopharmaceutical manufacturers. For parenteral applications in which a biological drug enters directly into the bloodstream, even more stringency is required to ensure a product is endotoxin-free with minimal bioburden. New USP 232/233 requirements for elemental impurities put even more demand on the certifications for raw materials. The bioCERTIFIED product label identifies products that have undergone additional testing for bioburden, endotoxin and elemental impurities.

Chemical Type	Chemical Name	Brand	CAS	Catalog No.	Grade	Sizes
Cleaning In Place	bioCERTIFIED 20% Ethanol	Spectrum Chemical bioCERTIFIED	64-17-5	E9210	cGMP	1, 5, 55 Gallons
Cleaning In Place	bioCERTIFIED Benzyl Alcohol	Spectrum Chemical bioCERTIFIED	100-51-6	B8200	NF, EP, BP, JP, cGMP	1, 4, 25 L
Cleaning In Place	bioCERTIFIED Hydrochloric Acid Solution 0.1N	Spectrum Chemical bioCERTIFIED	7647-01-0	H9801	cGMP	4, 20, 200 L
Cleaning In Place	bioCERTIFIED Hydrochloric Acid Solution 0.5N	Spectrum Chemical bioCERTIFIED	7647-01-0	H9802	cGMP	4, 20, 200 L
Cleaning In Place	bioCERTIFIED Hydrochloric Acid Solution 6.0N	Spectrum Chemical bioCERTIFIED	7647-01-0	H9803	cGMP	4, 20, 200 L
Cleaning In Place	bioCERTIFIED Sodium Hydroxide Solution 0.1N	Spectrum Chemical bioCERTIFIED	1310-73-2	S9291	cGMP	500 ML, 5, 25, 200 LT
Cleaning In Place	bioCERTIFIED Sodium Hydroxide Solution 1.0N	Spectrum Chemical bioCERTIFIED	1310-73-2	S9290	cGMP	500 ML, 5, 25, 200 LT
Cleaning In Place	bioCERTIFIED Sodium Hydroxide Solution: 0.5N	Spectrum Chemical bioCERTIFIED	1310-73-2	S9292	cGMP	500 ML, 5, 25, 200 LT

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