

Product Data Sheet

Product

BioVXR - Acid Resistant HPMC Capsules

Specification No.: DFXR-02

Specification valid from: 2020-12-10

General parameters

Description	Empty, two-piece, cylindrical hard, acid resistant, vegetable capsules, typical in taste and odour.		
Manufacturer	Dah Feng Capsule Industry Co., Ltd.		
Manufacturer certifications	ISO22000, GMP, ISO9001, Halal, Kosher, and Vegetarian Society		
Legal status	EU legislation for food supplements	Country of origin	Taiwan
Composition	Hydroxypropyl methyl cellulose (HPMC, E-464 & USP), amidated pectin (E440ii), and water		
Colour range	Transparent, semi-transparent and opaque, with colours according to agreement		
Imprint	Text and colour according to agreement	Ink type	Edible
Vegetarian and Vegan	The manufacturer is licensed by the Vegetarian Society of the UK for the production of vegan and vegetarian products (www.vegsocapproved.com), and the capsules fulfil the requirements for vegan and vegetarian as defined by the consumer protection ministers of the federal states of Germany agreed on April 2016, and endorsed by the EVU (European Vegetarian Union).		

Galenic properties (AQL-defect rates: Critical: 0.01 %, Major: 0.10 %, Minor: 0.40 %, on fully automatic testing machines)

Size	00	0	1
Weight, mg	118 ±11.8	95 ±9.5	74 ±7.4
Volume, cc	0.95	0.68	0.50

Dose (mg/capsule) as function of bulk density

- 0.6 g/cc	570 mg	408	300
- 0.8 g/cc	760 mg	544	400
- 1.0 g/cc	950 mg	680	500
- 1.2 g/cc	1140 mg	816	600

Length, mm

- Cap	11.73 ±0.38	11.18 ±0.38	10.01 ±0.38
- Body	20.20 ±0.38	18.40 ±0.38	16.50 ±0.38
- Pre-closed (empty)	25.80 ±0.85	23.75 ±0.85	21.23 ±0.85
- Overall closed (filled)	23.30 ±0.50	21.30 ±0.50	19.20 ±0.50

External diameter, mm

- Cap	8.63 ±0.08	7.75 ±0.08	7.00 ±0.08
- Body	8.28 ±0.08	7.45 ±0.08	6.70 ±0.08

Single wall thickness, mm

- Cap	0.110 ±0.025	0.105 ±0.020	0.100 ±0.020
- Body	0.110 ±0.025	0.105 ±0.020	0.100 ±0.020

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Analytical parameters

Galenic properties

Disintegration Simulated gastric fluid TS pH 1.2 (37.2 ±2°C): After 1 hour, no evidence of disintegration
 Simulated intestinal fluid TS pH 6.8 (37.2 ±2°C): Less than 20 minutes

Chemical

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, transparent	NMT 2.0% w/w	
Sulphated ash, opaque	NMT 7.0% w/w	
Loss on drying	4.0% - 9.0 % w/w	105°C, 4 hours or constant weight

Microbiology

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
Staphylococcus aureus	Negative in 10 g	
Salmonella	Negative in 10 g	

Packaging

Size	00	0	1
Capsules/box	70 000	100 000	125 000
Packaging material	Moisture-proof, heat-insulation, food grade aluminium foil bag in sturdy cardboard-box		
Box dimensions	590 x 390 x 730 mm (length x width x height)		

Storage and handling

Storage Store between 19°C and 27°C and relative humidity (RH) between 40% and 60%, in tightly closed packing, protected from direct light.

Pre-filling Recommended storage between 19°C and 27°C and RH between 40% and 60% at least 12 hours before opening.

Handling and Filling Temperature between 19°C and 27°C and RH between 40% and 60% during usage.
 Use only stainless-steel scoops and spatulas.
 Do not leave capsules in a filling machine hopper for prolonged period, when not in use.
 Keep mouth of the bag closed when not in use.

Shelf Life 5 years from date of manufacturing, when stored and handled as described.