

Quality & Development

Device Life Cycle

We play an active role across various distinct but concurrent stages of a device's life cycle; right from leveraging our in-house design (DFM) competencies and material expertise for designing and validating the product to manufacturing and scaling up production using innovative assembly techniques under cleanroom manufacturing conditions.



Quality

At Shaily, we believe in upholding the highest standards of quality. Our Quality Management System is both ISO 13485 and ISO 15378 certified, complying with:

- FDA 21 CFR 820 Quality System Regulation & cGMP
- MDD 93/ 42 EEC Medical Device Directive

Our QMS employs a risk-based approach for all processes along with a mix of time tested and cutting-edge techniques to ensure adherence to quality standards, while optimizing operational efficiencies. These techniques include:

- Six Sigma
- Continuous Improvement Initiatives
- Process Capability Monitoring, through the use of Statistical Process Control methods
- Root Cause Analysis & CAPA
- DFMEA & PFMEA
- Use of CMM and Custom Fixtures for In-process Quality Control

Sustainability



Sustainability has become more relevant today than at any point in history, it is an important pillar of any successful business strategy.

We at Shaily believe in operating in a manner that has a positive impact on the planet and the people that live within our communities and we believe that both hold equal value in ensuring Shaily's survival and success in the future. Our goal is to constantly improve our processes in way that results in

reduction of power, water and the other essential natural resources. We see this as the only way to constantly remain competitive in an increasingly dynamic business environment and continue to provide sustainable growth and profitability to our stakeholders.

Lean Six Sigma forms a significant part of our overall sustainability strategy, often resulting in better quality, increased productivity and reduced waste in both our manufacturing operations as well as our business processes. In 2017 Shaily undertook a major challenge of reducing its

Shaily Manufactures Your Products using Renewable Energy

dependence on fossil fuels based energy and as a result we now use more than 50% of our total energy needs from renewable sources, both Biomass and Solar.

Across our other business verticals such as Home Furnishings and FMCG, we have also been successful in being able to convert products manufactured from virgin materials to both recycled plastics as well as bioplastics whilst still being able to meet RoHS and other necessary compliances.



Regd. Office & Plants

Survey No. 366, Rania, Vadodara,
Gujarat 391780, India
T +91-2667-244307
F +91-2667-244372
E sales@shaily.com

Correspondence Address

8 J.P. Nagar, Old Padra Road, Vadodara,
Gujarat 390007, India
T +91-265-2332706
E sales@shaily.com

Halol Plant

707, GIDC, Halol, Dist. Panchmahals,
Gujarat 389350, India
T +91-2676-222913/222914
E halol.plant@shaily.com

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Making Quality Healthcare Effective, Efficient & Affordable



About Us

Established in 1987 in the western state of Gujarat, India, Shaily Engineering Plastics Ltd today has five facilities generating revenue of USD 50.0 million.

Shaily Engineering Plastics is one of India's leading injection molding companies that specializes in the design, development, and manufacturing of complex precision components and assemblies requiring stringent quality and tight tolerances using high performance engineering polymers.

With 100+ state-of-the-art injection molding machines ranging from 35 tons to 1000 tons spread across 5 facilities, and our robust Quality Management Systems based on global standards, Shaily caters to business segments as varied as Engineering, Automotive, Home Furnishings, Switchgears, Appliances, Home and Personal care, and Healthcare. Shaily's clients include leaders and innovators in their respective sectors such as Sanofi, Unilever, P&G, GE, Electrolux, Sun Pharmaceuticals, ABB, and IKEA to name a few.

ISO Class 8 Cleanroom



Healthcare Business Unit

Shaily's vision is to design, develop and manufacture quality healthcare products at lower costs in order to increase our customers' competitiveness.

Shaily is today a global player involved in the development and manufacture of complex drug delivery devices such as pen injectors, dry powder inhalers and pumps. Shaily also manufactures a wide range of primary packaging products for both solid and liquid dosage forms such as HDPE bottles, child resistant closures, ophthalmic packaging, otic packaging and various other specialized packaging and applicators. Shaily is certified to both ISO 13485 and ISO 15378, compliant with FDA 21 CFR 820 and also supports its customers with DMF, NDA, ANDA, and 510k filings

Drug Delivery Devices

We believe in partnering with our clients to design, develop, and manufacture innovative, sustainable, and cost effective solutions that promote adherence and compliance while delivering superior patient experience.

Precision Injection Molding



Polymer Expertise



Quality & Compliance



In 1987, Shaily started off as a supplier of precision clock gear components for a Japanese corporation. We have only strengthened this capability and are today manufacturing complex components and assemblies for life saving medical devices. We have the ability to manufacture components that weigh less than 0.03 grams with tolerances of 5 microns.

Our extensive experience in processing filled and unfilled polymers such as PA6/66/12, PES, PPS, PBT, LCP, PC, Torlon, and PEEK has enabled us to specify types and grades of resin for each individual component of the Wockhardt insulin pens.

Our Quality Assurance and Regulatory compliance teams not only have adequate experience but are also proficient with various global standards that enable us to support our customers with the following filings:

- CE Mark
- 510k
- Master Files for Devices:
 - Design History File
 - Device Master Record

Comprehensive Design Review

In line with FDA's 21 CFR 820.30 and ISO - 13485, we conduct comprehensive design reviews with our clients and external design agencies at regular intervals, including design & process FMEA's.

Collaborative Tool Design & Manufacturing

We actively collaborate with our tool manufacturing partner, our clients and their external design agencies to design the most cost effective and robust products. Our toolmakers have the capability of manufacturing multi -cavity molds at a precision level of ± 0.003 mm.

Innovative Assembly Solutions

We specialize in innovating manual, semi automated and automated assembly processes that optimize cost while maintaining 100% quality.

Efficient Supply Chain

Our robust SCM system cascades across all stages of design and production; ranging from movement and storage of raw materials to work-in-process inventory to transportation of finished products across various geographies.



Primary Packaging

Providing superior protection for your active pharmaceutical ingredients and delivering significant value through our expertise in materials, manufacturing, quality and regulatory compliance.

Solid Dosage Forms



Liquid Dosage Forms



Speciality Packaging



Shaily's high quality packaging for Solid Orals, and Liquid Formulations are available in various sizes, form, and functionality and provide superior protection for your formulations. Shaily also specializes in design, development, and manufacturing of speciality packaging for various therapies where the primary pack also aids in delivery of the formulation. A combination of material expertise, precision molding capability, state of the art infrastructure, and our Quality Management Systems (ISO 15378) ensure 100% product quality.

Our Infrastructure Includes

- ISO Class 8 Cleanroom
- All Electric Injection Molding Machines
- Injection Blow Molding Machines
- High-End Vision systems for bottles, and closures detecting:
 - Sealing surface
 - Bottle base
 - Bottle outer surface
 - Bottle inside
 - Thread area

Type III Drug Master Files

Primary Packaging

US DMF No. 28979
Canadian DMF No. 2015-200
Ophthalmic & Otic droppers
US DMF No. 031692

Safer Design with Shaily CRCs

High Performance

One of the highest performing closures in both child resistant and adult test

Proven Track Record

Designed by Global Closure Systems, based on the market leading Medi-loc® and Clic-loc®

Smarter Design

An audible click sound is produced while turning the closure to alert adults

US Pharmacopeia Standards

Shaily's Primary Packaging products are fully compliant with US Pharmacopeia Standards. The following are various tests that we perform on our primary packaging products:

- USP 661.1
- USP 661.2
- USP 671
- USP 39
- USP 87
- 16 CFR 1700

