Nutra'V

Technical Dossier

Hard two-piece hypromellose capsules
for consumer healthcare applications

Qualicaps

Nutra'V

offers the consumer healthcare industry a high-performance, plant-based capsule for the protection and delivery of beneficial ingredients

FEATURES

Rapid dissolving product, releasing ingredients in the stomach.
Low moisture content (4% to 7%), so little to no brittleness upon drying and less moisture transfer with capsule fills. Ideal for moisture-sensitive ingredients.
Free of allergens, gluten, GMOs, preservatives, sugar.

PRODUCTION

Excellent performance on high-speed capsule filling machines.

MARKETING

100% plant-based; free of animal origin.
With patented characteristics that make these capsules ideal for a broad range of nutraceutical and nutritional applications.
Kosher and Halal certifications available.
Meet the increasing clean-label demands of health-conscious consumers, as well as the specific dietary needs of vegetarians and vegans.
Constant solubility in liquids over a broad range of temperatures, so products can be taken with either warm or cold drinks.
Diversity of size, colour and printing options for differentiation in final market dressing.

Contents

1. Raw Material Specifications

HYPROMELLOSE

Nutra'V capsules are made from hypromellose that complies with the principal Pharmacopoeiae: the United States Pharmacopoeia (USP/NF), the European Pharmacopoeia (EP) and the Japanese Pharmacopoeia (JP), as well as with the purity criteria defined for E464 (HPMC) in Commission Regulation (EU) No 231/2012.

COLOURANTS

The colourants used are in compliance with the EC Directives and when required with the requirements of the EP, USP/NF.

PURIFIED WATER

The water used by Qualicaps® complies with the requirements of the EP, USP/NF and JP.

ADDITIVES

Nutra'V capsules contain small amounts of carrageenan as a gelling agent and potassium chloride as a gelling promoter. In addition, carnauba wax is applied as a surface lubricant on the capsules. These additives comply with the requirements of the following regulations: carrageenan - the EEC food regulations, EP, USP/NF, and Japanese Pharmaceutical Excipients (JPE) regulations; potassium chloride - the EP, USP/NF, JP and EEC food regulations; carnauba wax and maize (corn starch) - the EP, USP/NF, JP and EEC food regulations.

2. Dimensional Specifications

- **Weight:** The average weights shown in the table are determined from the gross weight of a sample of 100 capsules at the standard moisture content of 4.0% to 7.0%. The average weight of the capsules can vary by ± 10% from the target value. These values are not applicable to individual capsules but rather to the average of the batch. Customers should determine tare weights for filling by testing samples from in-house batches.

- **Length:** Capsule lengths are controlled in the manufacturing process and audited for each batch.

- **Closed Joined Length:** This value is given as a filling machine setup recommendation and not as an approval/rejection criterion for empty capsules. The closed joined length has been calculated to ensure the correct location of the special positive locking features on the cap and body. If the filling machine is set so that the capsules are closed to a shorter length, then the cap or body may be damaged and the locking mechanism may fail; if longer, they may come apart. It is recommendable to provide this value to packaging equipment manufacturers prior to making a decision on blister pocket specifications.

- **Outside Diameter:** The outside diameters, provided as a guideline for evaluating packaging material dimensions, are measured by passing the caps and bodies through calibrated bushes under specified conditions that simulate those of filling machines. This dimension should never be considered as an approval/rejection criterion.

NUTRA'V CAPSULE SPECIFICATIONS

Size		00	0E	0	1	2	3	4
Weight	Target weight (mg)	120.0	110.0	90.0	72.0	61.0	49.0	38.0
	Weight limits (mg)	108.0 - 132.0	99.0 - 121.0	81.0 - 99.0	64.8 - 79.2	54.9 - 67.1	44.1 - 53.9	34.2 - 41.8
Capacity	Approximate body volume (ml)	0.93	0.76	0.67	0.48	0.37	0.28	0.21
	Powder fill weight (mg)							
	Powder density 0.6 g/ml	558	456	402	288	222	168	126
	Powder density 0.8 g/ml	744	608	536	384	296	224	168
	Powder density 1.0 g/ml	930	760	670	480	370	280	210
	Powder density 1.2 g/ml	1116	912	804	576	444	336	252
Outside diameter	Cap diameter (mm)	8.57	7.69	7.68	6.92	6.36	5.83	5.33
	Cap diameter limits (mm)	8.51 – 8.63	7.63 – 7.75	7.62 – 7.74	6.86 - 6.98	6.30 - 6.42	5.77 - 5.89	5.27 – 5.39
	Body diameter (mm)	8.23	7.34	7.34	6.61	6.07	5.56	5.06
	Body diameter limits (mm)	8.17 – 8.29	7.28 – 7.40	7.28 – 7.40	6.55 - 6.67	6.01 - 6.13	5.50 - 5.62	5.00 – 5.12
Length	Cap length (mm)	11.84	11.99	10.72	9.78	8.94	8.08	7.21
	Cap length limits (mm)	11.34 - 12.34	11.49 - 12.49	10.22 - 11.22	9.28 - 10.28	8.44 - 9.44	7.58 - 8.58	6.71 - 7.71
	Body length (mm)	20.17	20.98	18.44	16.61	15.27	13.59	12.19
	Body length limits (mm)	19.67 – 20.67	20.48 – 21.48	17.94 – 18.94	16.11 - 17.11	14.77 - 15.77	13.09 - 14.09	11.69 – 12.69
Closed joined length	Closed joined length (mm)	23.60	24.20	21.70	19.40	18.00	15.90	14.30
	Closed joined length limits (mm)	23.30 – 23.90	23.90 – 24.50	21.40 – 22.00	19.10 - 19.70	17.70 - 18.30	15.60 - 16.20	14.00 – 14.60

Note: Tailor-made specifications may be possible, upon request.

3. Visual Quality Specifications

The visual quality of a capsule batch is determined using sampling plans defined in ANSI/ASQ Z 1.4–2008.

The specifications are derived from the ANSI/ASQ Z 1.4–2008 and assessed on a combined sample taken randomly throughout the batch from √N + 1 cartons (N is the total number of cartons in the controlled batch).

Qualicaps® capsules are controlled statistically to ensure conformance to the specifications found in the following section.

4. Visual Acceptable Quality Level (AQL)

AQL as defined in ANSI/ASQ Z 1.4-2008, is the maximum percent of defective units that for the purpose of sampling inspection can be considered satisfactory as a process average. A normal inspection level, single sampling plan is used.

Defect classification	AQL
Critical	0.015%
Major	0.065%
Minor	1.0%

5. Classification and Descriptions of Visual Defects

Visual defects are classified according to the following definitions:

- **Critical:** Affects the performance of a capsule as a package for the final product, or could contribute to a major subjective problem in filling.
- **Major:** Would cause a problem on a capsule filling machine.
- **Minor:** Has no effect on the performance of a capsule as a package; it is a slight blemish that makes the capsule visually imperfect.

Critical	
Cracked	A cap or body with many splits
Double dip	Extra thick cap due to being dipped twice which makes the capsule not separate properly
Failure to separate	A joined cap and body that does not separate properly
Hole	An irregular opening in the cap or body
Joined in lock	A capsule in locked position
Long cap/body	Length of cap or body 1 mm more than specified length
Mashed	A mechanically damaged capsule that has been squashed flat
Pinched	Inward cap or body pinches > 3 mm
Short cap	Cap length 1 mm less than specified length
Short body	Body length 0.6 mm less than specified length
Split	A split in the film starting from the cap or body edge > 2 mm
Telescope	A closed capsule with a protruding piece of either cap or body produced by a double split
Thin spot (cap shoulder)	A thin area in the cap shoulder that may rupture when the capsule is filled
Trimming	A piece > 5 mm of, or the whole trimmed end of a cap or body inside a closed capsule
Uncut cap/body	An untrimmed cap or body

Major	
Damaged edge-large	Roughly trimmed cap edge. The imperfection at its greatest is > 1 mm into the specified length
Double cap	A capsule with an additional cap covering the body end
Different dye speck	A coloured spot different from the colour of cap or body
Grease	Mould release aid spots on the inside of capsule
Inverted end	A cap or body with the end pushed inwards > 3 mm in length
Long joined	A capsule not closed sufficiently to engage the prelock
Small pinched	Inward cap or body pinches < 3 mm
Thin spot	A thin area in the cap or body wall which may rupture when the capsule is filled
Turned edge	Folded-over edge > 2 mm on body cut line
Unjoined	A single cap or body

Minor	
Black speck	A non-contaminant black spot > 2 mm
Bubble	An air bubble in the visible part of the capsule with a diameter > 0.4 mm (excluding overlapping area between cap and body)
Chips, tails	Small fragments of hypromellose > 3 mm still attached or free within the capsule
Crimp	Cap or body has external surfaces crimped > 3 mm
Damaged edge-small	Roughly trimmed cap edge. The imperfection is V shaped and < 1 mm into the specified length
Dent	A depression formed in the end of cap or body. The dent is less than half of the diameter of the capsule part
Dye speck	A colour spot from the colour of the cap or body > 2 mm
Grease light	Small grease marks > 3 mm
Scrape	A scratch mark > 3 mm on the surface of a cap or body
Starred end	An individual imperfection of the tip of cap or body > 3 mm generated by turbidity or surface deformation
Strings	Strings between 3-4 mm at the cutting edge

6. Print Quality Specifications

The print quality of a capsule batch is determined using statistical sampling plans defined in the ANSI/ASQ Z 1.4–2008.

The specifications are derived from the ANSI/ASQ Z 1.4–2008 and assessed on a combined sample taken randomly throughout the batch from √N + 1 cartons (N is the total number of cartons in the controlled batch).

Qualicaps® printed capsules are controlled statistically to ensure compliance with the specifications found in the following section.

7. Print Acceptable Quality Level (AQL)

AQL as defined in ANSI/ASQ Z 1.4-2008, is the maximum percent of defective units that for the purpose of sampling inspection can be considered satisfactory as a process average. A normal inspection level, single sampling plan is used.

Defect classification	AQL
Critical	0.015%
Major	0.065%
Minor	1.5%

8. Classification and Descriptions of Print Defects

Critical	Major	Minor
Unprinted	Ink line/Spot > 5 mm	Ink Line/Spot (1-5 mm)
Incorrect Image	Misplaced Image (off-register; not identifiable)	Misplaced Image (off-register; still identifiable)
	Multiple Images (image is illegible)	Multiple Images (image is still legible)
	Partial Image (half of image is missing, and is illegible)	Partial Image (part of image is missing, but still legible)
	Smudged Image (image is illegible)	Smudged Image (image is still legible)

9. Chemical Specifications

Parameter	Specification
Moisture content/Loss on drying	4.0% - 7.0%

10. Microbiological Specifications

Parameter	Specification
Total Aerobic Microbial Count (TAMC)	10^3 cfu/g
Escherichia coli	Absence in 1 g
Total Yeats and Mould Count (TYMC)	10^2 cfu/g

11. Packaging

Qualicaps® capsules are supplied in a package that has two components:

- An inner liner made of a laminate of pharmaceutical-grade materials: PET/aluminium foil/polyethylene. This is heat-sealed after inserting the capsules, creating a container that is moisture proof.
- A cuboid cardboard carton of standard dimensions*. This protects the inner liner during transportation.

Capsule size	00	0E	0	1	2	3	4
Capsules per carton in 000's**	75	75	100	135	175	225	300

Cartons size: 60 cm long x 40 cm wide x 75 cm high
** Polypropylene carton box upon request*
*** Tolerance: Capsule quantity variance is ± 5% per delivered carton box*

12. Storage

Qualicaps® packaging is designed to maintain the quality of the empty capsule between manufacturing and filling. It is essential to read and understand the following information in order to ensure that Nutra'V capsules maintain their quality during this period.

TRANSPORTATION

Nutra'V capsules are supplied in sturdy cardboard cartons, each having heat-sealed, moisture-proof liners. These cartons may be grouped on a European size case pallet.

WAREHOUSING CONDITIONS

The conditions in the areas in which capsules are stored or filled can affect the machinability of the Nutra'V capsule. The ideal temperature for the storage of capsules should be 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. Properly stored and sealed containers will provide optimum capsule performance in production.

CAPSULE SHELF LIFE

Under the aforementioned storage conditions, Nutra'V capsules will maintain their quality for five years from the date of manufacture.

13. Filling Area Conditions

The moisture content of capsules is directly related to the relative humidity of the air to which they are exposed. When capsules are removed from their original packaging (sealed aluminium liner) and exposed during the filling process, their moisture content will equilibrate to filling room conditions.

The ideal conditions for a filling area are a temperature between 20°C and 25°C and a relative humidity between 35% and 50%, which will maintain the moisture content of the capsules within the desired range of 4.0% to 7.0% for Nutra'V.

An important consideration is to expose the minimum number of capsules required for the process at any one time. Some filling machines can generate significant heat during running, and this may affect capsules in use.

The capsule filling machine may be located in a controlled area but the climatization system may be operated only during the working day. Empty capsules should preferably be removed from the hopper on the filling and/or intermediate conveying equipment if climatic conditions vary from the ideal during idle hours.

For capsule handling, it is best to avoid the use of plastic utensils because this could result in static electrical charging that could cause feeding problems on the filling machine.

14. Regulatory Information

Nutra'V capsules are made from hypromellose that conforms to current editions of EP/USP/JP monographs and with the purity criteria defined for E464 (HPMC) in Commission Regulation (EU) No 231/2012.

- Hypromellose, used as the main raw material in the manufacturing process of empty Nutra'V capsules, is derived from pine trees.
- None of the ingredients of Nutra'V capsules are of bovine origin and therefore, there is no TSE/BSE problem associated.
- Nutra'V capsules are allergen-free.
- Nutra'V capsules do not contain GMOs (genetically modified organisms).
- Nutra'V capsules do not contained preservatives and are not treated with either Ethylene Oxide nor gamma radiations.
- Neither gluten, sugar, nor lactose are used in the manufacturing process of Nutra'V capsules.

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. Chitila Nr. 423M – Sector
1 012391 Bucharest
Romania
Tel: +40 372 193 200
Fax: +40 372 710 290

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