Quali-V® Extra Dry

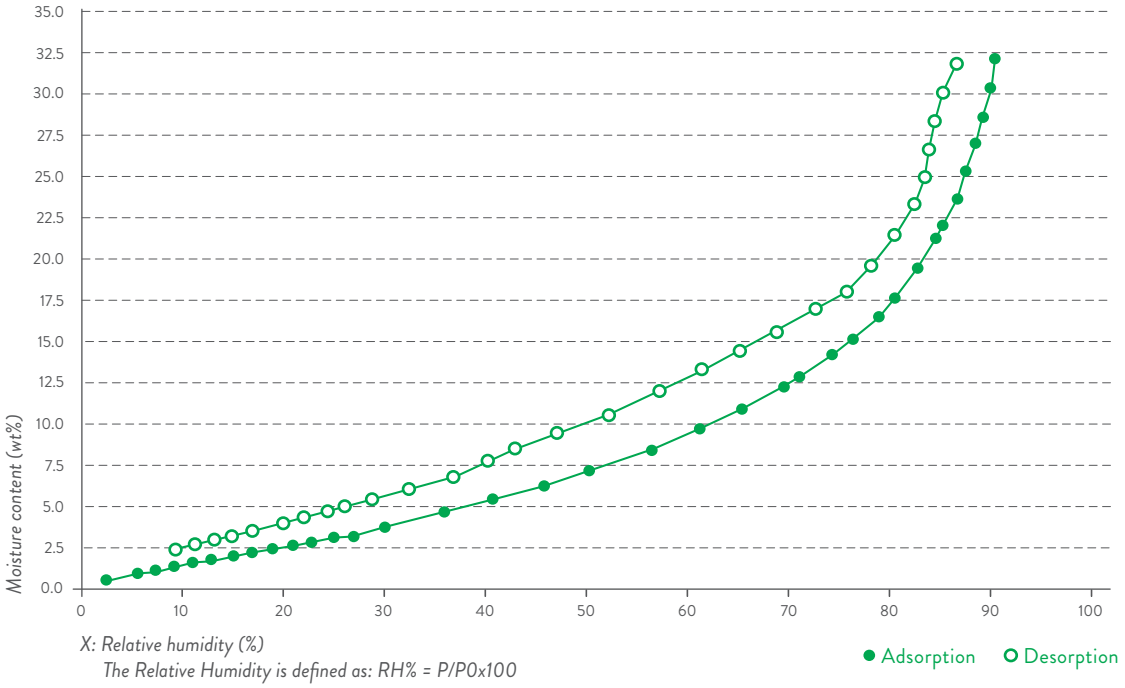
The low moisture hard two-piece HPMC capsule for delivering hygroscopic pharmaceutical drugs

Qualicaps

Qualicaps® continues to innovate by presenting an extra dry cellulose capsule that will enable the development and production of moisture-sensitive and hygroscopic drugs.

The stability, activity, and expiry date of certain active pharmaceutical ingredients (APIs) depend on the moisture content to which they are exposed. Also, determined hygroscopic compounds (e.g. polyethylene glycols, acid glycerol esters, acid triglycerides) widely used as excipients thanks to their outstanding solubility or absorption properties, cannot be used inside gelatin or standard cellulose capsules without reducing their resistance.

WATER ADSORPTION /DESORPTION ISOTHERM CURVE (25°C) (QUALICAPS® JAPAN)



RH (%)	wt/%
14.94	1.9771
16.90	2.1951
18.92	2.4111
20.95	2.6282
22.96	2.8464
24.91	3.067
26.74	3.286
30.11	3.7131
36.02	4.5543

The present data are obtained by means of a volumetric method as per USP41<1241>, EP9.0 2.9.39.

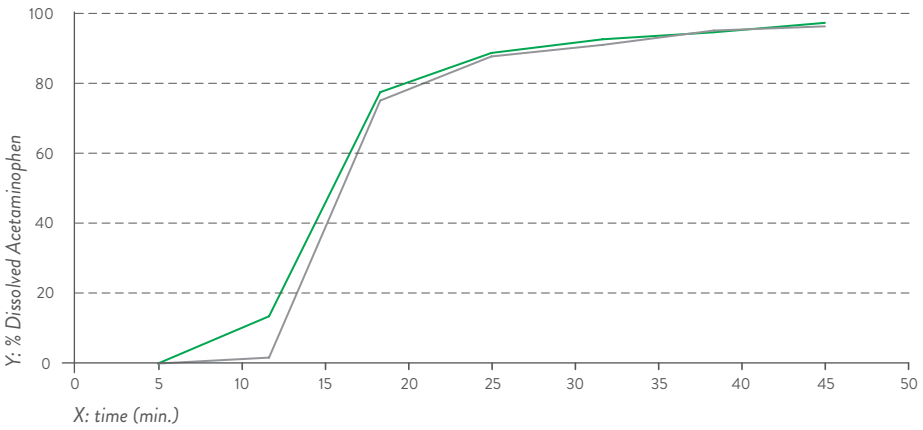
Quali-V® Extra Dry capsules **maintain their physical stability and show minimal brittleness** when exposed to ambient conditions with low humidity.

COMPRESSION TEST (EMPTY CAPSULE; 60 PSI) (ITENE SPAIN)

	LOSS ON DRYING TEST *Moisture content (mean) (%)*	BRITTLENESS TEST *Broken capsules* (n=400 capsules) (%)
Sample 1	2.53	0
Sample 2	2.97	0
Sample 3	2.58	0

DISSOLUTION PROFILES

pH 1.2



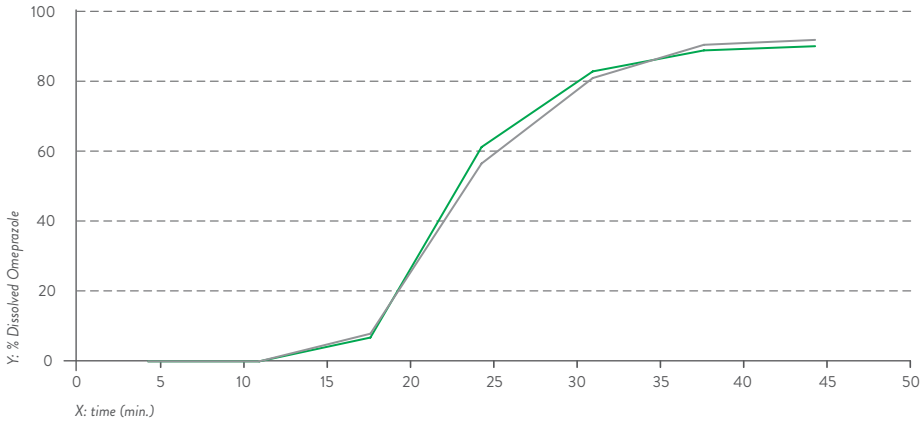
Capsule fill formulation:
Acetaminophen
Capsules:
Size 3 (n=6)
Dissolution method:
Paddle at 50 rpm –
"Acetaminophen Capsules" USP monograph

Quali-V® Extra Dry capsule
Quali-V® standard capsule

Time (min)	Quali-V® Extra Dry Acetaminophen dissolved (mean) (%)	RSD%	Quali-V® Acetaminophen dissolved (mean) (%)	RSD%
0	0.0	0	0.0	0
10	77.5	15	75.1	18
15	88.7	4	87.7	9
20	92.6	2	91.0	3
30	94.6	2	95.1	2
45	97.3	1	96.3	1

Quali-V® Extra Dry capsules comply with the **USP dissolution test requirements** (≥ 80% dissolved Acetaminophen at 45 min.)

pH 6.8



Capsule fill formulation:
Omeprazole pellets
Capsules:
Size 3 (n=6)
Dissolution method:
Paddle at 50 rpm –
"Omeprazole Delayed-Release Capsules"
USP monograph

Quali-V® Extra Dry capsule
Quali-V® standard capsule

Time (min)	Quali-V® Extra Dry Omeprazole pellets dissolved (mean) (%)	RSD%	Quali-V® Omeprazole pellets dissolved (mean) (%)	RSD%
0	0.0	0	0.0	0
10	6.8	69	7.9	72
15	61.2	28	56.5	15
20	82.8	8	80.9	7
30	88.8	2	90.4	3
45	90.0	4	91.8	3

Quali-V® Extra Dry capsules comply with the **USP dissolution test requirements** (≥ 80% dissolved Omeprazole at 45 min.)

Pharmaceutical Grade

Preservative Free
QUALICAPS® INNOVATION

100% Vegetal Origin
QUALICAPS® INNOVATION

Lower Moisture Content
(2.0 - 3.5%)

Standard HPMC Equivalent
Dissolution Profile

Inhalation Grade
QUALICAPS® INNOVATION

Chemically Inert

Minimal Brittleness

- **Pharmaceutical grade quality.** Our production and quality processes are carried out following strict pharmaceutical criteria and certified according to ISO 9001 and ISO 14001.

- Quali-V® Extra Dry capsules **are made from vegetal ingredients** and are thus acceptable for consumption within certain dietary regimens that restrict animal sources.

- Just as our Quali-G™ and Quali-V® hypromellose capsules, Quali-V® Extra Dry capsules are **manufactured without preservatives.**

- Quali-V® Extra Dry capsules are **chemically inert** and **do not undergo cross-linking** reactions, making them ideal for drug development.

- With a **very low moisture content** (2.0-3.5%), Quali-V® 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 (CDTI).

- Precise manufacturing and an exhaustive control enable Quali-V® Extra Dry capsules to **be filled and packaged on automatic high-speed machines*.**

	MG2	Bosch	IMA	IMA
Model	Planeta 100	GKF-1400	MATIC-120	Adapta 100
Speed Caps / h	100,000	84,000	120,000	100,000
Capsule Size Tested	0, 0EL	0	0	0
Motion	continuous	alternate	continuous	alternate

Machine room conditions: RH 15% - Temp. 21ºC

Handling conditions:
Conditions in the areas where capsules could be exposed to air may affect the final quality properties and/or machinability of the Quali-V® Extra Dry capsules.
The ideal conditions for a filling area are a temperature between 20°C and 30°C and a relative humidity between 15% and 25%, which will maintain the moisture content of the capsules within the desired range of 2.0% to 3.5%.

- Quali-V® Extra Dry capsules represent a **very versatile drug delivery system offering different formulation possibilities:** powders, pellets, tablets, semi-solids, and nonaqueous liquids.

- An **alternative specific to inhalation via DPIs is available** with improved mechanical properties and the required microbial pharmacopoeia specifications.

Contact our Scientific Business Development experts regarding this and other specific capsule products, as well as for support during every stage of drug development design, from dosage form to clinical trials.

Our **Technical Service Engineers** can assist and give on-hand support at runnability trials from first pilot batches, through clinical trials to industrial-scale production runs.

QUALI-V® EXTRA DRY CAPSULES, FOR USE WHEN A MINIMUM MOISTURE CONTENT IS REQUIRED

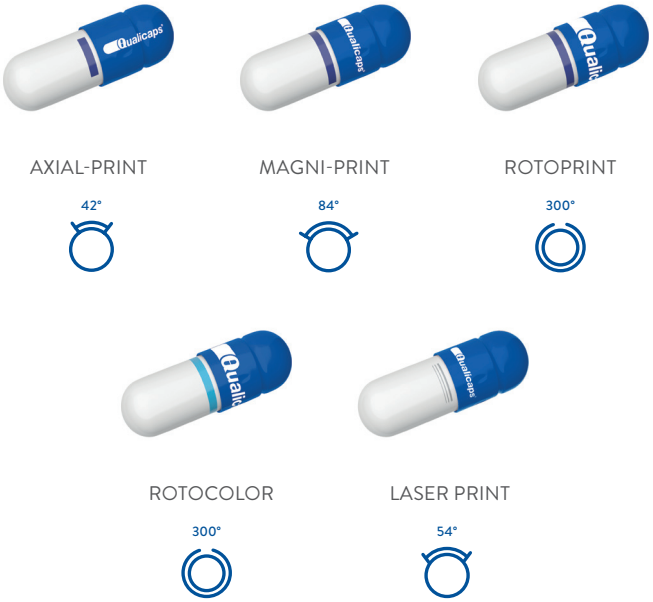
Quali-V® Extra Dry capsules can be used at all stages in the development process, from pre-clinical toxicological testing through all phases of clinical trials, and finally to product launch.

CAPSULE COLORS

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

Qualicaps® also offers TiO_2 -free Quali-V® Extra dry capsules upon request.

CAPSULE PRINTING



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.

Certifications:

- Patented composition and manufacturing process.
- Approved by the FDA.
- In compliance with Pharmacopoeia USP/EP.
- DMF registered for the USA and Canada.
- Kosher and Halal certifications available.

Packaging:

- Produced under specific conditions, Quali-V® Extra Dry capsules are packaged in heat-sealed, moisture-proof aluminum liners to ensure the specified moisture content for 18 months. These liner bags are then placed in sturdy cardboard boxes for shipping; fiber-free boxes are also available.

Storage conditions:

- To prevent variability in shell moisture content, capsules should always be stored within the recommended temperature range, between 15°C and 30°C (59°F and 86°F).
- The containers should be kept away from exposure to direct heat and sunlight. Maintaining the capsules within the liner bag (without perforations) safeguards them from both light degradation and loss of moisture, regardless of ambient humidity.

QUALICAPS EUROPE, S.A.U.

QUALICAPS SPAIN
Avenida Monte Valdelatas, 4
28108 Alcobendas, Spain
Tel: +34 91 663 08 00
Fax: +34 91 663 08 30

QUALICAPS ROMANIA
SOS. Chitilei Nr. 423M – Sector 1
012391 Bucharest, Romania
Tel: +40 372 193 200
Fax: +40 372 710 290

www.qualicaps.com

Q 070/2-2021E