

Press release

Medical grade TPE for direct contact with medications

Waldkraiburg, October 2017

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Reliable seals with THERMOLAST® M

Aptar Pharma relies on medical grade TPE for eye drop packaging

With several functional components manufactured using a newly developed, medical grade TPE from KRAIBURG TPE, Aptar Pharma launched its ophthalmic squeeze dispenser (OSD). The Thermoplastic Elastomer components come into direct contact with the medical eye drop formulation. Aptar Pharma requires classification as a medical grade plastic in compliance with the stringent regulations for the primary packaging of sensitive medications.

Dry eyes can be caused by various medical conditions, such as diabetes, rheumatism and thyroid disorders, and also by draughts or contact lenses, or by prolonged exposure to computer monitors. Moisturising eye drops are a time-proven remedy. However, they seldom contain preservatives, which cause allergic reactions in many people. Due to its microbiological safety as well as easy and precise dosing capabilities, the ophthalmic squeeze dispenser (OSD) from Aptar Pharma is in widespread use as dispenser for eye drops that contain no preservatives.

To further optimise the product, the manufacturer sought a thermoplastic processable material that allows direct contact with medications. KRAIBURG TPE supported Aptar Pharma in choosing the material through to series production with a comprehensive medical technology service package. The result is a new component manufactured from a new THERMOLAST® M material developed by KRAIBURG TPE for the medical and pharmaceutical market. "In close cooperation with KRAIBURG TPE we were able to further improve the exemplary safety and integrity of the ophthalmic squeeze dispenser from Aptar Pharma, without compromising its intuitive and convenient use," says Stefan Ritsche, President Global Market Development at Aptar Pharma.

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Maximum purity and conformity

Purity, tolerance, quality, continuous availability and safety of the materials used are top priorities in medical technology and are subject to stringent regulations. THERMOLAST® M compounds from KRAIBURG TPE are tested in accordance with relevant standards such as USP Class VI, ISO 10993-4 (haemolysis), ISO 10993-5 (cytotoxicity), ISO 10993-10 (intracutaneous irritations) and ISO 10993-11 (acute system toxicity). In addition, a drug master file (DMF) for the materials is on file with the US Food and Drug Administration (FDA). KRAIBURG TPE is therefore committed to consistent adherence to the specified formulation and manufacturing process. Any necessary changes are announced and implemented in accordance with a defined change control process. After announcement of a change, KRAIBURG TPE guarantees delivery for a period of 24 months and also has the purity of the raw materials guaranteed by its suppliers.

Compounds for medical technology or medical applications are manufactured at KRAIBURG TPE only on special equipment reserved for these products. The company offers its customers in the medical and pharmaceutical sector an extensive service package that ensures maximum control with respect to quality, safety and reliability.

Guaranteed integrity

The ophthalmic squeeze dispenser from Aptar Pharma is the only reusable dosing system thus far approved by the FDA for liquid medications that do not contain preservatives. The design contains no metal parts whatsoever in the drug flux and is therefore also suitable for very sensitive formulations. The purely mechanical functioning principle of the seal membrane and spring unit eliminates the possibility of microbiological contamination of the liquid.

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KRAIBURG TPE has been working in cooperation with Aptar Pharma for a number of years. "Early integration in the project allowed us to contribute our full range of know-how and experience and to offer our customer a TPE solution that fulfils all requirements, including the specified sterilisation," says Oliver Kluge, Medical Product Consultant at KRAIBURG TPE.

About Aptar Pharma

Aptar Pharma is part of the AptarGroup, Inc (NYSE: ATR), which is a worldwide market leader with a broad spectrum of innovative dosing systems for cosmetic and personal hygiene articles, as well as medications, foodstuffs and beverages. Aptar Pharma has been setting standards for decades when it comes to spray and dosing systems in medical technology, including nose spray pumps, inhalers, drop dispensers and injectors. The group of companies, with headquarters in Crystal Lake, Illinois (USA), has production plants in North and South America, Europe and Asia. For more information, please visit www.aptar.com.

About KRAIBURG TPE

KRAIBURG TPE (www.kraiburg-tpe.com) is a globally operating manufacturer of Thermoplastic Elastomers. Founded in 2001 as a subsidiary of the long-standing KRAIBURG Group founded in 1947, KRAIBURG TPE assumed a pioneering role from the very beginning. With production plants in Germany, the USA and Malaysia, the company offers a broad portfolio of compounds for automotive, industrial and consumer applications, as well as for medical applications, which are subject to stringent regulations. The well-known THERMOLAST®, COPEC®, HIPEX® and For Tec E® product lines offer manufacturers numerous benefits with respect to product design and processing in injection molding and extrusion processes. KRAIBURG TPE offers reliable service, innovation and worldwide customer orientation with custom engineered product solutions.

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The company is certified to ISO 50001 at all locations in Germany and Malaysia and to ISO 9001 and ISO 14001 at all locations worldwide. In 2016, KRAIBURG TPE, with about 550 employees, earned revenue of 167 million euros.



Ophthalmic squeeze dispenser (OSD) from Aptar Pharma with components made of medical grade Thermoplastic Elastomers of the product group THERMOLAST® M from KRAIBURG TPE for direct contact with medications. (Photo © 2017 Aptar Pharma)