





QUALICAPS®

HISTORY

Over one hundred years of experience in the manufacturing and filling of hard two-piece capsules

Qualicaps® originated within Eli Lilly & Co., as a capsule manufacturing plant in Indianapolis opened in 1897. This **century-long heritage** dictates a profound understanding of the needs of our pharmaceutical customers, for whom we have focused on delivering at **high-quality standards** since the very beginning.

Along with our innate **customer-centric perspective** that accompanies a lifetime of dedicated service to our customers, Qualicaps® also has a **proven record of innovation**. We were the first to develop a preservative-free gelatin capsule, the first to produce a pharmaceutical-grade capsule of vegetal origin with a dissolution profile similar to that of gelatin, and the first to design and offer a capsule for use in inhalation.

And beyond the capsules themselves, the Qualicaps® group offers a wide range of equipment to support the needs of solid oral dosage production, including capsule filling and sealing, visual and weight inspection, imprinting, and softgel manufacturing.

PARTNERSHIP

More than just a supplier, Qualicaps® is an implicated partner to our stakeholders

Qualicaps® is a **long-term capsule partner** for most of the leading global pharmaceutical companies, as well as for many relevant local and regional ones. We know that these customers value us in terms of quality, anticipation of market requirements, and flexibility to fulfill special customer needs.

Our **global presence** in all major pharmaceutical markets and the stability and solidity we offer as part of **Mitsubishi Chemical Holdings Corporation (MCHC)** guarantee the assurance of supply necessary for successful product launches and ongoing market requirements.

The Qualicaps® team is comprised of not only expert commercial representatives, but also **highly knowledgeable and experienced personnel** that collaborate with both R&D and academia in more scientific endeavors, as well as technical engineers that support our customers' production centers in runnability and yields.

ENGINEERED TO PERFORM

QUALICAPS® CAPSULES ARE DESIGNED AND MANUFACTURED WITH FUNCTIONALITY AND PRECISION IN MIND AND DEED

- We take pride in engineering and producing each individual capsule with the objective of delivering superior performance
- We analyze performance from many perspectives: pharmaceutical-grade quality, productivity in filling machines, stability through shelf life, protection of the active ingredient contained within, and patient adherence and ease-of-use
- We not only offer high standards of performance from our capsules, but also from our team, made up of subject matter experts who collaborate with our customers on meeting their business goals





THE KAITEKI COMPANY

QUALICAPS® INTEGRATES THE “KAITEKI” PHILOSOPHY INTO THE BUSINESS

- Commitment to sustainable development for the benefit of individuals, society, and the Earth
- Value philosophy based on the management of three strategic pillars within the company: economy, technology, sustainability
- Contribution to the resolution of social and environmental issues through our products and services, and as a driver of innovation
- Collective consciousness and joint efforts among the 55,000+ employees of the Mitsubishi Chemical Holdings Corporation (MCHC) Group, of which Qualicaps® is a wholly-owned subsidiary

QUALI-V® CAPSULES



THE ROUTE OF ADMINISTRATION IS CRITICAL FOR MEDICINES, AND IN THE CASE OF ORAL DOSAGE FORMS, THE DIFFERENT PHARMACOPOEIAS ALL DICTATE STRICT LIMITS OF TIME WHEN AN ACTIVE INGREDIENT MUST BE RELEASED INTO THE STOMACH.

With Quali-V® capsules, Qualicaps® was the first to develop and offer to the market an alternative to hard gelatin capsules that is equivalent with regard to dissolution time.

Qualicaps® has been a pioneer in new forms of drug administration, and in fact is responsible for several milestones in the history of hard capsule development within the pharmaceutical industry. We are a leader in being the first to design and implement features in our capsules so widely accepted and trusted, that they have since become industry standards. Our Quali-V® capsules are a clear example of this.

IN ADDITION TO ITS EQUIVALENCE TO GELATIN, QUALI-V® HYPROMELLOSE CAPSULES PRESENT CERTAIN BENEFITS IN COMPARISON:

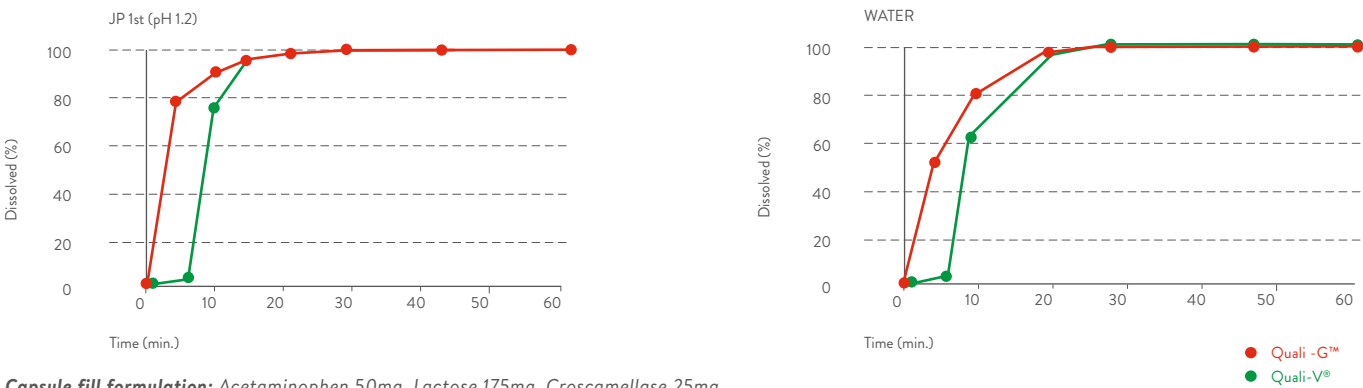
- Free of ingredients originating from animals
- Reduced moisture content
- Reduced water permeability
- No brittleness
- No crosslinking
- Minimal static charge

| | Quali-G™ (gelatin) | Quali-V® (HPMC) |
|-----------------------|--------------------|-----------------|
| Origin | Animal | Plant |
| Structure | Protein | Cellulose |
| Moisture content | 13.0% - 16.0% | 4.0% - 6.0% |
| Water permeability* | 1.00 | 0.55 |
| Brittleness at low RH | Yes | No |
| Risk of crosslinking | Yes | No |
| Triboelectrification* | 1.00 | 0.05 |

* Expressed in relative units

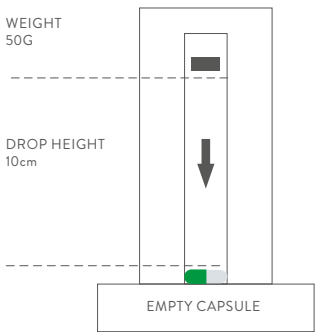
QUALI-V® CAPSULES ARE A PLANT-BASED ALTERNATIVE TO GELATIN CAPSULES, WITH SUPERIOR PROPERTIES FOR HYGROSCOPIC DRUGS

- Quali-V® capsules have a **lower moisture content** than gelatin capsules (4.0% to 6.0%).
- Quali-V® capsules are **equivalent in their dissolution profile** to the traditional hard gelatin capsules.



- Quali-V® capsules **do not become brittle**, even when dried to 1 % RH.

BRITTLENESS TESTER (QUALICAPS®)

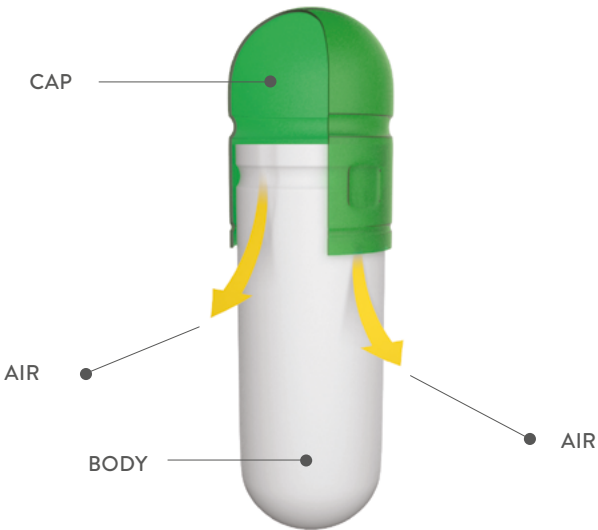


- Quali-V® capsules maintain their **physical stability** when filled with hygroscopic materials or are exposed to low humidity conditions. They also hold many types of formulations: powders, pellets, tablets, semi-solids, and non-aqueous liquids.
- Quali-V® capsules are **chemically inert** and do not undergo cross-linking reactions.

QUALI-V® CAPSULES ARE DESIGNED TO MEET THE DEMANDING REQUIREMENTS OF THE PHARMACEUTICAL INDUSTRY



- **Pharmaceutical-grade quality.** The manufacturing process is carried out following strict pharmaceutical criteria and certified according to ISO 9001 and ISO 14001. Drug Master Files for the US and Canada have been registered.
- Quali-V® capsules are **continuously monitored by Quality Control experts** in the production process to ensure compliance with the most demanding of pharmaceutical requirements.
- All Quali-V® capsules are **inspected using an automatic camera system** to detect and remove defective units.
- For inhaled drugs, Qualicaps® offers Quali-V®-I capsules specifically designed **for use with dry powder inhalers** (see our Quali-V®-I brochure).
- Qualicaps® manufactures axial, radial, and laser printing machines that provide a **superior print quality**. Laser technology is effective as an anti-counterfeit measure, as very fine details of logos are visually ascertained.
- Quali-V® capsules are **available in a wide range of colors**, developed in-house and made using market-accepted colorants.
- Quali-V® capsules are **available in all pharmaceutical sizes**, including capsules for clinical trials or mini capsules for early trials with small rodents.
- Our scientists and subject matter experts can provide **R&D support** in capsule-form dosage delivery. Qualicaps® also has the luxury of tapping into resources available in the Mitsubishi Chemical Holding Corporation (MCHC) research laboratories.
- Quali-V® capsules have the required dimensions and strength that enable them to be filled and packaged on **automatic high-speed machines**.
- The **unique POSILOK® design** of Quali-V® capsules prevents separation when empty or filled on high-speed filling and packaging machines.
- Our technical service engineers can **assist in achieving productivity yields in capsule filling**, applying their vast knowledge and experience with leading equipment suppliers.



HARD TWO-PIECE CAPSULES, A SOLID ORAL DOSAGE FORM WITH ADVANTAGES

Solid oral dosage forms (tablets and capsules, both hard and soft) are the most popular delivery option among patients, doctors, and pharmaceutical companies.

They are “patient-friendly”: readily portable, convenient to auto-administer, easy to swallow, stable and precise in delivering the active ingredient.

HARD TWO-PIECE CAPSULES ALSO OFFER ADDITIONAL ADVANTAGES OVER TABLETS, MAINLY:

- Less complex formulations, using less excipients.
- Possibility of combining drug products.
- Possibility of using two colors (cap and body).
- More efficient product manufacturing process (reduced amount of steps), reducing validation and analytical costs.
- Absence of compression forces in product manufacturing.

QUALI-V® HPMC CAPSULES, THE TREND IN MARKET PREFERENCE

Quali-V® capsules can be used at all stages in the development process, from pre-clinical toxicological testing through all phases of clinical trials, and finally to product launch.

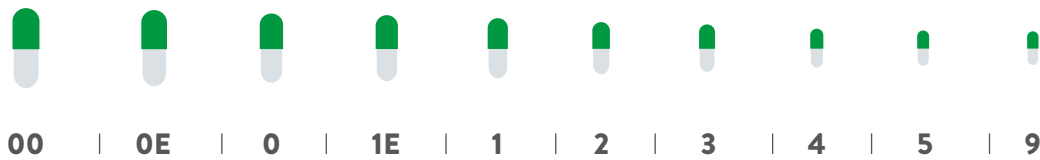
CAPSULE COLORS

Quali-V® capsules are available in a wide range of colors.

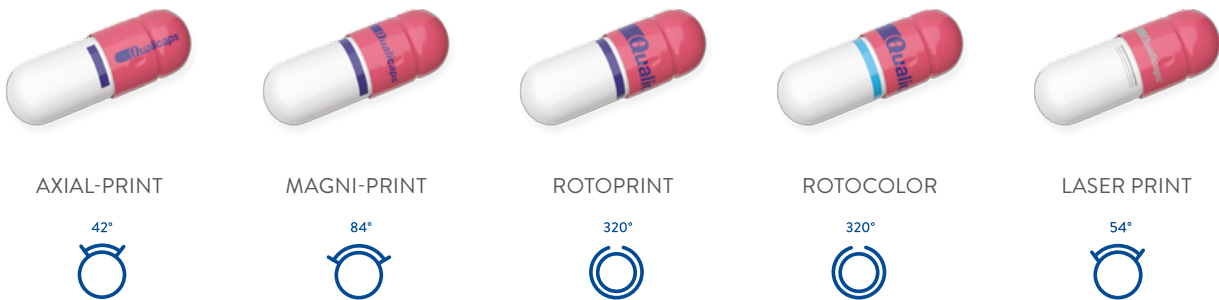


CAPSULE SIZES

Quali-V® is available in all sizes used by pharmaceutical companies, from size 9 for early trials with rodents up to size 00, the largest used in human medicine.



CAPSULE PRINTING



**Qualicaps[®]
innovation:
1st in bringing
a capsule
of vegetal
origin to the
pharmaceutical
market**



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