

SEALING SOLUTIONS FOR TABLET PRESSES



In the pharmaceutical industry, safe processes are particularly important due to the strict cleanliness requirements. As such, applications in the pharmaceutical industry call for media-resistant sealing solutions that seal reliably. This is the only way to avoid contamination in the processes and, ultimately, in medicines.

Choosing the right material

The pharmaceutical industry synthesizes pharmaceutical products from basic chemicals. These need to be especially clean so that no unwanted byproducts are generated during synthesis. Before a tablet is pressed, the active substances and carriers are produced according to the formula, wet-granulated, then dried and ground. For seals, this means that they need to survive in a dusty environment. In addition, the medicines are pressed into their final shape under high pressure. There is a risk of abrasion from the seal contaminating the medicine during pressing. This can change the composition or color of the medicine or even negatively impact its medical effect – as a consequence, whole batches could be contaminated and would need to be destroyed. This must be prevented. The seals used in tablet presses therefore need to fulfill a particularly high standard of cleanliness. Freudenberg Sealing Technologies offers a range of different elastomeric material variants and technical plastics that meet these standards. They include PTFE Y002, 95 AU 2100, 95 AU 1730, and 70 EPDM 291.

In the pharmaceutical industry, it is not sufficient to rely on existing certifications such as those from the USP (United States Pharmacopeia) and FDA (Food and Drug Administration) when selecting the sealing material. Unlike extractables studies, they do not take into account the interactions between pharmaceutical products and the elastomers from which the seals are made. These interactions often occur in a medium with a higher solvent strength than the product and at high temperatures. The aim of these studies is to identify all extractable components of the elastomer that could migrate from elastomer sealing materials during the production, filling, and packaging of pharmaceutical products. This makes it possible to determine the ideal sealing material individually for a specific requirement profile. We support you in choosing the right sealing material by performing extractables studies and providing optimum consultation based on the results. One example of this is the study on the process purity of fluorinated materials. Here, Freudenberg Sealing Technologies tested the extract quantity of the materials 75 Fluoroprene® XP 41 and 85 Fluoroprene® XP 43 used in the pharmaceutical industry and other sectors.

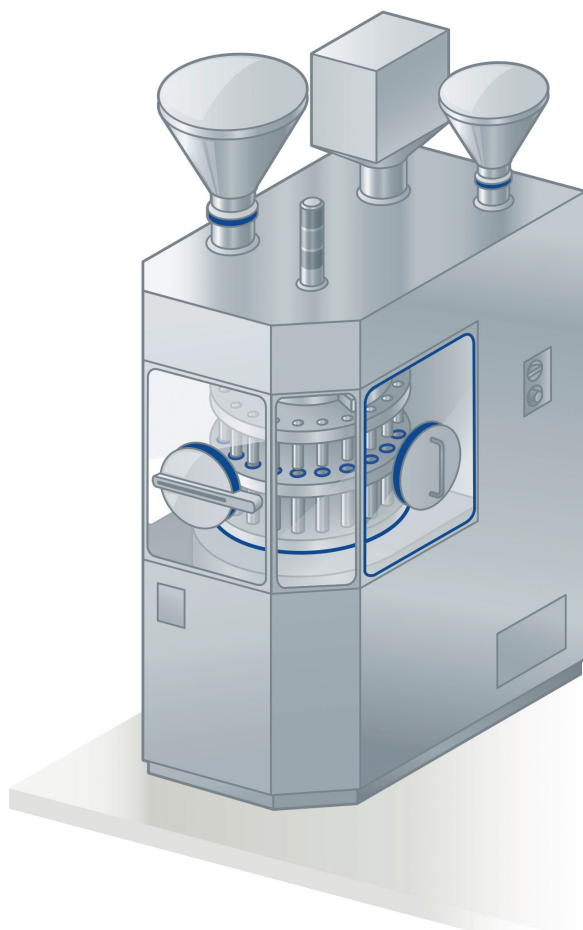
Sealing of the tablet stamp and rotary table

To press a powder or granulate into the shape of a tablet, rotary tablet presses are generally used. The mixture is poured in and pressed into the shape of a tablet using two stamps. Our polyurethane wipers prevent dust or powder from being released during this process. They are wear resistant to such abrasive substances. What is more, the lubrication system and pressing area should be reliably separated from one another to ensure that the tablet is not contaminated. To prevent this from happening, our bellows are used in conjunction with the wipers. Like the wipers, they have to withstand not only the lubricants, but also the dynamic requirements. What is more, Freudenberg Sealing Technologies has developed special U-packings from polyurethane which are used to seal the tablet stamp. The pressing room also needs to be completely sealed so that no germs can get into the process through gaps in the windows and doors of the system. This can be prevented using our inflatable seals. They ensure permanent easy opening and closing of the doors. Furthermore, dynamically applied axial seals from Freudenberg Sealing Technologies prevent powder or dust from accumulating beneath the rotary table. The flexibility and wear resistance of the seal are critically important here. For sealing at the filling nozzles, we sell O-rings made from the material 70 EPDM 291, as this meets the necessary requirements of the FDA and EU (Regulation) 1935/2004.

Benefit from our know-how

Freudenberg Sealing Technologies has developed an extensive material and product portfolio for the special requirements of the process industry. Thanks to many years of experience, research, and work in associations, we possess unique technical knowledge. Intensive collaboration with renowned cleaning product manufacturers has enabled us to compile an extensive resistance database which allows us to make precise statements on the compatibility of cleaning media and sealing materials from Freudenberg. You can benefit from this know-how online with our Resistance Guides for testing chemical and CIP/SIP resistance.

TABLET PRESS



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