DURLON®
SEALING SOLUTIONS



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SEALING SOLUTIONS FOR THE

Pharmaceutical Industry



We succeed **when you succeed.**

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Our Vision

Evolution isn't a choice in today's business landscape; it's the only way to succeed.

Progress relies on everything moving forward, from people to machinery to production. Everything must flow.

As we engineer our way to a better world, we are breaking down barriers, making sure each process is in place, always reflecting and improving. We are experts at delivering the best sealing solutions to help our customers unlock their highest potential.

Our global community of industry-leading specialists drive our innovative production and materials to consistently raise the bar.

Whether subjected to the stresses of everyday use, specialized applications, high-temperature environments, or liquid and gas service, our products are engineered to provide reliable sealing integrity.

At Durlon®, we succeed when you succeed.

DURLON®
by Gasket Resources Inc.

Sealing Solutions for the **Pharmaceutical Industry**

The pharmaceutical industry is a vital component of the healthcare sector, responsible for the research, development, manufacture, and distribution of pharmaceutical products.

The products produced by the pharmaceutical industry are numerous and varied. They include prescription drugs, over-the-counter medications, vaccines, medical devices, and diagnostic tests, among others.

Prescription drugs and vaccines are among the most widely recognized products of the pharmaceutical industry. These drugs are typically developed through a rigorous process of research and development, clinical trials, and regulatory approval.

Over-the-counter medications are another important product of the pharmaceutical industry. These are medications that can be purchased without a prescription, typically for the treatment of mild to moderate symptoms. Common over-the-counter medications include pain relievers such as aspirin and ibuprofen, as well as cold and flu medications, allergy medications, and digestive aids.

The manufacturing process for these products involves several stages, each of which plays a critical role in ensuring the quality, safety, and efficiency of the final product.

Pharmaceutical products typically progress through research and development. This stage involves the discovery and development of new drugs, medical devices, or diagnostic tests. Scientists and researchers work to identify potential new products and conduct preclinical studies to evaluate pharmacological activity, safety, and other characteristics before clinical testing. Once a potential product has been identified, clinical trials are conducted to further evaluate its safety and efficacy in human patients.

Once a product has been approved for manufacturing, the next stage is formulation development. This stage involves the development of the formulation for the final product. The formulation must be carefully designed to ensure the appropriate dosage, bioavailability, and stability of the product. Various ingredients are combined in a specific manner to produce the final product.

The next stage is manufacturing. This stage involves the actual production of the product in large quantities. Manufacturing operations vary by dosage form and may include weighing and dispensing, mixing, granulation, filtration,

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reaction, sterilization, filling, compression, coating, or other controlled processing steps. Pharmaceutical manufacturing is carried out under controlled conditions appropriate to the product and process. Sterile products require additional environmental and contamination-control measures.

Quality control is a critical aspect of the manufacturing process. Throughout the manufacturing process, various tests are conducted to ensure that the product meets strict quality standards. These tests may include physical, chemical, and microbiological tests. Samples of the product are taken at various stages of the manufacturing process and tested to ensure that they meet the required specifications.

Packaging and labeling are the next stages of the manufacturing process. Once the product has been manufactured and tested, it must be packaged and labeled appropriately. This involves the selection of appropriate packaging materials, such as bottles, tubes, or blister packs, and the application of labels that include important information such as dosage instructions, storage requirements, and expiration dates.

Following packaging and release, finished products enter the distribution process. Once the product has been packaged and labeled, it is distributed to healthcare providers, pharmacies, and other distribution channels. The product must be stored and transported appropriately to ensure that it remains safe and effective until it reaches the end user.





Innovative products
Unparalleled service

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Polytetrafluoroethylene (PTFE) gasket material

Aggressive chemicals, high pressures and extreme temperatures can all create challenging conditions. Durlon® designs and manufactures high-performance sealing solutions for pharmaceutical, chemical-processing, and related hygienic-process applications

Durlon® filled PTFE gaskets/sheets are exclusively manufactured at Triangle Fluid Controls Ltd. in Belleville, Ontario, Canada. Our compression-molding and skiving processes provide controlled physical properties, dimensional consistency, and performance characteristics.With engineered filler formulations, Durlon® PTFE products can meet your tough chemical applications and engineering specifications.

PTFE (polytetrafluoroethylene) has excellent chemical resistance and its unique properties lend themselves well for use in a variety of industrial, manufacturing, and engineering facilities. The superb chemical resistance and performance across a broad service-temperature range has not only improved the efficiency of many industries, but the safety for the employees that work around those conditions as well.

General properties of PTFE

- Excellent chemical resistance
- Wide range of service temperature
- Excellent dielectric properties
- Non-stick, low friction
- Good resistance to aging and environmental degradation
- Smooth surface finish can be achieved
- Non-wetting
- Outstanding corrosion protection
- Electrical insulation
- High thermal stability and flame resistance
- Resistance to weathering
- Select grades comply with applicable food-contact requirements

Durlon® 9000 & 9000N PTFE

Various shapes of inorganic fillers have been homogeneously blended with pure PTFE resins to give Durlon® 9000 its physical and mechanical properties. It is suitable for use in steel flanges and is formulated to reduce creep and cold flow problems associated with virgin PTFE or the hardness problems of some other filled PTFE products. It cuts easily and separates cleanly from flanges after use. Durlon® 9000 is for use in general industrial applications where resistance to highly aggressive chemicals is required. In addition, the shape of the fillers is designed to minimize wiciking which can cause corrosion on flange surfaces.

PTFE is highly resistant to corrosion due to its chemical inertness. Unfortunately, that same chemical inertness prevents PTFE from being cross-linked like elastomers and is subject to the phenomenon of cold flow – otherwise known as “creep”. To reduce and diminish cold flow, additives are introduced during the preparation of PTFE compounds. Glass fillers found in Durlon® 9000 and 9000N gaskets, not only reduce creep but also maintain chemical inertness against aggressive and caustic chemicals but are still considered safe for use by food, drug, and medical services.

Certifications

Durlon® 9000 – API 6FA Fire Test, TA-Luft (VDI 2440), Pamphlet 95 (Chlorine Institute), Meets applicable FDA 21 CFR 177.1550 requirements and USP Plastic Class VI requirements at 121°C (250°F).

Durlon® 9000N – Meets USP Plastic Class VI requirements at 121°C (250°F) and applicable FDA 21 CFR 177.1550 requirements.

Durlon® Product Recommendations



Durlon® 9000



Durlon® 9000N



Durlon® 9200

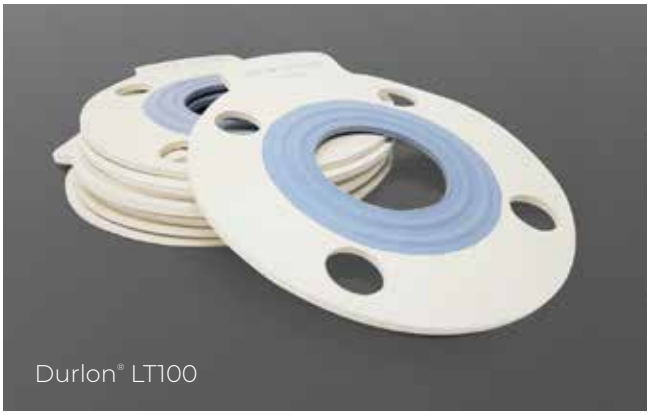

Durlon® 9600



Durlon®
Joint Sealant



Durlon® 9645


Durlon® LT100

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Physical Properties & Certifications

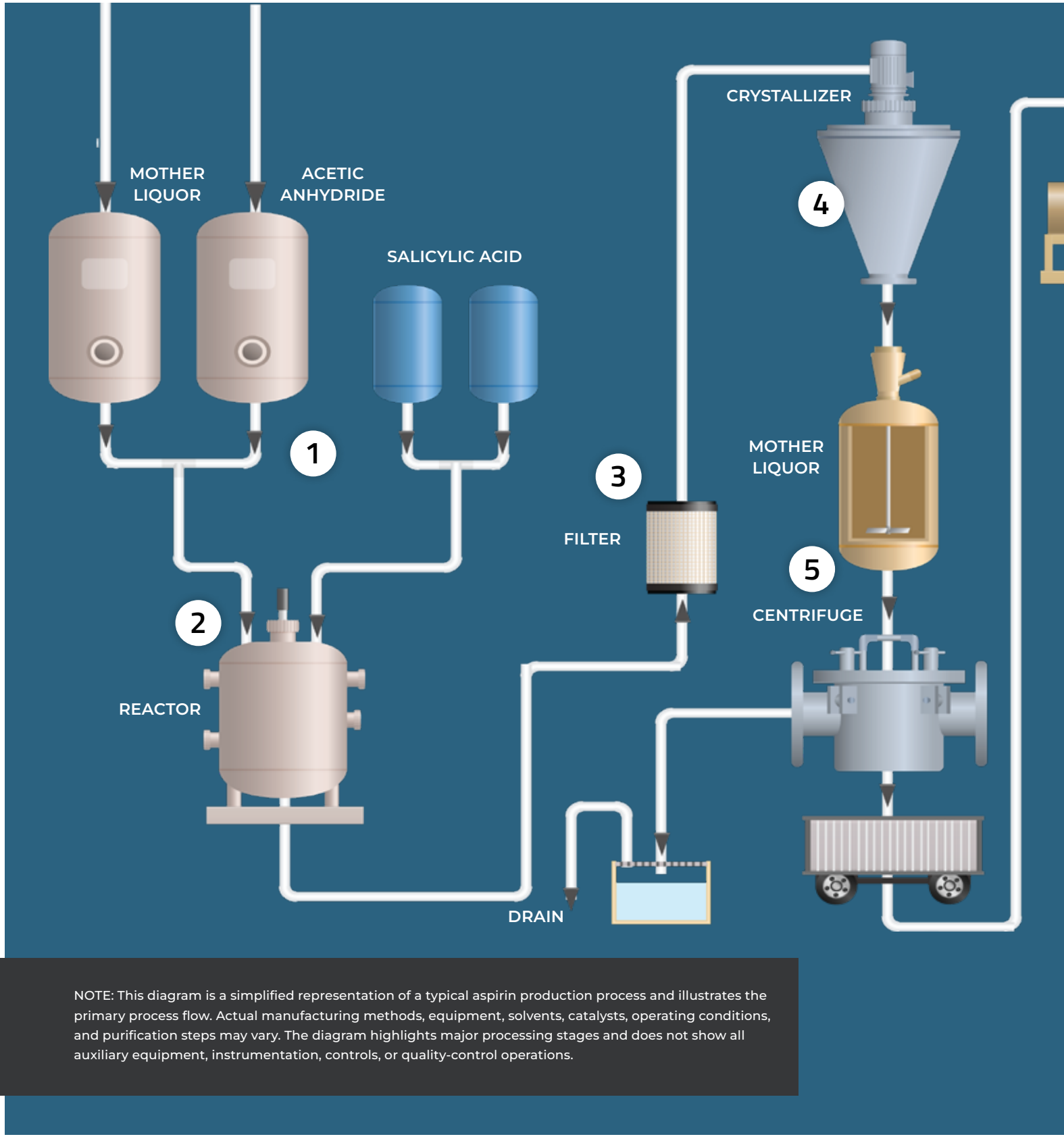
Physical Properties	9000/9000N	9200	9600	Joint Sealant	9645	LT100
Composition	Inorganic Filler / Pure PTFE Resins	Barium Sulfate Filler / Pure PTFE Resins	100% Pure Expanded PTFE	100% Pure Expanded PTFE	Modified PTFE with rigid PTFE core	Pure PTFE, Bonded to EPDM
Color	Blue/White	Off White	White	White	White	White/Blue
Temperature: Min Max Continuous, Max	 -212°C (-350°F) 271°C (520°F) 260°C (500°F)	 -268°C (-450°F) 260°C (500°F) -	 -268°C (-450°F) 316°C (600°F) 260°C (500°F)	 -268°C (-450°F) 316°C (600°F) 260°C (500°F)	 -260°C (-436°F) 260°C (500°F) -	 -40°C (-40°F) 150°C (300°F) -
Pressure, max, bar (psi)	103 (1,500)	83 (1,203)	200 (2,900)	200 (2,900)	60 (870)	17 (250)
Density, g/cm³ (lb/ft³)	2.2 (138)	-	0.9 (56.2)	0.65 (40.6)	1.3 (81)	-
Compressibility, %	8–16	4–10	50–60	-	>44	-
Recovery, %	40	40	>10	-	>6.3	-
Creep Relaxation, %	30	15	22	-	<26	-
Tensile Strength, MPa (psi)	13.8 (2,000)	14 (2,030)	20 (2,800)	-	-	-
Sealability ASTM F2378 (Nitrogen)	 0.01 mL/min	 -	 -	 -	 -	 -
pH range, Room Temperature	 -	 -	 -	 0–14	 -	 -

Style	Certifications
9000	Passed API 6FA, 3rd Edition Fire Test. Meets USP Plastic Class VI requirements at 121°C (250°F) and conforms to FDA 21 CFR 177.1550. Material approved according to TA-Luft (VDI Guideline 2440), holds ABS-PDA approval, and is listed in Chlorine Institute Pamphlet 95. Complies with (EC) 1935/2004 and EU 10/2011.
9000N	Meets USP Plastic Class VI requirements at 121°C (250°F), conforms to FDA 21 CFR 177.1550 for food and drug contact, holds ABS-PDA approval, is listed in Chlorine Institute Pamphlet 95, and complies with (EC) 1935/2004 and EU 10/2011.
9200	Complies with TA-Luft (VDI Guideline 2440), BAM oxygen-service requirements, ABS-PDA, Chlorine Institute Pamphlet 95, (EC) 1935/2004 and EU requirements, Blow-Out and DVGW-approved materials, and conforms to FDA 21 CFR 177.1550 for food and drug contact.
9600	Conforms to FDA 21 CFR 177.1550 for food and drug contact. Meets USP Plastic Class VI requirements at 121°C (250°F), complies with the RoHS and REACH Declaration, and holds ABS-PDA approval.
Joint Sealant	Complies with the RoHS and REACH Declaration and conforms to FDA 21 CFR 177.1550 for food and drug contact.
9645	Conforms to FDA 21 CFR 177.1550 for food and drug contact; material approved according to TA-Luft (VDI Guideline 2440).
LT100	Manufactured with FDA-compliant materials. Designed for low-torque sealing applications requiring high sealing integrity.

Note: ASTM properties are based on 1/16" sheet thickness, except ASTM F38 which is based on 1/32" sheet thickness. This is a general guide only and should not be the sole means of accepting or rejecting this material. The data listed here falls within the normal range of product properties, but should not be used to establish specification limits nor used alone as the basis of design. For applications above Class 300, contact our technical department.

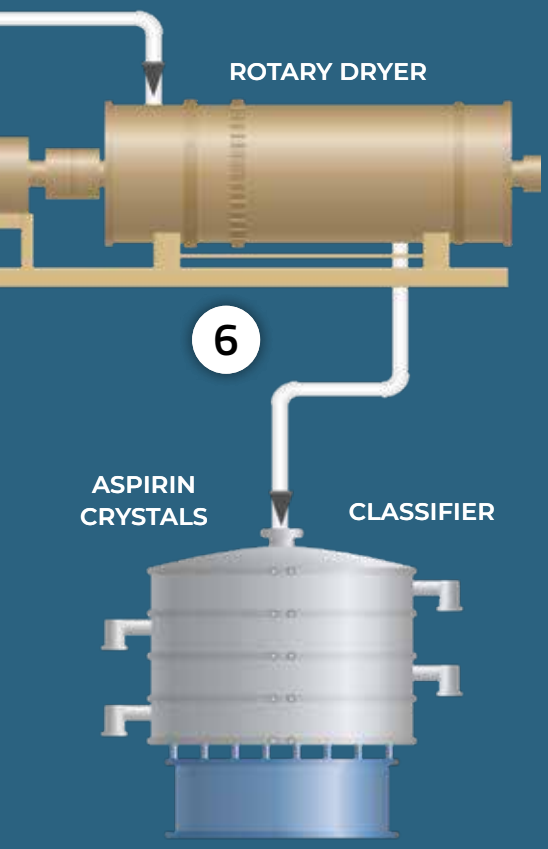
Warning: Durlon® gasket materials should never be recommended when both temperature and pressure are at the maximum listed. Properties and applications stated are typical. No applications should be undertaken by anyone without independent study and evaluation for suitability. Never use more than one gasket in one flange joint and never reuse a gasket. Improper use or gasket selection could cause property damage and/or serious injury. Data reported is a compilation of field testing, field service reports and/or in-house testing. While the utmost care has gone into publishing the information contained herein, we assume no responsibility for errors. Specifications and information contained within are subject to change without notice. This edition cancels and obsoletes all previous editions.

Aspirin Production Process Flow Diagram



NOTE: This diagram is a simplified representation of a typical aspirin production process and illustrates the primary process flow. Actual manufacturing methods, equipment, solvents, catalysts, operating conditions, and purification steps may vary. The diagram highlights major processing stages and does not show all auxiliary equipment, instrumentation, controls, or quality-control operations.

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Durlon® Product List

1. 9000, 9000N, 9600
2. 9000, 9000N, 9600
3. 9000, 9000N, 9600
4. 9000, 9000N, 9600
5. 9000, 9000N, 9600
6. 9000, 9000N, 9600

The production of aspirin typically involves the following steps:

1. RAW MATERIAL FEED
Salicylic acid and acetic anhydride are introduced into the process. A suitable acid catalyst may also be added according to the selected production method.

2. REACTOR
Salicylic acid reacts with acetic anhydride to form acetylsalicylic acid (aspirin) and acetic acid under controlled reaction conditions.

3. FILTRATION
The reaction mixture may be filtered or otherwise conditioned to remove insoluble material and prepare the product stream for crystallization.

4. CRYSTALLIZER
The aspirin-containing solution is cooled and/or combined with an appropriate solvent or antisolvent to promote crystallization of acetylsalicylic acid.

5. CENTRIFUGE
Aspirin crystals are separated from the mother liquor by centrifugal separation. The crystals may also be washed during this stage to remove residual soluble impurities.

6. DRYING / CLASSIFICATION
The separated crystals are dried to reduce residual moisture and volatile components. The dried material may then be classified or screened to obtain the required particle-size distribution before subsequent formulation or processing.



The core of the Durlon® brand is to provide fluid sealing solutions that make sense, both financially and strategically. We accomplish this through process-oriented design, sector-specific knowledge, and extensive testing. Our goal is to ensure performance and safety while operating under a quality management system registered to ISO 9001:2015.

At Durlon®, we offer specially developed sealing solutions tailored to your specific needs.

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