

HPMC Capsule

1. Trade Mark

EMBO VG Capsule

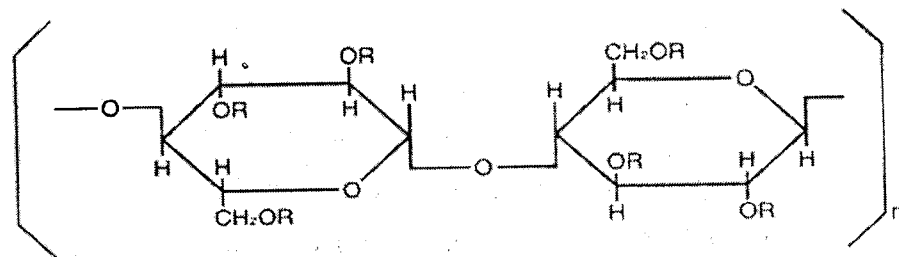
2. Characteristics of HPMC Capsule

1 HPMC Capsule Composition (Clear Capsules)

- | | | |
|--------------------------|-------------------------------|---------------------------|
| - Main raw materials | Hydroxypropyl methylcellulose | (USP, EP, JP) |
| - Gelatinizing agent | LM Amide PECTIN(CFR, FCC | + Glycerin(USP, EP, JP) |
| - Auxiliary for gelation | Calcium Gluconate | (USP, EP, JP) |
| - Auxiliary for gelation | Glacial Acetic acid | (USP, EP, JP) |
| - Emulsifying agent | Sucrose Fatty acid esters | CFR, FCC) |

2. What is HPMC?

1) Structural Formula



R -H, -CH₃, -CH₂CH(OH)CH₃

2) Origin and Stability of HPMC

Hydroxypropylmethyl Cellulose(HPMC) is a nonionic water-soluble cellulose ether prepared from cellulose(pulp), which is one of natural materials widely being used for foods and pharmaceuticals worldwide. The cellulose is not reacted with medicines, but with caustic soda. Its raw materials are very high in stability, and also used for increasing viscosity of liquid agents as well as used as binder.

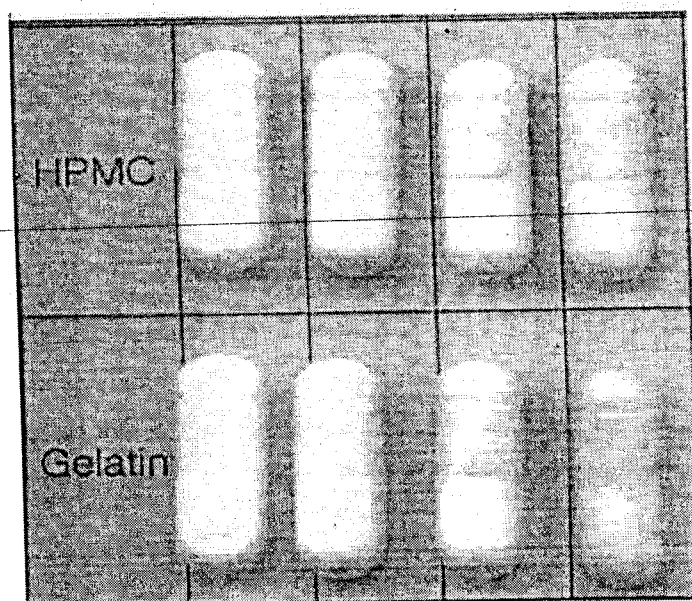
3. Manufacture of HPMC Capsules

HPMC Capsule are manufactured by Su-Heung's own technologies and have been applied for patents to Korea USA, Japan and EC. They are manufactured in the same way with gelatin capsules, and they feature moisture content of only 5% while gelatin capsules maintain an average moisture content of 13.5%. Accordingly, it leads to lowering productivity of HPMC capsules.

3. Comparison of HPMC Capsule and Gelatin Capsule

Section	HPMC Capsule	Gelatin Capsule
Moisture Content	3% ~ 7%	12.5% ~ 16.0%
Disintegration	Within 20min	Within 20min
Solubility	Within 10min	Within 10min
Polish	Lower than gelatin capsules	Good
Oxygen Permeability	HIGH	LOW
Light Shading	YES	YES
Dye Addition	YES	YES
Transformation by Heat	LOW	HIGH
Average Molecular Weight	21,000 ~ 29,400	80,000 ~ 150,000

Chemical reaction to contents
(filled with vitamin-C)

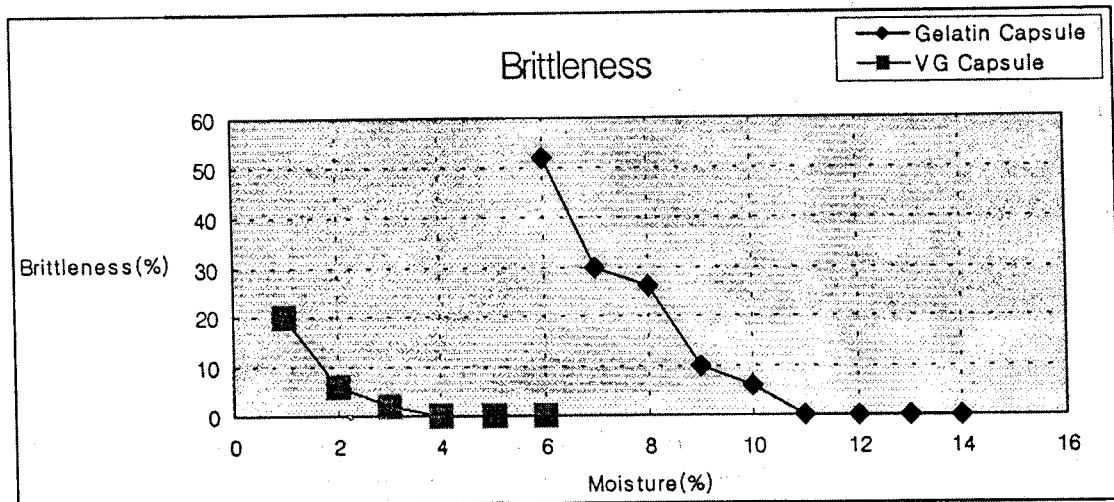


VG Capsules are less reactive to contents than gelatin capsules.

4. Physical Characteristics of HPMC Capsule

● Mechanical Strength of HPMC Capsule

Leave capsules laid at full length and let a 50g weight free-fall from a 10cm height, and then check breakage of capsules. (n = 50)



5. HPMC Capsule Specification

Item	HPMC Capsule Specs.	Remark
1. Purity	1) Solubility : Within 10minutes($37 \pm 2^\circ\text{C}$) 2) Odor : None 3) Solution : Neutral or Slightly Acid	Same with Gelatin capsules. (Please refer to specs of gelatin capsule)
2. Residue on ignition	Clear Capsules : Within 3.0% Opaque Capsules : Within 7.0%	Gelatin Capsule Clear Capsules : Within 2.0% Opaque Capsules: Within 7.0%
3. Arsenic	Within 3ppm	Gelatin Capsule : Within 1ppm
4. Heavy metal	Within 10ppm	Gelatin Capsule : Within 20ppm
5. Microbial limit test	1) Bacterial Count : 300cfu/g 2) Fungi : 100cfu/g 3) Escherichia coil : Negative/10g 4) Salmonella : Negative/10g	Same with gelatin capsule (Please refer to specs of gelatin capsule)

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6. Length (mm)	<table border="1"> <thead> <tr> <th data-bbox="384 389 592 443">Size</th> <th data-bbox="592 389 772 443">Cap Length</th> <th data-bbox="772 389 956 443">Body Length</th> </tr> </thead> <tbody> <tr> <td data-bbox="384 443 592 497"># 00</td> <td data-bbox="592 443 772 497">11.80</td> <td data-bbox="772 443 956 497">20.20</td> </tr> <tr> <td data-bbox="384 497 592 551"># OEL</td> <td data-bbox="592 497 772 551">12.00</td> <td data-bbox="772 497 956 551">20.70</td> </tr> <tr> <td data-bbox="384 551 592 604"># 0</td> <td data-bbox="592 551 772 604">11.10</td> <td data-bbox="772 551 956 604">18.50</td> </tr> <tr> <td data-bbox="384 604 592 658"># 1</td> <td data-bbox="592 604 772 658">9.70</td> <td data-bbox="772 604 956 658">16.50</td> </tr> <tr> <td data-bbox="384 658 592 712"># 2</td> <td data-bbox="592 658 772 712">9.20</td> <td data-bbox="772 658 956 712">15.30</td> </tr> <tr> <td data-bbox="384 712 592 766"># 3</td> <td data-bbox="592 712 772 766">8.20</td> <td data-bbox="772 712 956 766">13.50</td> </tr> <tr> <td data-bbox="384 766 592 819"># 4</td> <td data-bbox="592 766 772 819">7.40</td> <td data-bbox="772 766 956 819">12.20</td> </tr> <tr> <td data-bbox="384 819 592 873">Tolerance</td> <td data-bbox="592 819 772 873">± 0.4</td> <td data-bbox="772 819 956 873">± 0.4</td> </tr> </tbody> </table>			Size	Cap Length	Body Length	# 00	11.80	20.20	# OEL	12.00	20.70	# 0	11.10	18.50	# 1	9.70	16.50	# 2	9.20	15.30	# 3	8.20	13.50	# 4	7.40	12.20	Tolerance	± 0.4	± 0.4	Same with gelatin capsule (Please refer to specs of gelatin capsule)		
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