



*The leading manufacturer of empty capsules*

# **PRODUCT SPECIFICATION**

## **of HPMC Capsules**

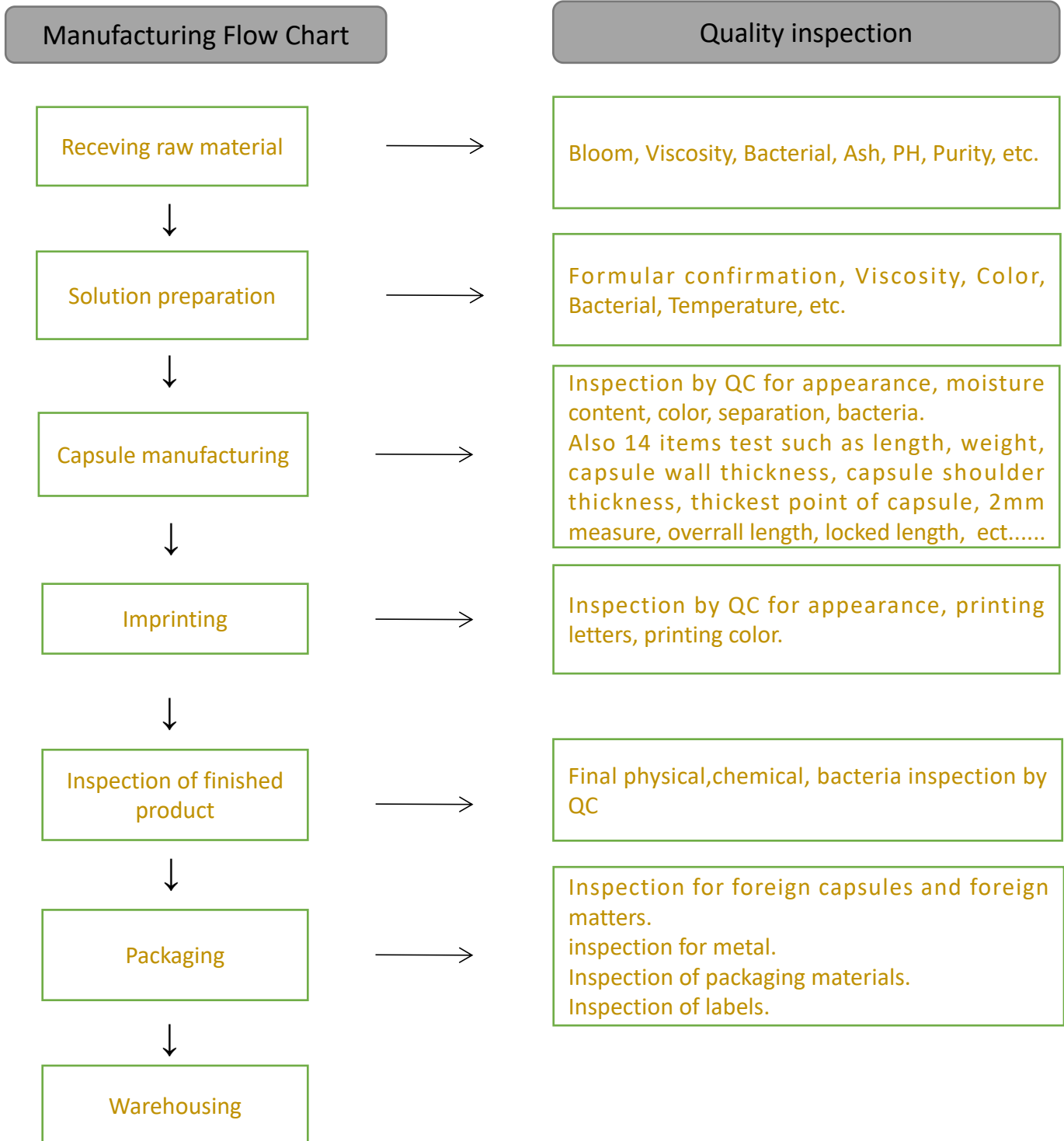
Based On the United States Pharmacopeia

**BY CAPSTECH CO. & SHAANXI GENEX BIO-TECH CO., LTD**

***Everlasting Guarantee for Health***



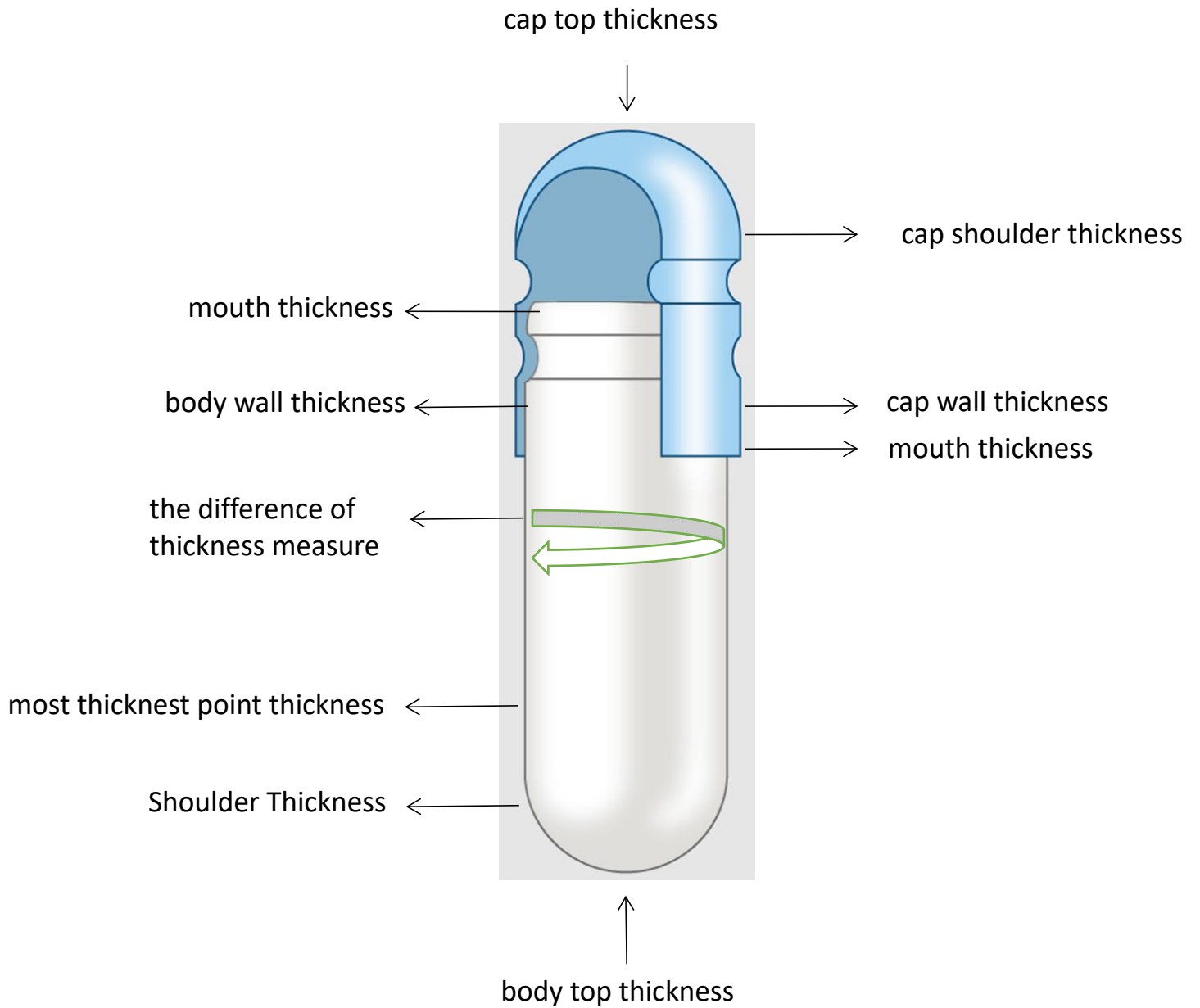
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## PURE VEGE<sup>®</sup> HPMC CAPSULES





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### *Identity Test*

Solution	Gelatin Capsules	HPMC Capsules	Pullulan Capsules
In Cool Water	Insoluble Capsule Swelling	Soluble	Soluble
In 40-50°C water	Soluble	Soluble	Soluble
In 60°C water	Soluble	Flocculation Solution	Soluble





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### Key Advantages with our HPMC CAPSULES

- High quality
- Excellent machinability on both high-speed and semi-automatic filling machines
- Derived from 100% vegetable material
- No cross-linking reaction
- Complies with USP / EP / ChP regulations
- Suitable for hygroscopic and moisture sensitive ingredients



### Length

Specification		00EL#	00#	0#	1#	2#
cap	length (mm)	11.80±0.30	11.80±0.30	11.00±0.30	9.80±0.30	9.00±0.30
body		22.10±0.30	20.30±0.30	18.60±0.30	16.60±0.30	15.40±0.3
Unlocked length		27.70±0.35	25.50±0.35	23.70±0.35	21.30±0.35	19.60±0.35

Sampling method: Sample 40 capsules from a manufacturing lot at random.

Test method: Measure each cap body of 40 pairs of capsules with Vernier Caliper (precision 0.01mm) and evaluate the fitness for specification with the results.



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### Analytical Data

Item	Specification	USP Standard
Disintegration Time	Not more than 15 minutes	30 minutes
Loss on Drying	3%~8%	1-13%
Residue on Ignition (clear capsule) Residue on Ignition (color capsule)	Not more than 3.0% Not more than 6.0%	————
Heavy Metals	≤ 10 ppm	————
Arsenic(As)	≤ 3 ppm	————
Lead (Pb)	≤ 1 ppm	————
Cadmium (Cd)	≤ 1 ppm	————
Mercury (Hg)	≤ 0.1 ppm	————

The whole production without preservative additive and ethylene oxide disinfection.



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### *Microbiological Data*

Item	Specification	USP Standard
Total Aerobic Bacteria Count	≤ 500 cfu/g	1000 cfu/g
Molds & Yeasts Count	≤ 100 cfu/g	100 cfu/g
Escherichia Coli	Negative in 1 gram	————
Pseudomonas Aeruginosa	Negative in 1 gram	————
Staphylococcus Aureus	Negative in 1 gram	————
Salmonella	Negative in 10 gram	————

*Our enterprise standard QS-P-00800 for raw material and products is developed reference to and in compliance with EP / USP / ChP*



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### The Appearance of The Capsules

GENEX Standards (sample quantity: 1250 pcs)				Industry Standards (sample quantity: 1250 pcs)			
Inspect Item	AQL	AC	RE	Inspect Item	AQL	Ac	Re
Minor defect	0.40%	10	11	Minor defect	1.00%	21	22
Major defect	0.10%	3	4	Major defect	0.15%	5	6
Critical defect	0.01%	0	1	Critical defect	0.04%	1	2

### Printing Appearance Standards

GENEX Standards (sample quantity: 1250 pcs)				Industry Standards (sample quantity: 1250 pcs)			
Inspect Item	AQL	AC	RE	Inspect Item	AQL	Ac	Re
Minor defect	0.40%	10	11	Minor defect	1.00%	21	22
Major defect	0.10%	3	4	Major defect	0.65%	14	15
Critical defect	0.01%	0	1	Critical defect	0.04%	1	2

Remark: AQL (Acceptable Quality Limit) Ac (Acceptable Number) Re (Rejected Number)





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### Capsule Weight

Size	Weight
00 EL	136 mg
00	129 mg
0	102 mg
1	78 mg
2	63 mg



*Deviation should be within  $\pm 10\%$  of the specified value.*

**Sampling method:** Sample 40 capsules from a manufacturing lot at random.

**Test method:** Weigh each of 40 capsules accurately on a electrical balance. (sensitivity 0.1mg)



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### Outside Diameter

Size	Cap	Body
00 EL	8.67±0.06	8.32±0.06
00	8.67±0.06	8.32±0.06
0	7.75±0.06	7.42±0.06
1	6.76±0.06	6.72±0.06
2	6.48±0.06	6.14±0.06

Sampling method: Sample 40 capsules from a manufacturing lot at random.

Test method: Measure outside diameter of each cap and body of 40 pairs of capsules with outside calipers (precision 0.01 mm) and evaluate the fitness for specification with the results.

### Capacity

		00 EL#	00#	0#	1#	2#
Volume (ml)		1.15	0.96	0.66	0.50	0.38
Capacity (mg)	0.6g/cc	0.69	0.576	0.396	0.30	0.228
	0.8g/cc	0.92	0.768	0.528	0.40	0.304



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## **PURE VEGE<sup>®</sup> HPMC CAPSULES**

GENEX capsules are all packed in carton boxes with an 10 fold corrugated fiber board liner and two inner PE bags to protect the capsules from heat sources and other environmental extremes.

Carton Count for HPMC Capsules	
Size	Quantity
00 EL	70,000
00	80,000
0	100,000
1	140,000
2	180,000





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### *Storage Coniditions*

Genex supports the validity date if recommendations for storage are observed (recommended:15~25°C and 35%~65% relative humidity)

Cartons should be stord on pallets (right side up) in a well protected area

Heat sources such as space heaters or sunlight through windows should be avoided

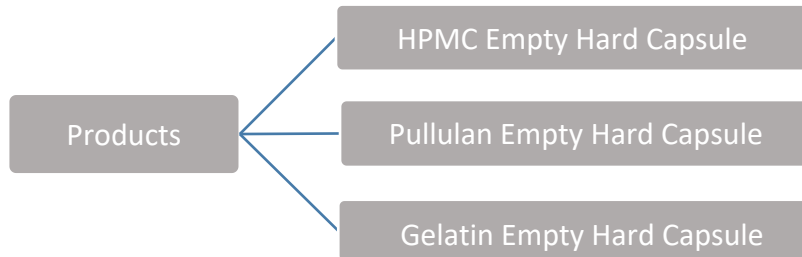
Capsules should be kept more than one meter away from steam pipes or incandescent electric lamp

Capsules should be kept more than 15cm away from the wall of the building





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**T**he factory is designed with hierarchical cleaning principles and a grade C standard production environment to ensure the safety of the products.

**E**quipment: High-precision automatic production lines provide a basic guarantee for uniformity of the capsules for stability of usage in capsule filling machines.

**R**aw Material: Strictly selected healthy raw materials will ensure product quality from our sources.

**P**rocess: The production process is inspected at all levels, and the quality of the product is monitored and regulated throughout the production process.

**M**anagement: Our production is in strict accordance with GMP standard and ISO9000, and also conform to the HALAL and KOSHER requirements.

