

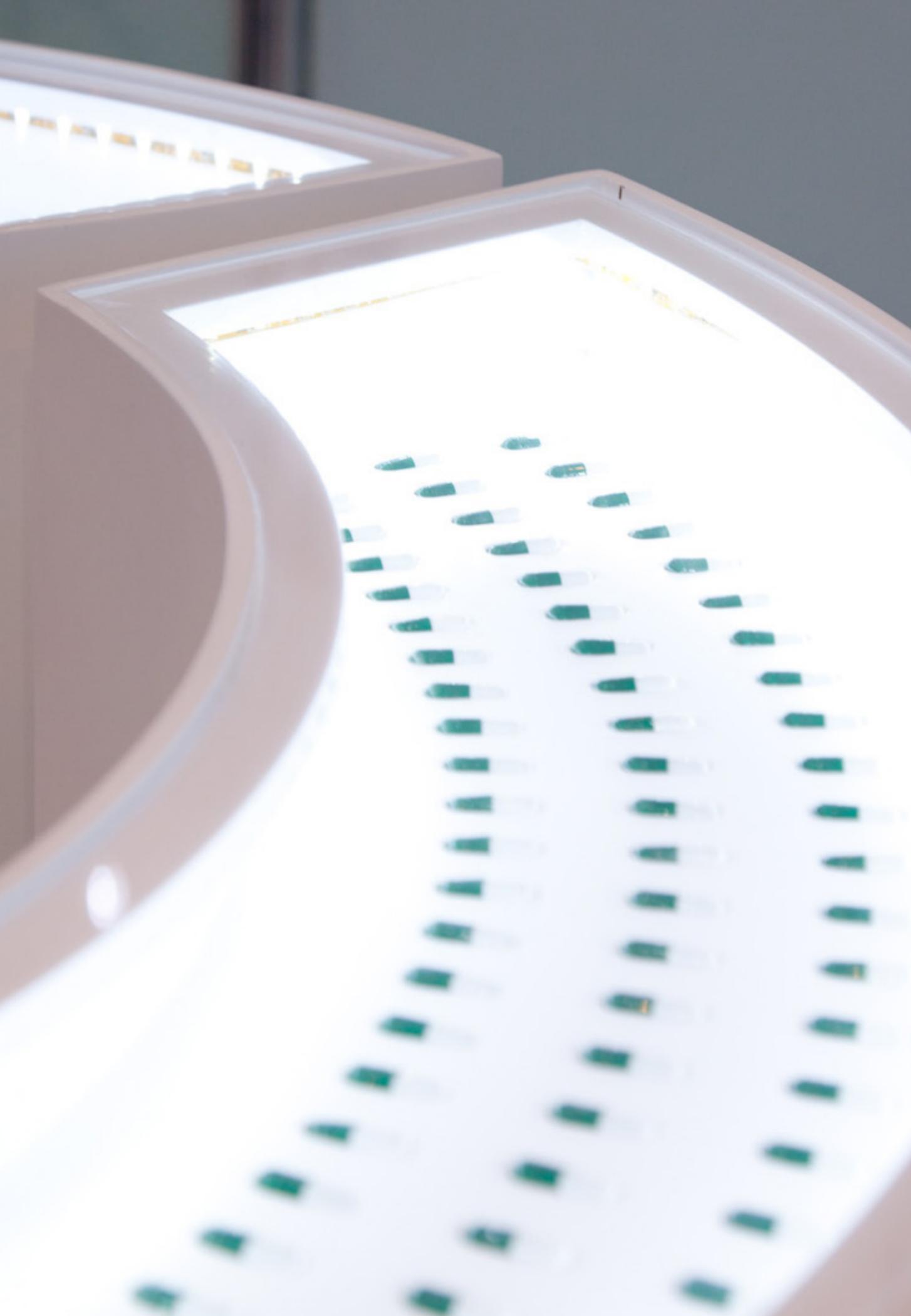
Quali-V[®]
Extra Dry

NEW



LOW MOISTURE
HARD TWO-PIECE
HPMC CAPSULES
FOR PHARMACEUTICAL
APPLICATIONS

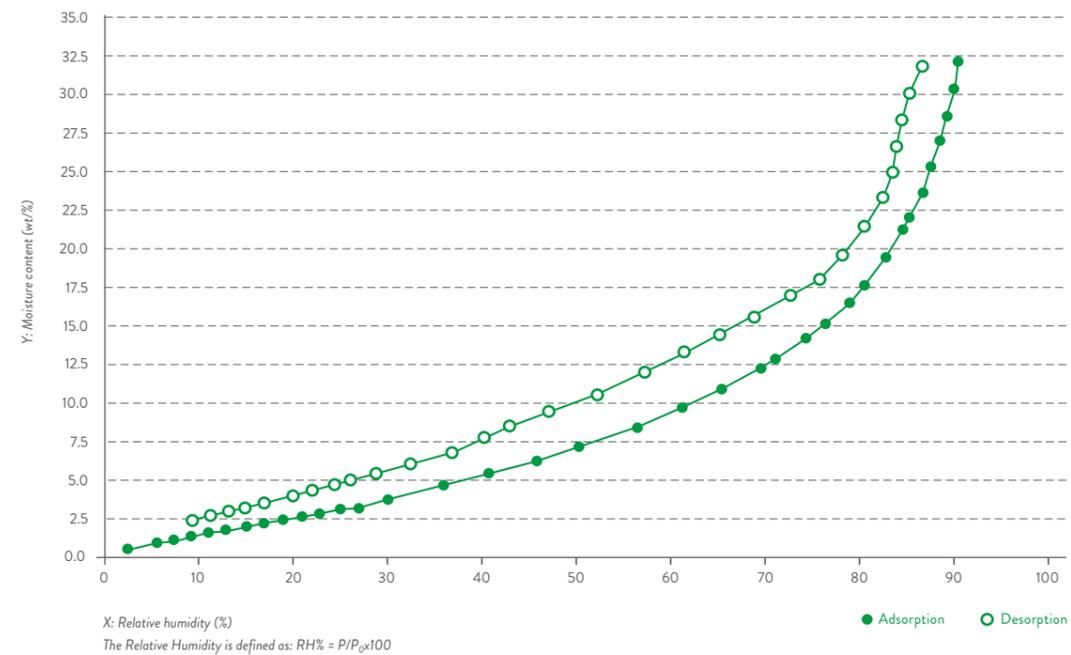
Qualicaps



QUALI-V® EXTRA DRY CAPSULES, WITH A VERY LOW MOISTURE CONTENT (2.0-3.5%), ARE SPECIFICALLY DESIGNED FOR DELIVERING MOISTURE-SENSITIVE OR HYGROSCOPIC PHARMACEUTICAL DRUGS

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

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



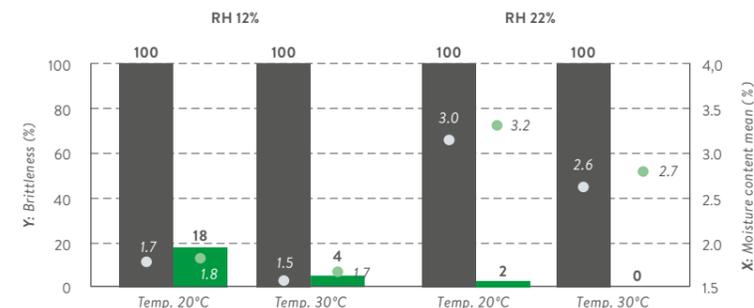
P/P ₀	wt/%
0.1494	1.9771
0.169	2.1951
0.1892	2.4111
0.2095	2.6282
0.2296	2.8464
0.2491	3.067
0.2674	3.286
0.3011	3.7131
0.3602	4.5543

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.

CAPSULE BRITTLENESS

IMPACT TEST (EMPTY CAPSULE; N=50)
(QUALICAPS® JAPAN)



- HPMC capsule shell with additional drying
- Quali-V® Extra Dry capsule

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



Pharmaceutical grade



100% Vegetal origin



Preservative free



Lower moisture content
(2.0 - 3.5%)



Minimal brittleness



Inhalation grade

- **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.
- As our standard Quali-V® capsules, **Quali-V® Extra Dry capsules comply with the USP dissolution test requirements** (≥ 80% dissolved acetaminophen at 45 min.).
- 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
Tested Size	0,0EL	0	0	0
Motion	continuous	alternate	continuous	alternate

Machine room conditions: RH 15% - Temp. 21°C

***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 **inhalation-grade option 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.

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