



Medical-Design-Technology

With its stability and biocompatible properties, silicone is leading the way to a new generation of drug delivery products and enhanced medical devices that will profoundly improve patient care.

There are two main categories of devices involving silicone combined with an active pharmaceutical ingredient. The first is liquid silicone rubber (LSR) combined with an API before being fabricated into a silicone part, usually part of a precise drug-delivery system. The second is a finished silicone part immersed in a drug-loaded solvent as a way to impregnate it with a drug, such as an antibacterial or antimicrobial.

In this article, we'll look at the advantages, drawbacks, and manufacturing considerations of each process, along with examples of devices currently in use or development.

Drug delivery: adding an API to raw silicone

The advantage of adding an API to silicone before fabrication is the ability to achieve an accurate mass ratio of drug to silicone.

Typically, the ratio can be held to plus or minus 5% or better of the target mass ratio.

Thus, this process is ideal for creating devices designed to deliver a precise dose of medication, such as a skin patch for pain medication, a vaginal ring for contraception, or a bio-absorbable device for treating eye disease.

Most often, the API is combined with both the A and B sides of the silicone immediately before extrusion, molding, or sheeting. The API is usually added to the silicone in powder form, as this is typically the most stable form of the drug, but liquid formulations can be added.

There are several crucial manufacturing factors to consider when combining APIs with raw silicone. First, some APIs can poison the silicone cure. For example, chlorhexidine, a common antimicrobial, is available as a base and an acetate. If the acetate mixes and cures well with silicone, the base will poison the silicone cure.

Second, temperature plays a key role when adding APIs at this stage because the upper stability limit of many drugs is relatively low. For example, most hormones used in contraceptives begin to degrade at temperatures over 120 °C, but many silicone formulations have a cure temperature of 200 °C. In this case, and many others, it's important to select a low-temperature curing silicone and understand that the manufacturing process must be carefully controlled to ensure the temperature doesn't exceed the stability limit of the drug.

Third, many APIs are hazardous in powdered form. For example, the amount of a micronized hormone that operating personnel can be subjected to is very small³/₄micrograms or even nanograms per day. Stringent engineering controls must be put in place and safety procedures carefully monitored.

Finally, all drug delivery products are subject to FDA or other regulatory body approval. So, whether the drug being delivered via the device is new or has already gained FDA approval, a full set of FDA trials (lab tests, animal tests, and human tests) are often required.

Device enhancement: impregnating vulcanized silicone with an API

There are several advantages to adding API to an existing silicone device through immersion: it's a relatively mature technology, the timeline is usually short because the design/manufacturing process for the device doesn't change, the bar is often lower for FDA approval, and the results are highly repeatable.

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following implantation is becoming key to successful outcomes. New devices, such as those that stimulate the nerves in the lower back to decrease pain, require a robust form of infection control to avoid introducing bacteria in the sensitive spinal area.

Summary

It wouldn't be far off base to say that medical devices combining silicone with an API are more than the sum of their parts. Moreover, these combinations are a win/win as drug makers find new uses for existing formulas. Device makers improve their products' performance, and patients receive the benefits of drug additives combined with medical devices.



FTIR system (Fourier Transform Infrared Spectroscopy) used to determine detailed chemical composition of test samples Credit: Trelleborg