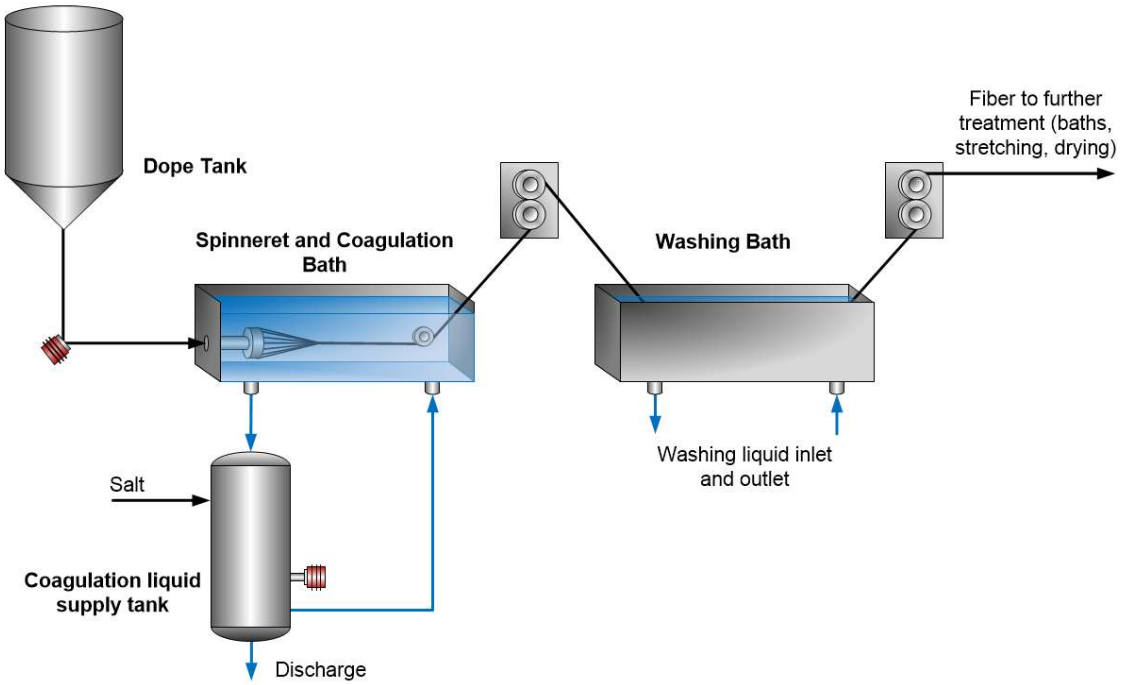
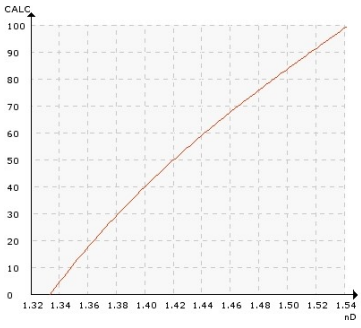


SODIUM ALGINATE, $NaC_6H_7O_6$, CALCIUM CHLORIDE $CaCl_2$

Typical end products

Alginate fibers, such as sodium alginate, calcium alginate or hybrids for the production of wound dressings and medical fabrics.

Chemical curve: R.I. per BRIX at Ref. Temp. of 20˚C



Introduction

Alginates are biopolymers extracted from brown algae species such as seaweed. Extraction is performed from the harvested material by treatment with aqueous alkaline solutions. The extract is then filtered and the alginate salt is precipitated by the addition of calcium chloride or an acid. After purification, drying and milling, a water-soluble sodium alginate powder is produced.

Alginates have found a variety of uses in different industries because of their unique properties. These materials have been extensively used in pharmaceutical applications as they are gel forming, non-toxic and highly absorbent.

Fibers made of alginate have become very popular for the production of wound dressings. These fibers are biocompatible, have hemostatic properties and accelerate the healing process by creating a gel that keeps a moist interface on the surface of the wound. The composition of the fibers can be modified by a controlled process to enhance their hemostatic properties and obtain fibers with additional healing effects.

Application

Alginate fibers are produced by a wet-spinning process. It is called wet-spinning because the fibers are extruded directly into a solution or bath. The bath is usually a salt solution or a mixture of salts, containing metal ions, but it can also be an inorganic acid solution or an organic solvent depending on the desired final product. The most common salt is calcium chloride, but salts containing zinc, silver, and other bioactive additives, which are beneficial for wound healing are also used.

For the production of the fibers, a spinning dope or spinning solution is prepared by mixing sodium alginate with water, to form a homogenous solution. The concentration ranges between 5 and 10 %. This solution is then spun directly in the coagulation bath

through a spinneret or a nozzle, to convert the solution into fibers. As the sodium alginate contacts the salt bath, water is removed from the formed fiber leaving behind only the biopolymer (alginate).

Coagulation happens when the sodium ions come into contact with the polyvalent ions of the bath (e.g. Ca^{2+}). The sodium ions exchange places with the calcium ions to form calcium alginate, which is not soluble in water. The resulting fiber is washed, stretched and dried to obtain the final product. Additional baths can be used to alter the composition of the fiber and obtain additional wound healing properties.

The concentration of both, the solution dope and the coagulation bath, play an important role in the final product quality. If the concentration of sodium alginate in the solution dope falls too low neither coagulation nor formation of the alginate filament will take place. In addition, the hemostatic property depends on the concentration of the alginate.

As sodium alginate is extruded, the coagulation bath inevitably gets diluted. The concentration of the bath should also be monitored as the morphological structure of the fibers is affected by the composition of the salt.

Instrumentation and installation

K-Patents Sanitary Refractometer PR-43-A provides real-time, accurate and reliable concentration measurements for ensuring the highest quality, purity and consistency in pharmaceutical applications.

A refractometer is installed directly on the filling line to measure continuously and precisely the concentration of sodium alginate solution pumped into the bath. A second refractometer monitors the concentration of the coagulation liquid as water content builds-up. To ensure a high product quality, the water content should be kept under 20 %.

K-Patents refractometers provide Ethernet or 4-20 mA output signals for real time process control. The concentration of the bath, for example, can be controlled and kept at its ideal value by a circulation system where more coagulation agent is added to restore the concentration by the information provided from the refractometer.

The PR-43-A has been design to meet all the pharmaceutical industry standards and regulations, and it is the ideal in-line process instrument for the Process Analytical technology (PAT) framework.

Instrumentation	Description
	K-Patents Sanitary Refractometer PR-43-A system consists of a compact or probe refractometer and a graphical user interface. The refractometer is a stand-alone device capable of operating independently. User interface options range from a rugged, multichannel, industrial computer to a compact light-weight and a web-based version. The refractometer is installed in the main processing line or vessel. The user interface can be installed locally in the field, remotely in the control room. K-Patents PR-43-A is Sanitary 3-A and EHEDG certified to meet the highest hygiene requirements of food and pharma production.
	K-Patents Pharma compact refractometer PR-43-PC system consists of a compact refractometer and a graphical user interface. The user can choose between a rugged, multichannel, industrial computer or a compact light-weight user interface. The refractometer is installed in the main processing line. The user interface can be installed locally in the field or remotely in the control room. K-Patents validation procedure and equipment help the user to prove the suitability of the refractometer for its designated function. These include an optional laboratory test cuvette for off-line testing of drug samples prior to installation in the full-scale production. The PR-43-PC is designed to meet industry standards and guidelines including Sanitary 3-A and EHEDG, PAT, GMP, CIP/SIP, 21 CFR Part 11 and validation.
Measurement range:	Refractive Index (nD) 1.3200 – 1.5300, corresponding to 0-100 Brix.