

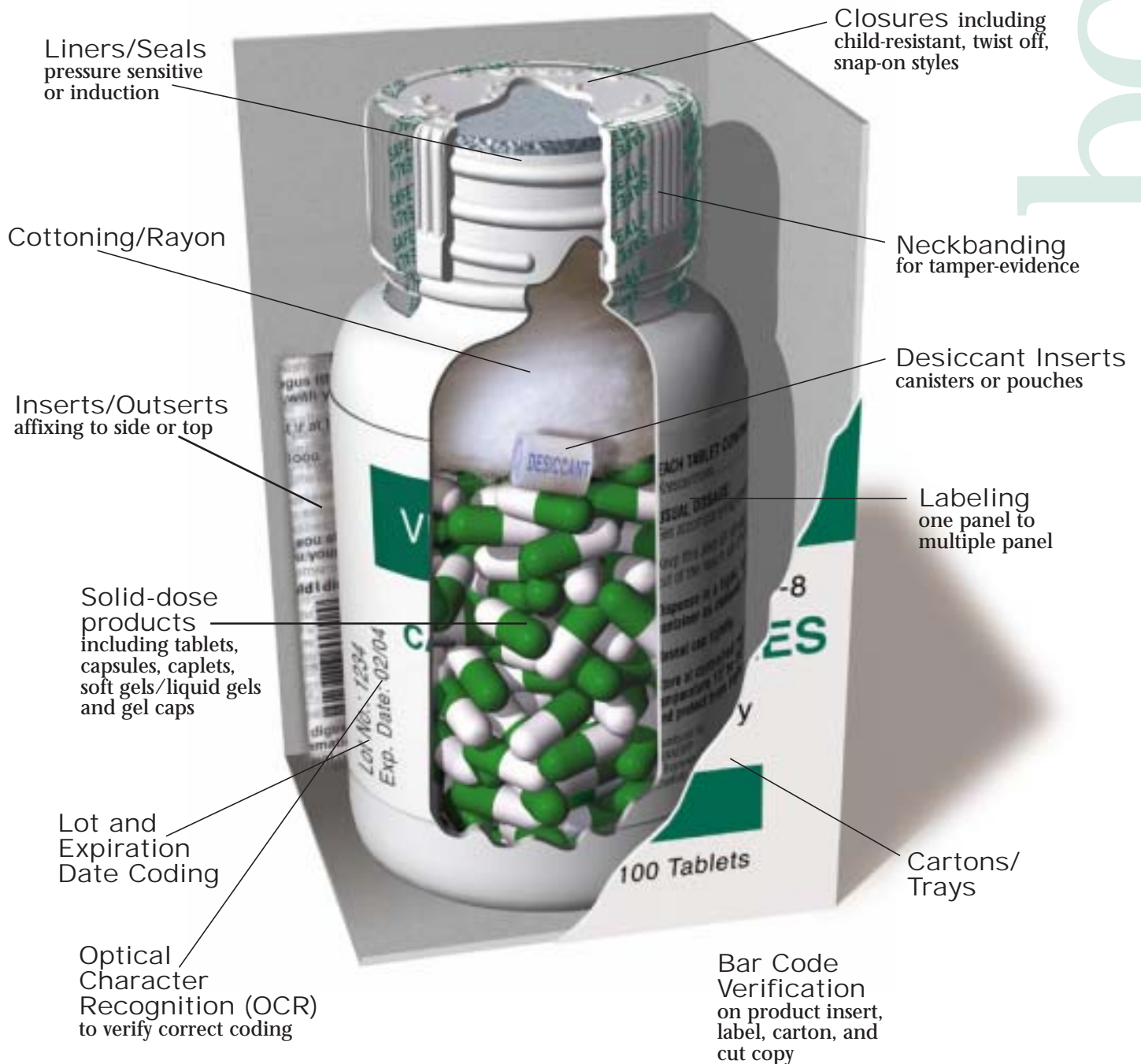


Filling Your Bottling Needs

Sharp has the equipment and expertise to meet the highest bottling standards, whether for commercial production, product sampling or clinical trials. Sharp offers comprehensive service, a variety of packaging options and strict Quality Control procedures to ensure consistent satisfaction.

Currently Sharp can provide solid-dose product bottling for both high-volume and small quantity needs. Our turnkey services include carton printing, purchasing of all components, in-line cartoning as well as scheduling flexibility. Trust Sharp to be your single source for excellence in bottling.

bottling



Bottling Overview

Bottle Types

Sharp can package a variety of bottle sizes from 30cc to 600cc in various bottle configurations. Plastic bottles are most commonly used, but glass containers can be accommodated.

Filling

Either slat or electronic filling systems may be used to achieve the best efficiency. Solid dose products can be in tablets, capsules, caplets, soft gels/liquid gels or gel caps form. A gross underload optical sensor verifies that the product level is accurate.

Cottoning

Cotton or rayon weights typically range from 8 to 12g, and the average length of cotton per bottle is 3". Cottoning can be modified to customer specifications. A sensor on the bottling line verifies that the cotton is placed in the bottle and not wicked (above the seal line), to assure a proper seal.

Desiccant Inserts

Canister or sachet desiccants are most commonly used, but the equipment will accommodate alternative desiccants.

Liners/Seals

Aluminum foil/lepel and pressure-sensitive seals are used. A liner verification sensor assures placement

Closures

The following closure formats are available:

- Child-resistant
- Twist-off
- Snap-on Metal or plastic components may be used. A cap inspection device assures proper placement and tightness.

Neckbanding

Preprinted neckbands can be added and heat-shrunk to the bottles during the packaging process. The bands may also be perforated online.

Labeling

Pressure-sensitive bottle labels can be applied online. Lot and expiration dates can be printed and applied during this process. All cut labels are inspected using optical character recognition (OCR) to assure proper date and lot codes. Standard bar code scanners are available.

Inserts/Outserts

Patient information inserts or coupons can be automatically affixed to the bottle or carton.

Cartons/Trays

Filled bottles can be placed in individual cartons, packed in multiples in containers or trays, then bulk-packed in corrugated boxes. Sharp prints and produces the cartons and trays to expedite the packaging timeline. Carton ends may be glued or secured using reverse tuck.

Special Capabilities

Sharp is DEA registered for Class II-V products and has secured packaging and storage areas for Class II controlled substances and clinical bottling. Stability packaging in bottles can also be provided. In-house tooling design and production at Sharp allows for the production of bottling equipment

tooling. Our experienced engineering staff can set-up the bottle line to meet the specific packaging requirements

Validation

Sharp will validate the bottling process selected for each project. Sharp has a validation protocol that may be used, or the process can be adjusted to meet specific needs.

Quality Controls

Each bottle line is enclosed in its own temperature and humidity controlled packaging suite. This ensures maximum packaging efficiency due to product comfort. A multitude of sensors and inspection devices, including reject stations positioned at every activity on the bottling line, assure quality throughout the process. Our dedicated quality assurance/quality control personnel maintain strict cGMP compliance to SOPs and FDA regulations. Every operation is carefully monitored and accompanied by accurate, detailed batch record documentation.

Other Packaging Options

In addition to bottling, Sharp offers a full range of packaging options including blister packages, carded blister packages, pouches, kit packaging, and other specialty services services.

For more information

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