

Diaphragm Development

Diaphragm development is a significant part of ITT Pure-Flo's Research and Development activities. We are continuously advancing the state of the art with respect to diaphragm technology.

Pure-Flo diaphragm recipes must comply with FDA regulations and with USP Class VI. The applicable FDA regulations are provided in 21CFR177, Indirect Food Additives: Polymers. In the case of EPDM, the specific requirements are provided in 21CFR177.2600, Rubber Articles Intended for Repeated Use. These regulations limit the EPDM polymer types which may be used, as well as type and quantity of vulcanization agents, accelerants, plasticizers, fillers, etc. In addition, these regulations require that samples be subjected to extraction testing in distilled water at reflux temperature. The purpose of extraction testing is to ensure that elastomers do not give off materials to an extent that would affect food or drug purity. It's important to note that FDA does not "approve" specific recipes; rather, it limits the ingredients and specifies testing criteria as noted above.

USP Class VI refers to testing outlined in United States Pharmacopeia, Sections 87 and 88. In these tests, living organisms are exposed to samples of the elastomer or plastic material, in order to evaluate the toxicity of the material. Class VI refers to the highest possible classification; that is, the least apparent toxicity to the organisms. Testing is conducted by independent third party labs.

Diaphragm manufacturing is a complex process. In addition to the elastomer ingredients, major considerations include the mixing and calendaring (sheet-making) process, assembly of the uncured diaphragm, fabric selection and placement, stud

placement, and vulcanization process parameters. Vulcanization is the process of 'curing' the material and relies on appropriate application of heat, pressure, and a curing agent such as sulfur or peroxide. Prior to vulcanization, elastomers flow and resemble thick liquids. Vulcanization results in the cross-linking of the polymer chains, thus giving elastomers their familiar toughness and elastic characteristics.

At ITT Pure-Flo, diaphragm recipes and manufacturing process variables are selected and evaluated using advanced statistical techniques, including Taguchi parameter design and Weibull statistics. These methods are used to minimize the number of tests required, while ensuring meaningful results.

Diaphragm qualification testing includes both shutoff and cycle testing while exposed to vacuum, hot water, and steam conditions. For example, sample diaphragms must survive 30,000 cycles in 45 psi saturated steam to be considered acceptable.

All of ITT Pure-Flo's experience and expertise have gone into the development of our new compound, Grade 17HP EPDM. This compound exhibits a cycle life improvement of more than 60% over the current standard Grade 17 EPDM. In fact, we are aware of no other weir-type elastomer diaphragm on the market that is available with this level of performance.

For more information on Grade 17HP EPDM or any other ITT diaphragms please contact:

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