QUALICAPS® CAPSULES PORTFOLIO





CAPSULES ARE THE VERY ESSENCE OF QUALICAPS®

As a company dedicated to capsules, we have a unique perspective on how to contribute to health. Qualicaps® delivers pharmaceutical-grade capsules together with a comprehensive service along the drug product life cycle through our global team of commercial, scientific and technical experts.

Qualicaps® is a responsible company dedicated to the supply of two-piece hard capsules and related services that takes pride in producing each capsule with the aim of promoting the basic principles of wellbeing.

As one of the principal suppliers to the pharmaceutical industry, Qualicaps® brings a wealth of expertise to the consumer health market:

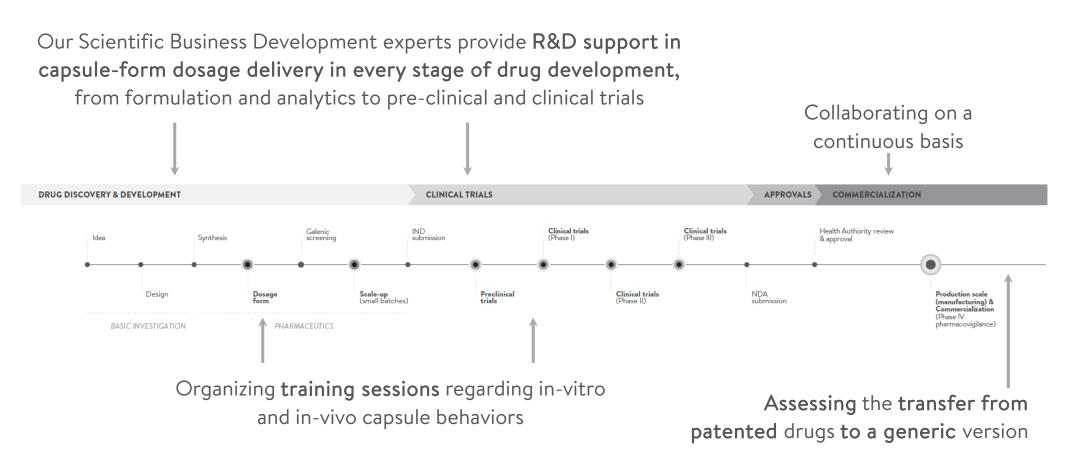
- Over 120 years of capsule manufacturing experience.
- Proven track record in capsule innovation and custom capsule applications.
- Capsule, equipment and technology synergies to meet pharmaceutical and nutritional product manufacturing needs.
- Commitment to personalized customer service.

As a business, what we think, see and create is born from the capsule



CONTACT OUR SCIENTIFIC BUSINESS DEVELOPMENT EXPERTS

Our scientific experts offer a wide range of services around the hard capsules dosage form, able to present you with the option of either start-to-finish development or focused support at any critical stage of the drug product's life cycle.



PHARMACEUTICAL APPLICATIONS

Qualicaps® manufactures capsules for a wide range of formulation types ranging from dry powders and pellets to pastes and liquids. We produce high-quality pharmaceutical-grade capsules, and offer them in a wide range of sizes, colors and printing options for your product to stand out in the market.



Please click on the product to see more information





The first preservative-free formula in gelatin capsules, the market standard dosage form



Pharmaceutical Grade



Preservative Free **QUALICAPS® INNOVATION**



100% Bovine Bone **PREMIUM**





COMPOSITION

Gelatin

Water

Dyes

MOISTURE CONTENT

• 13.0% – 16.0%

MAIN FEATURES

- Excellent dissolution profile
- Unique POSILOK® design helps prevent separation on high-speed filling and packaging machines
- Ideal for oxygen-sensitive pharmaceutical drugs
- 5-year shelf life
- An inhalation grade is available:

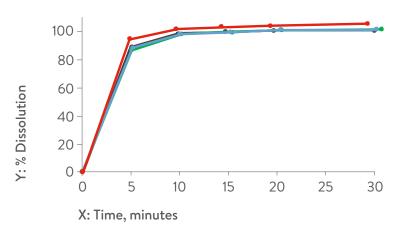


Qualicaps[®] also offers TiO₂ Free capsules upon request:



DISSOLUTION PROFILE

Quali-G™ capsules demonstrate a very predictable dissolving drug profile in which 85% of the API is released in the first 15 minutes at different pH levels.



Acetaminophen (AC) / Lactose / Disintegrant=20/70/10. Paddle, 50 rpm, with sinker, N=6. Test medium: Purified water, solution of:

- Water
- pH 1.2 (JP 1st test fluid, 77.8 mM HCl, 43.2 mM NaCl)
- pH 6.8 (JP 2nd test fluid, 12.5 mM KH2PO4, 12.5mM, Na2HPO4)
- pH 4.0 (Mc Ilvaine buffer ¼, 9.64 mM Na2HPO4, 15.36 mM citric acid)











The capsule specifically designed to reduce the britleness at low moisture contents



Pharmaceutical Grade



Preservative Free
QUALICAPS® INNOVATION



100% Bovine Bone
PREMIUM



100% Automatic Camera Inspection **QUALICAPS® INNOVATION**

COMPOSITION



Gelatin



Water



Dyes

- Contains 5% PEG4000
- Compared to standard gelatin capsules, the mechanical strength in low-moisture condition of capsules increases dramatically
- The disintegration of Quali-G[™] PEG and Quali-G[™] are the same. The addition of PEG does not change the disintegration properties
- The solubility is no different from conventional gelatin capsules
- Less of a problem on handling even in environments with low humidity
- 5-year shelf life
- Well suited for the filling of pharmaceutical products that have high hygroscopic property







The capsule specifically designed to reduce the brittleness at low moisture contents



Pharmaceutical Grade



Preservative Free
QUALICAPS® INNOVATION



100% Bovine Bone
PREMIUM



Strict Microbiological Control



100% Automatic Camera Inspection **QUALICAPS® INNOVATION**

COMPOSITION



Gelatin



Water



Dyes

MOISTURE CONTENT

• 13.5% – 16.5%

- 100% Porcine free assuring compatibility with regard to certain dietary and religious restrictions on other animal sources
- Strict process controls ensure the compliance of microbiological requirements without the use of preservatives (as active ingredients are inhaled directly into the lung, capsules for this delivery route require lower microbial levels than those used in oral administration)
- Available in three sizes (size 3, the most common in inhalation, and sizes 2 and 0 for higher doses) and in a wide range of colors with different print options
- 5-year shelf life
- Specifically designed for use in dry powder inhalers (DPIs)







The first vegetal capsule for pharmaceutical applications, setting the trend in market preference







Preservative Free **OUALICAPS® INNOVATION**



100% Vegetal Origin QUALICAPS® INNOVATION



Gelatin Equivalent Dissolution Profile



Minimal Brittleness

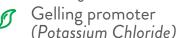


100% Automatic Camera Inspection QUALICAPS® INNOVATION

COMPOSITION







Dyes

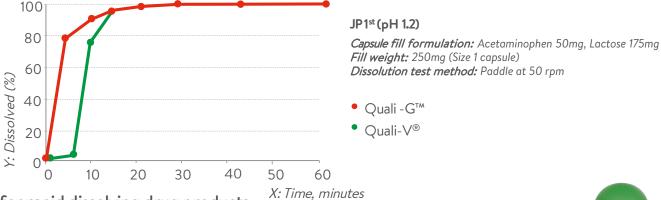
MOISTURE CONTENT

• 4.0% - 6.0%

MAIN FEATURES

DISSOLUTION PROFILE

Quali-V® capsules are equivalent in their dissolution profile to traditional hard gelatin capsules



- Quick and predictable dissolution profile for rapid dissolving drug products
- Lower moisture content and water permeability than gelatin
- Physically stable, with better performance than gelatin in terms of brittleness
- Chemically stable and does not undergo crosslinking reactions
- 5-year shelf life
- An even lower moisture content version is available:
- Qualicaps® also offers TiO₂ Free capsules upon request:









The first cellulose capsule with an extremely low moisture content for pharmaceutical applications

















Pharmaceutical Grade

100% Vegetal Origin QUALICAPS® INNOVATION

100% Vegetal Origin QUALICAPS® INNOVATION

Minimal Brittleness

Chemically Inert

Lower Moisture Content $(2.0\ 3.5\%)$

Ihnalation Grade

100% Automatic Camera Inspection QUALICAPS® INNOVATION

COMPOSITION



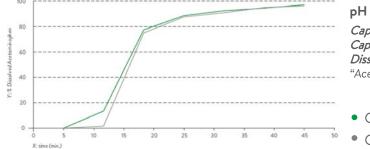




Dyes

DISSOLUTION PROFILE

Quali-V® capsules are equivalent in their dissolution profile to traditional hard gelatin capsules



pH 1.2

Capsule fill formulation: Acetaminophen Capsules: Size 3 (n=6) Dissolution test method: Paddle at 50 rpm -"Acetaminophen Capsules" USP monograph

- Quali-V[®] Extra Dry
- Quali-V® (standard capsule)

MOISTURE CONTENT

• 2.0% – 3.5%

MAIN FEATURES

- The extra-dried capsules maintain their physical stability and show minimal brittleness when exposed to ambient conditions with low humidity
- They are chemically inert and do not undergo cross-linking reactions, making them ideal for drug development
- 5-year shelf life
- An inhalation grade is available:



Ideal for moisture-sensitive and hygroscopic pharmaceutical drugs









The first HPMC capsule with properties specific to inhalation to be introduced in the pharmaceutical marketplace

















Pharmaceutical Grade

Strict Microbiological Control

Better Aerosolization

Superior Puncturing Properties

Inner Surface Control

Reduced Powder Adhesion

100% Automatic Camera Inspection

OUALICAPS® INNOVATION

COMPOSITION









MOISTURE CONTENT

• 4.5% – 6.5%

- Specifically designed for use in dry powder inhalers (DPIs) for moisture-sensitive formulations
- Moisture content slightly higher than Quali-V[®] for optimized puncturing
- Control of internal lubrication for enhanced aerosolization
- Complies with strict microbiological requirements
- Available in three sizes (size 3, the most common in inhalation, and sizes 2 and 0 for higher doses) and in a wide range of translucent colors, developed in-house and made using market-accepted colorants
- 5-year shelf life
- An even lower moisture content version is available:











The capsule with an extremelly low moisture content for use in DPIs















Pharmaceutical Grade

Strict Microbiological Control

Better Aerosolization

Superior Puncturing Properties

Inner Surface Control

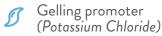
Lower Moisture Content (2.0 - 3.5%)

100% Automatic Camera Inspection **QUALICAPS® INNOVATION**

COMPOSITION







Dyes

MOISTURE CONTENT

• 2.0% – 3.5%

- Strict process controls ensure the compliance of microbiological requirements without the use of preservatives
- Quali-V®-I Extra Dry capsules are produced with a special drying process and unique equipment developed by Qualicaps® Europe, with funding awarded by the European Union through the Centre for the Development of Industrial Technology.
- 5-year shelf life
- With a very low moisture content for use in dry powder inhalers (DPIs) for hygroscopic / very moisture-sensitive inhalation formulations





CONSUMER HEALTHCARE APPLICATIONS

Qualicaps[®] is contributing to proactive and preventive health and individual wellbeing by meeting the requirements of product manufacturers and the preferences of healthconscious consumers with superior quality capsules.



Please click on the product to see more information







Contributing to proactive and preventive health and individual wellbeing











COMPOSITION

- Polymer(Hypromellose)
- Gelling agent (Carrageenan)
- Gelling promoter (Potassium Chloride)
- Dyes (optional)

MOISTURE CONTENT

• 4.0% – 7.0%

- Rapid dissolving product, releasing ingredients in the stomach
- Constant solubility in liquids over a broad range of temperatures, so products can be taken with either warm or cold drinks
- Low moisture content, so little to no brittleness upon drying and less moisture transfer with capsule fills. Ideal for moisture-sensitive ingredients
- Band-sealing suitable for liquid-fills to prevent against leakage and provide tamper evidence
- Excellent performance on high-speed capsule filling machines
- Ready-available supply (shipment of stock orders within 24-48 hours in standard sizes and colors used in the nutritional industry)
- 5-year shelf life
- Ideal for OTC categories, amino acids, vitamins, minerals, herbal products







Incorporating inherent delayed-release functionality into a capsule





Clean Label
*Free of allergens, gluten,
GMOs, preservatives, sugar



Easy to Swallow





COMPOSITION

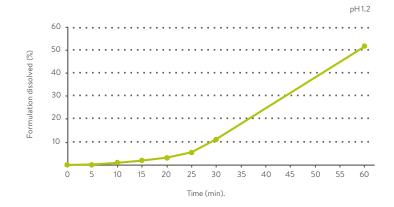
- Polymer(Hypromellose)
- Gelling agent (Carrageenan)
- Gelling promoter (Potassium Chloride)
- Dyes (optional)

MOISTURE CONTENT

• 4.0% – 7.0%

DISSOLUTION PROFILE

• Nutra'V Slow capsules are specifically designed to target moisture-sensitive and acid-labile ingredients by slowing down capsule rupture and release of contents



- Same characteristics as Nutra'V with built-in acid-resistant properties
- Coating-free capsule; there is no need to add chemicals, solvents or other external protection to enable its delayed-release capability
- Band-sealing suitable for liquid-fills to prevent against leakage and provide tamper evidence
- 5-year shelf life
- Ideal for acid-sensitive ingredients, reflux-prone ingredients, moisture-sensitive ingredients, probiotics, enzymes









Responding to the ever-increasing needs of the Consumer Health market











COMPOSITION

- Gelatin
- Water
- Dyes (optional)

MOISTURE CONTENT

• 13.0% – 16.0%

- Rapid dissolving, with constant solubility
- Made from 100% bovine bone gelatin, are acceptable for consumption within certain religious and dietary constraints
- Manufactured in a cGMP compliant facility
- Excellent performance on high-speed capsule filling machines
- 5-year shelf life
- Ready-available supply (shipment of stock orders within 24-48 hours in standard sizes and colors used in the nutritional industry)









Providing effective protection of lower viscosity and aqueous fills











COMPOSITION

- Gelatin
- Water
- Dyes (optional)

MOISTURE CONTENT

• 13.0% – 16.0%

- Same characteristics and composition as Nutra'G, specifically designed for semi-solid and liquid fills
- Available in size 0
- Wide range of color and imprint options for custom capsule applications to enhance distinctive brand images and product differentiation
- Excellent performance on high-speed capsule filling machines; in-line filling and band-sealing recommended for the best guarantee against leakage
- 5-year shelf life
- Maximum fill capacity recommended for optimal performance is ≤ 75% of the capsule body volume



QUALICAPS® CAPSULES PORTFOLIO

Capsule colors

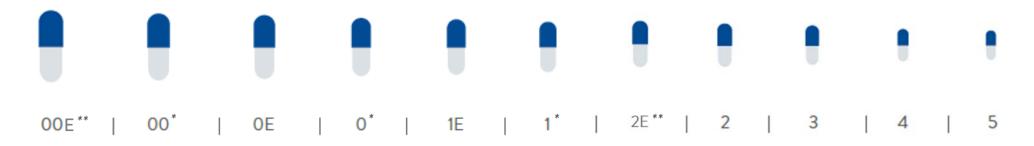
Qualicaps® capsules are available in a wide range of colors for product customization.

The standard offer consists of the following options:



Capsule sizes

Qualicaps® capsules are available in all sizes used by pharmaceutical and consumer healthcare companies.



^{*} Standard offer

^{**} Only for Quali-G™ products

QUALICAPS® CAPSULES PORTFOLIO

Capsule printing

Qualicaps® offers the perfect opportunity for product identification by way of capsules imprinted with text such as company name, logo, product brand, ingredient information, etc.



Capsule imprinting with color promotes product identity distinction and increases brand recognition, while also aiding in anti-counterfeiting measures.

Qualicaps® uses only edible printing inks available in the following colors:



Note: Residual solvents in the ink applied to a capsule comply with limits in the ICH Q3C Guideline for Residual Solvents.

DEDICATED ACCOUNT MANAGEMENT TEAMS

As an integral part of our efforts for Qualicaps® being a truly customer-centric organization, we have defined dedicated Account Management Teams (AMT) to better serve companies as yours in achieving capsule-related business metrics on a continuous basis.

These AMT, continuously supported by the breadth of the Qualicaps® Company (including Operations and Quality Assurance & Quality Control) are multi-functional in nature, comprised of a member from each of our specialized areas of expertise:

- Commercial (Regional Account Director)
- Customer Service (Customer Service Representative)
- Technical Service (*Technical Service Engineer*)
- Scientific Business Development (SBD manager)

Considering our multi-language skilled team (main European languages are supported), you will benefit of having a dedicated person in each role that best fits for your company. Moreover, we have the resources to ensure that during holidays, sickness or for any other reason you will receive an answer within 48 hours.

Your assigned AMT is:

	RAD	CSR	TSE	SBD
NAME				
EMAIL				
PHONE				



QUALICAPS EUROPE, S.A.U.

QUALICAPS SPAIN

Avenida Monte Valdelatas, 4 28108 Alcobendas Spain

Tel: +34 91663 08 00 Fax: +34 91663 08 30

QUALICAPS ROMANIA

SOS. Chitila Nr. 423M – Sector 1 012391 Bucharest Romania

Tel: +40 372 193200 Fax: +40 372 710290