Quali-V®

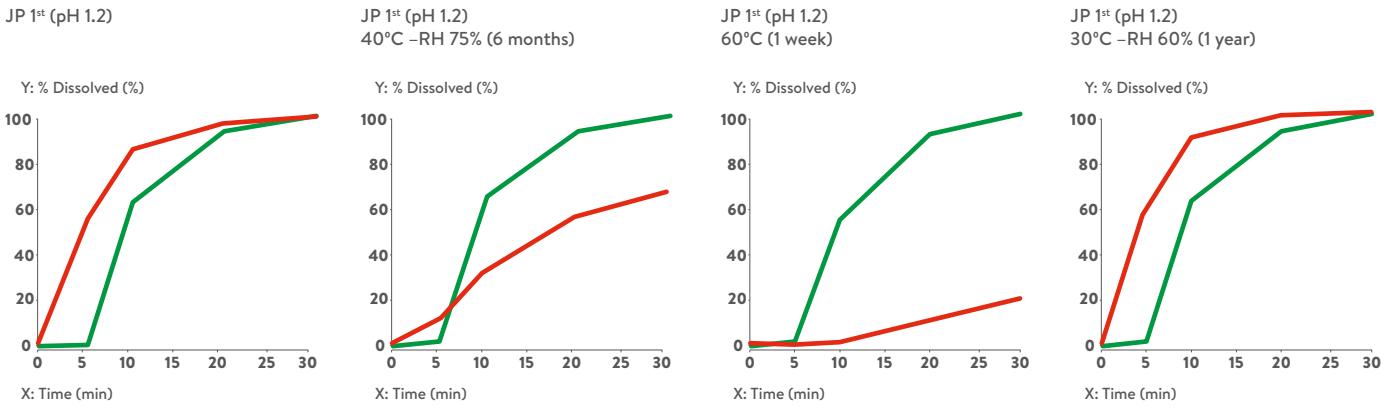
THE TREND IN MARKET PREFERENCE FOR PHARMACEUTICAL APPLICATIONS

QUALI-V®
THE PREFERRED CHOICE FOR PHARMACEUTICAL SOLID ORAL DOSAGE FORMS

QUALI-V® HPMC CAPSULES, THE BEST ALTERNATIVE TO GELATIN

- Quali-V® HPMC capsules are **equivalent in their dissolution profile** to traditional hard gelatin capsules, with a similar disintegration time[1] and release properties[2], proving **identical in-vivo performance behavior**.

- While gelatin capsules undergo cross-linking at **high temperature** or **high relative humidity**[3], such conditions **do not affect the Quali-V® HPMC dissolution profile,** as these capsules are chemically stable.



***Capsule fill formulation**: Acetaminophen 35 mg, Lactose 280 mg, Croscarmellose 35 mg*
***Fill weight**: 350 mg (Size 1 capsule)*
***Dissolution test method**: Paddle at 50 rpm*

● Quali-V® (HPMC) ● Quali-G™ (gelatin)

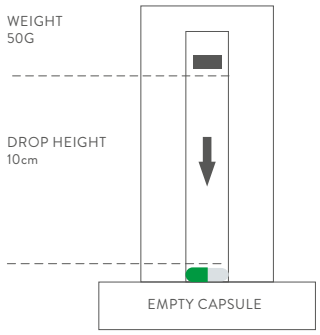
- In addition to having a lower moisture content (4.0%-6.0%), Quali-V® HPMC capsules demonstrate **better performance than gelatin capsules in terms of brittleness.** The moisture content of Quali-V® can be reduced minimizing significantly the occurrence of brittleness[4] that takes place when drying gelatin capsules below a certain threshold.
- Moisture has more influence on static electricity in gelatin capsules than in Quali-V® HPMC capsules[5].

Qualicaps *Engineered to perform*

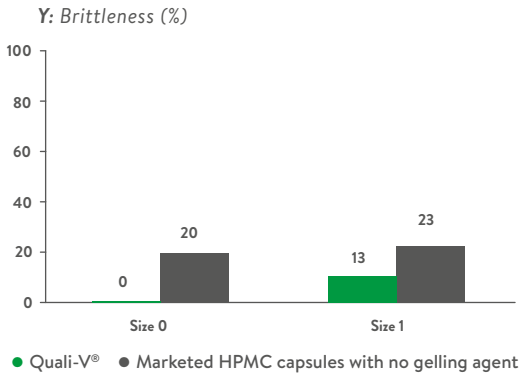
QUALI-V® CAPSULES, SUPERIOR PROPERTIES FOR HYGROSCOPIC DRUGS

- Quali-V® capsules **maintain their physical stability** when filled with hygroscopic materials or are exposed to low relative humidity conditions. They also hold many types of formulations: powders, pellets, tablets, semi-solids and non-aqueous liquids.
- Quali-V® capsules are proven to be **more resistant to breaking and fracturing** at very low relative humidity (12% RH), as they are **more elastic**[6].

BRITTLENESS TESTER (QUALICAPS®)



CAPSULE BRITTLENESS
IMPACT TEST (EMPTY CAPSULE; N=30)



	Capsule	Tensile strength [N]	Elongation al break (%)
RH 45 - 50% (ambient humidity)	**Quali-V®**	165 ± 16	14.6 ± 2.4
	HPMC with no gelling agent	153 ± 15	9.7 ± 0.8
RH 12% (low humidity)	**Quali-V®**	172 ± 21	11.1 ± 2.0
	HPMC with no gelling agent	119 ± 40	8.5 ± 1.2

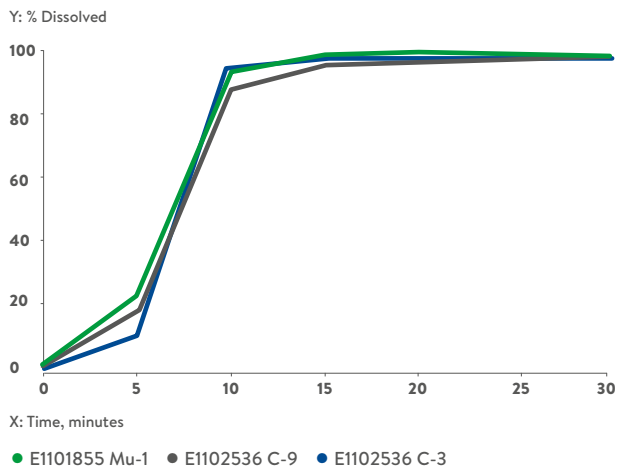
(size 1, N=10, Average ± SD)

- Superior resistance to breaking and superior de-blistering performance[4,6] make Quali-V® capsules the **ideal option to safeguard encapsulated products during long-term storage,** even in less than ideal conditions.

QUALI-V® CAPSULES, THE PERFECT CHOICE FOR RAPID DISSOLVING DRUG PRODUCTS

- Quali-V® capsules demonstrate a very **rapid and predictable dissolving drug product profile** where 85% of the API is released in the first 15 minutes at different pH levels.
- Quali-V® capsules show **high reproducibility of in-vitro performance** between manufactured lots.

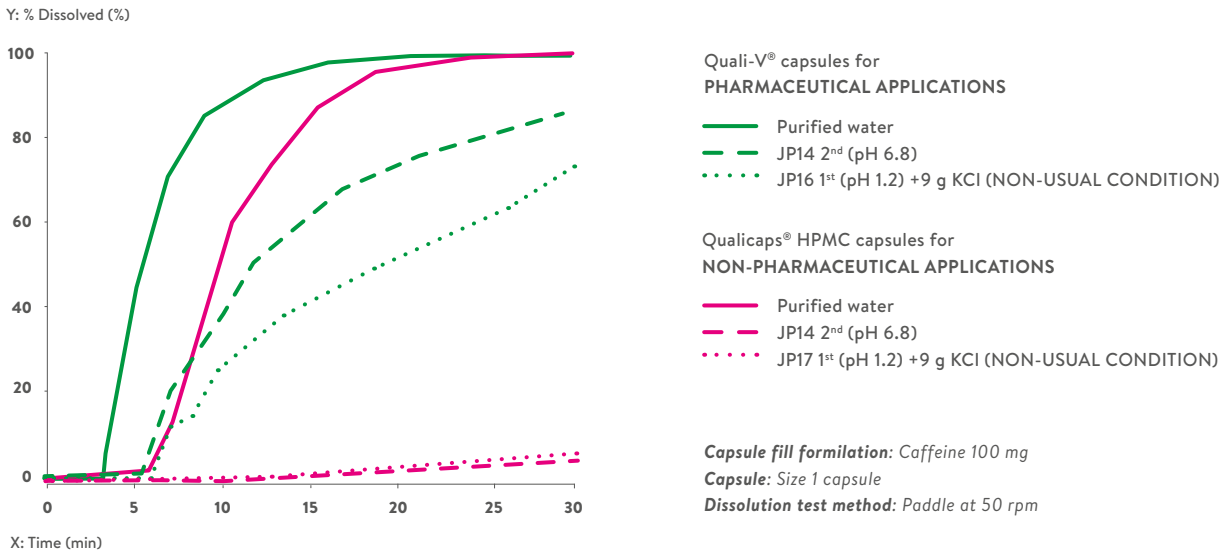
DISSOLUTION PROFILE FOR THREE QUALI-V® BATCHES (pH 1.2)



Studies of Universitat de València 2012-2013

- **Quali-V® capsules have a faster release profile,** with a shorter timeframe until first rupture[7], 3-4 minutes less than other HPMC capsules on the market. Quali-V® also shows quicker dissolution rates with less variation[6].

- Quali-V® capsules are specifically designed for oral **pharmaceutical applications** where dissolution properties are prioritized over mechanical properties to ensure a **consistent dissolution profile in standard conditions.**



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

- 100% plant-based and preservative-free, Quali-V® is acceptable for consumption within certain dietary and religious limitations. Quali-V® also responds to the clean label movement among today's consumers.

- 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 do not undergo any changes in physical and chemical performance throughout their 5-year shelf-life; all parameters meet the specifications during stability studies.

Our scientific business development team can support R&D in capsule-based dosage forms

Our technical service engineers can assist in achieving productivity yields in capsule filling

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References

1 Tuleu, C., Khela, M., Evans, D., Jones, B., Nagata, S. and Basit. A., 2004. A comparative scintigraphic assessment of the disintegration of HPMC and gelatin capsules in fasting subjects. Poster, AAPS Meeting, Baltimore, 2004. **2** Honkanen, O., Eerikäinen, S., Tuominen, R. and Marvola, M., 2001. Bioavailability of ibuprofen from orally administered hydroxypropyl methylcellulose capsules compared to corresponding gelatine capsules. S. T. P. Pharma Sci., 11, 181-185. **3** Nagata, S, Tochio, S., Sakuma, S. and Suzuki, Y., 2001. Dissolution profiles of drugs filled into HPMC and gelatin capsules. Poster AAPS Meeting, Denver, 2001 **4** Nagata, S., 2002. Advantages to HPMC capsules: a new generation's capsules. Drug Del. Technol., 2(2), 34-39. **5** Satoshi Sakuma, Shinji Tochio, Shunji Nagata. Shionogi Qualicaps CO., LTD. Investigation of the Static Electrical Charging of HPMC and Gelatin Capsules. Poster AAPS Meeting, Salt Lake City, 2003 **6** Evaluation of the properties of HPMC capsules manufactured using different methods. Tomo Uyama, Asami Inui, Tohru Kokubo. Qualicaps Co. Ltd., 321-5, Ikezawa-cho, Yamato-Koriyama, Nara 639-1032, Japan. Poster AAPS Meeting, New Orleans, 2010. **7** Ku, M.S., Lu, Q., Li, W., Chen, Y., Performance qualification of a new hypromellose capsule: Part II. Disintegration and dissolution comparison between two types of hypromellose capsules. Internationa Journal of Pharmaceutics, 386 (2010) 30-41.

QUALICAPS EUROPE, S.A.U.
Avenida Monte Valdelatas, 4
28108 Alcobendas
Spain
Tel: +34 91 663 08 00
Fax: +34 91 663 08 30
e-mail: info@qualicaps.com

QUALICAPS, INC.
6505 Franz Warner Parkway
Whitsett, NC 27377-9215 USA
Tel: +1 336 449 3900
Fax: +1 336 449 3333
e-mail: info@qualicaps.com

QUALICAPS, CO., LTD. 321-5
Ikezawacho Yamatokoriyama
Nara, 639-1032 Japan
Tel: +81 743 56 0651
Fax: +81 743 56 5113
www.qualicaps.co.jp

GENIX
Rua Coronel Cabrita, 121
Jardim da Gloria, São Paulo, SP
Brazil
CEP: 051545-030
Tel: +55 11 2020-7732
e-mail: Sales@genix.ind.br
www.genix.ind.br

THE KAITEKI COMPANY
Mitsubishi Chemical Holdings Group