



FLUOROPRENE[®] XP FOR THE PHARMACEUTICAL INDUSTRY

FREUDENBERG
SEALING TECHNOLOGIES

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HIGHEST DEMANDS

The purity requirements concerning processes and products in the pharmaceutical industry are particularly stringent. Sealing solutions must therefore reliably protect against process contamination beyond their media resistance.

The production of pharmaceutical products takes place in several process steps with different operating conditions. From the raw material to the final product, various types of risk factors affect the components.

Sealing solutions are used in the pharmaceutical industry in many areas, such as:

- manufacture of finished medicinal products,
- product preparation by blood fractionation or
- biopharmacy.

Freudenberg Sealing Technologies supplies suitable solutions – regardless of whether it is a biological fermentation or a chemical synthesis process, for example. From the customized molded part to the standardized clamp seal - the portfolio includes all sealing products. Thus, valves, pumps, mixers, reactors and containers, including their connecting lines, are hygienically and safely sealed.

Resistance to process media is an important topic in almost all industries. But nowhere is this requirement profile as distinct and complex as in the manufacture of pharmaceuticals. Sealing solutions are faced with twin tasks: They must be resistant to the product media that are needed to make an active ingredient. In addition, they must endure in the cleaning processes with the appropriate CIP/SIP media. Material transfers or migrations should be kept to a minimum. All this takes place under the difficult conditions of a hygienic plant design. In addition to static and dynamic applications, there are various environmental conditions such as dry, humid, cold and warm.

Furthermore, there are high normative requirements for the sealing material. Above all, it has to meet the following international regulations:

- USP Chapter 87 and 88
- FDA 21 CFR 177.2600
- EU (VO) 1935/2004

With Fluoroprene® XP, Freudenberg Sealing Technologies has developed a material that offers outstanding sealing performance in a wide range of applications at attractive prices.

EXTRACTABLES STUDY

As evidence of the purity of a sealing material, the classic approvals alone are not enough. Because they make no statement about possible interactions of the process medium with the seal used.

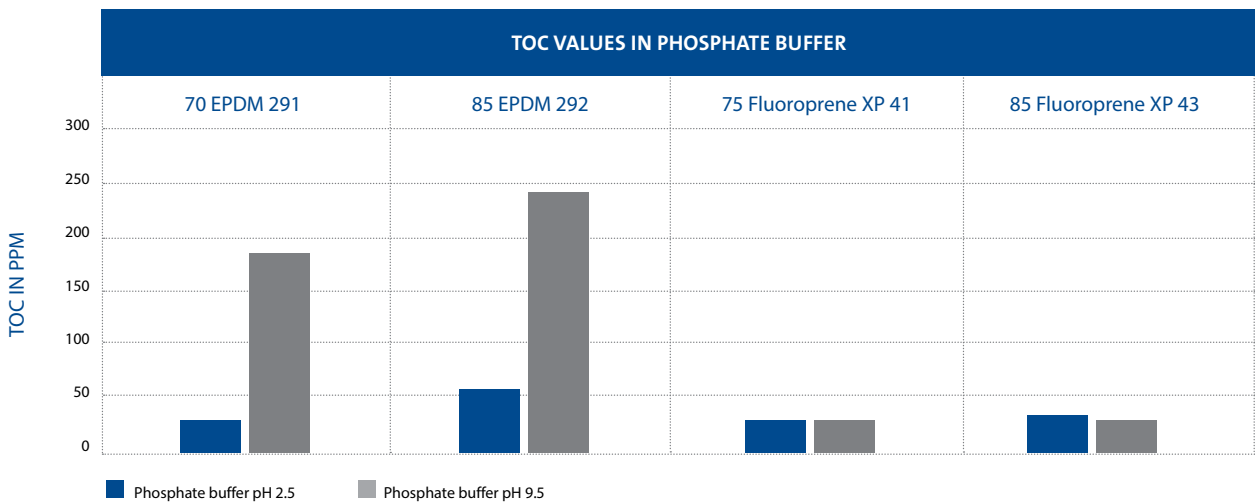
Extractables studies investigate the interactions between pharmaceutical products and sealing materials. They provide information on which and how many constituents are released from a seal under certain conditions in the manufacturing, packaging or cleaning process. If some components of the elastomer had a greater affinity to the medium or product, they would migrate out.

Freudenberg Sealing Technologies has tested in its own extractables study whether the material Fluoroprene XP is suitable for use in the pharmaceutical industry and whether it meets the high purity requirements. For this purpose, two fluorinated material variants were selected and compared with two EPDM materials.

MATERIALS	COLOR	HARDNESS SHORE A
Fluoroprene XP 41	Blue	75
Fluoroprene XP 43	Blue	85

Result of the extractables study

The two EPDM materials already had a very small, clearly definable extract quantity. This result was confirmed by another benchmark with materials from the competition. Fluoroprene XP performed even better than EPDM in the study: After 24 hours of immersion in ethanol and n-hexane, no migrated substances at all could be detected. In addition, total organic carbon (TOC) studies were performed as a measure of organic contamination. The result: The TOC levels in the phosphate buffers too were excellent for Fluoroprene XP. In the phosphate buffer with a pH value of 9.5, they were only one-fifth of the already pure values of the EPDM materials.



FLUOROPRENE XP

PROPERTIES OF THE UNIVERSAL MATERIAL

The highly fluorinated material Fluoroprene XP convinces with its extraordinary purity and durability.

For example, the unwanted extraction of components from the elastomer mixture is reduced to a minimum. This behavior makes it a predestined material of the pharmaceutical industry: both in the synthesis of active ingredients and in the packaging of the finished products.

Fluoroprene XP combines the properties of different types of elastomers. As a highly fluorinated material, it has excellent resistance in non-polar media, such as oils and media with high fat concentrations. For example, if a cold ointment is made with the addition of eucalyptus oils, the material remains resistant to flavors.

Fluoroprene XP also proves its excellent suitability for the pharmaceutical industry in polar media such as water, acids and alkalis. This makes it the optimal material for applications that are cleaned with aggressive CIP/SIP media. During sterilization, the material impresses with a temperature resistance of up to +160 °C in hot water and steam. Since gamma rays are also used for disinfection, the material was tested in this regard. Fluoroprene XP is capable of withstanding an irradiation of 50 kGray without any problems.

XP are:

- CIP/SIP cleaning
- Steam sterilization
- Flavoring agents and essential oils
- Non-polar media such as oils and fats
- Polar media such as water and organic solvents
- Disinfection by means of gamma rays

Fluoroprene XP family

The materials are available in two degrees of hardness to meet different pressure requirements. Depending on the area of application and the product, the suitable material variant is selected. For metal composite parts that require a good rubber-to-metal bonding, the material 75 Fluoroprene XP 45 was specially developed.

CIP/SIP Guide

Compatibility check of sealing materials and cleaning agents



www.resistanceguide.fst.com/cip-sip-guide

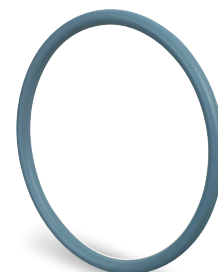
Suitable fields of application and utilization of Fluoroprene

MATERIALS	CONFORMITIES							SEALING PRODUCTS
	EU (VO) 1935/2004	USP CHAPTER 87	USP CHAPTER 88	FDA 21 CFR 177.2600	3-A® SANITARY STANDARDS	NSF 51	ADI FREE	
75 Fluoroprene XP 40	x		x	x	x		x	Diaphragms
75 Fluoroprene XP 41	x	x	x	x	x	x	x	• O-rings • Diaphragms • Molded parts • CNC machined
85 Fluoroprene XP 43	x	x	x	x	x		x	• O-rings • Diaphragms • CNC machined
75 Fluoroprene XP 45	x			x	x		x	• Molded parts • Hygienic Usit®

PRODUCT PORTFOLIO

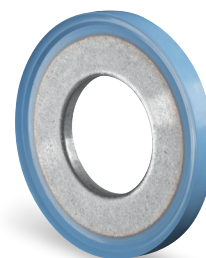
O-RINGS

Fluoroprene® XP **O-rings** impress with their universal applicability - both in terms of their shape and their material. Its broad chemical and thermal resistance, combined with international approvals for the food and pharmaceutical industries, makes this combination ideal for critical applications. As a standardized sealing element, O-rings are available in all dimensions according to DIN ISO 3601 as well as in special sizes.



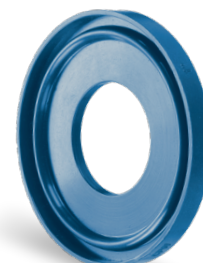
HYGIENIC USIT®

The **Hygienic Usit** from Freudenberg Sealing Technologies was developed to seal screw connections in or on the product space without dead space. Here, the washer with elastomer bead complies with the design rules according to Hygienic Design. The Usit ring has a smooth surface on which product residues find little support and are particularly easy to remove. Contamination of the pharmaceuticals produced can thus be prevented. The Hygienic Usit is available in sizes M4, M5, M6, M8, M10, M12 and M16. In addition, Kipp, under its NovoNox product brand, supplies hygienic special screws and cap nuts, which are highly polished and have a surface roughness of $R_a < 0.8 \mu\text{m}$.



SEALS FOR PIPE CONNECTIONS

Clamp seals made of Fluoroprene XP are ideally suited to protect critical procedures in pharmaceutical processes. They are used to connect two pipes and are standardized according to DIN 11851 and DIN 32676. In addition, Freudenberg Sealing Technologies offers O-rings for aseptic clamping connections according to DIN 11864, which are recommended by EHEDG. These comply with the hygienic design standard and ensure a seal without dead spaces.



DIAPHRAGMS

Custom-designed diaphragms can also be made of Fluoroprene XP. Diaphragms made of rubber-elastic materials have the task of forming a dense yet easily movable partition wall for a delimited volume. In addition, they can perform a balancing function, such as in a separator, in which the horizontal vibrations of the inner part to the outer element must be counterbalanced. The service life of the sealing product can additionally be improved by fabric inserts and foil overlays. Thus, you can find the optimal seal for every application.



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