

## Product Data Sheet

Product			
<b>Empty Hard Vegetable Capsules (HPMC)</b>			
Specification No.: DFH-06	Specification Valid From:	2016-09-01	
General Parameters			
<b>Description</b>	Empty, two-piece, cylindrical hard vegetable capsules, typical in taste and odour		
<b>Manufacturer</b>	Dah Feng Capsule Industry Co., Ltd.		
<b>Legal Status</b>	EU legislation for food supplements	<b>Country of Origin</b>	Taiwan
<b>Composition</b>	Hydroxypropyl methyl cellulose (HPMC, E-464 & USP) and water.		
<b>Colour range</b>	Clear transparent and opaque, with colours according to agreement		
<b>Imprint</b>	Test and colour according to agreement	<b>Ink type</b>	Edible
<b>Excipients</b>	Carrageenan and potassium chloride. <small><sup>1)</sup> The excipients are suitably controlled by the rules laid down by Commission Regulation 1333/2008/EC on food additives; however they are not required to be included in the list of ingredients as they serve no technological function in the finished capsules (Commission Regulation 1169/2011/EU, Article 20 (b)(i)).</small>		
<b>Organic Food Supplements</b>	Hard capsules prepared from HPMC (E-464), carrageenan (E-407), and water are permitted for preparation of non-animal based food supplements labelled as organic. (Source: Commissions Regulation No. 889/2008/EC, Article 27 and Annex VIII)		
<b>Shelf Life</b>	5 years from date of manufacturing, when stored and handled as described in the storage and handling section (page 2).		
Dimensions (AQL-defect rate: Critical: 0.01 %, Major: 0.10 %, Minor: 0.40 %, on fully automatic testing machines)			
Size	00	0	1
<b>Capsules/box</b>	70 000	100 000	125 000
Lengths, mm			
- Cap	11.80 ±0.40	10.90 ±0.40	9.80 ±0.40
- Body	20.20 ±0.40	18.60 ±0.40	15.50 ±0.40
- Empty (joined)	23.40 ±0.50	21.70 ±0.50	19.30 ±0.50
- Filled (closed)	11.80 ±0.40	10.90 ±0.40	9.80 ±0.40
Single Wall thickness, mm			
- Body	0.110 ±0.025	0.105 ±0.020	0.100 ±0.020
- Cap	0.110 ±0.025	0.105 ±0.020	0.100 ±0.020
<b>Weight, mg</b>	118 ±7 mg	95 ±7 mg	75 ±5 mg
External Diameter, mm			
- Cap	8.54 ±0.05	7.68 ±0.05	6.95 ±0.05
- Body	8.19 ±0.05	7.34 ±0.05	6.65 ±0.05
<b>Body volume</b>	0.95 cc	0.68 cc	0.50 cc
Dose (mg/capsule) as function of powder density			
- 0.60 g/cc	570 mg	408 mg	300 mg
- 0.80 g/cc	760 mg	544 mg	400 mg
- 1.0 g/cc	950 mg	680 mg	500 mg
- 1.2 g/cc	1140 mg	816 mg	600 mg

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<b>Analytical Parameters</b>			
<b>Galenic properties</b>			
Disintegration time	≤ 20 min. (EP)		
<b>Chemical</b>			
Arsenic (As)	NMT 3.0 mg/kg		
Lead (Pb)	NMT 1.0 mg/kg		
Cadmium (Cd)	NMT 1.0 mg/kg		
Mercury (Hg)	NMT 0.1 mg/kg		
Sulphated ash, clear trans.	NMT 2.0% w/w		
Sulphated ash, opaque	NMT 7.0% w/w		
Loss on drying	NMT 7.0 % w/w	105°C, 4 hours or constant weight	
<b>Microbiology</b>			
Total viable count	≤ 1000 cfu/g		
Yeasts and moulds	≤ 100 cfu/g		
E. coli	Negative in 10 g	Ph. Eur. 2.4.12./13 or equivalent	
Salmonella	Negative in 25 g		
<b>Storage and Handling</b>			
<b>Storage</b>	Store between 19°C and 27°C and relative humidity (RH) between 40% and 60%, in tightly closed packing, protected from direct light.		
<b>Pre-filling</b>	Recommended storage between 19°C and 27°C and RH between 40% and 60% at least 12 hours before opening.		
<b>Handling and Filling</b>	<p>Temperature between 19°C and 27°C and RH between 40% and 60% during usage.</p> <p>Use only stainless steel scoops and spatulas.</p> <p>Do not leave capsules in a filling machine hopper for prolonged period, when not in use.</p> <p>Keep mouth of the bag closed when not in use.</p>		