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LANXESS NEWS, POSITIVE**Pharma Seals Made Safer with Butyl Rubber****CLIPPING**

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Pharma Seals Made Safer with Butyl Rubber

This article focuses on the need for use of butyl rubber over natural rubber for Pharma closures or stoppers in order to prevent the unknown and unwanted reactions of natural rubber with active ingredients in the medicine.

Pharmaceutical seals and closures need to be impermeable i.e. must not allow migration of materials in either direction, must be elastic and also chemically inert i.e. must not release particles after puncture.

Butyl and even better, Halo-Butyl rubber meets these requirements, being resistant to heat, ozone, radiation acids/alkali, water, gas and moisture vapor. More than 90 per cent of pharmaceutical stoppers produced today (globally) are based on butyl and halogenated butyl rubbers (Chloro- and Bromo-Butyl rubber) because these polymers provide the best balance of properties for this application.

Butyl rubber is a polymer with unique physical and chemical properties like High purity (approximately 99 per cent Isobutylene), high saturation and high impermeability to gas and moisture.

The Vulcanisates made of butyl rubber have extremely low permeability to gases, vapors and moisture, good weathering,

ozone, hot air and chemicals (basic & acidic), leading to high stability (ie low reactivity and inertness).

Manufacture of Butyl Rubber

The raw materials for making butyl rubber are isobutylene and isoprene. These two components are polymerised at -100°C , the temperature at which butyl rubber forms. In a further step, Halo-Butyl rubber – a premium rubber product, is obtained by means of halogenation, the reaction with chlorine or bromine.

Only a few manufacturers worldwide have mastered this complex process and LANXESS has recently invested in a state-of-the-art plant in Singapore, apart from those existing in Germany and Canada.

Benefits

In India, natural rubber has historically been in use for several pharmaceutical applications like closures/stoppers in medicine bottles, injection vials/plungers



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for prefilled syringes, droppers, seals for aerosol gaskets and other closures in various pharmaceutical devices.

However, due to its high permeability and high reactivity (due to high unsaturation even after curing), natural rubber is deemed unfit for pharmaceutical applications. To make such rubber stable, several additives (like Sulphur as curatives) are used, which in turn could react with the medicinal content. When in contact with the drugs, the proteins and impurities in natural rubber leach into the contents of the bottles or syringes, rendering the contents unfit for use.

The ideal alternatives are butyl rubber and halo butyl rubber, which are used worldwide for pharmaceutical applications due to their low permeability to air and moisture, high purity of polymer and inertness after the curing process. It is also increasingly gaining acceptance in India. Butyl rubber especially halo butyl rubber, has much lesser curatives in its formulation and therefore, causes far less contamination and the leachables are practically negligible, making it one of the safest polymers for pharmaceutical applications.

Also since there is no natural rubber latex used in the manufacture of butyl rubber, there are no possibilities of allergies from latex.

Butyl or halo butyl rubber stoppers are used in several Pharmaceutical applications like infusion containers/pumps, injection vials, blood sampling vials, dental anesthetics, Butyl plunger seals, pre-filled syringes, insulin containers, aerosol gaskets in inhaler seals etc. However, it can be used in any application that requires less reactivity and impermeability to gas & moisture

Regulatory Requirements for Drug Closures

The compatibility with pharmaceuticals of all compounds used to make rubber closures must be checked before use. The properties must comply with the international regulations such as the Food and Drug Administration (FDA) in the US and any similar local regulatory requirements. The selection of rubber and the compounding ingredients must be based on the compatibility with the various national pharmacopeia and standards of specific pharmaceutical closures.

In different countries, the pharmacopeia has different requirements, however, every pharmacopeia has guidelines for some standard physical tests like sealing (tightness), self - sealing, permeability to water vapor; chemical tests for reducing substances, residue of evaporation, chlorides, compatibility and biological tests for aspects like toxicity and cytotoxicity.

In China, according to the State Food and Drug Administration regulations, starting from 1st January 2005, all medical stoppers, infusion, oral drugs, including a variety of dosage forms are no longer allowed to have the traditional natural rubber stoppers as packaging material and has been replaced by butyl rubber. Unfortunately in India, there's no such legislation which controls the use of natural rubber in pharmaceutical applications. In 1998, the Food and Drug Administration (FDA) initiated labeling of medical devices made from natural rubber latex; since that time substantial progress has been made in identifying latex-free alternatives. However, the rubber stoppers commonly found in pharmaceutical vial closures are exempt from FDA labeling requirements.

In India, the pharmaceutical industry is aware of this but there's no law that prohibits cork/stopper manufacturers from doing so. In the absence of a definite regulation in this regard, it will be ideal if the pharmaceutical manufacturers demand high quality rubber in applications that can otherwise put lives at risk.

Most of the rubber stopper manufacturers in India are already aware of the implications of the natural rubber and they already recommend use of advanced polymers like halo butyl rubber. However, at the consumer level, there may be a lack of awareness on this topic. It is only a matter of time that consciousness will increase on such issues.

Future Trends

Butyl or halo butyl rubber is definitely the way to go for most of the pharmaceutical applications for the reasons discussed above and also given the stringent regulations evolving in several countries. It is just a matter of time when Indian consumers, regulatory authorities and Pharmaceutical companies would also insist only for the safest polymers. Also with many leading global rubber closure manufacturers now setting up plants in India, there will be a rise in the usage of regular and halo butyl rubber over, natural rubber in India. ■

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