



**TECHNICAL DATA SHEET  
FOR EMPTY HARD CAPSULES OF VEGETABLE ORIGIN**

- K-CAPS<sup>®</sup> are manufactured with HPMC, additives and water.
- K-CAPS<sup>®</sup> meet all established requirements of the USP, EP and FCC.
- K-CAPS<sup>®</sup> have uniform dimensions within the specified tolerances.
- K-CAPS<sup>®</sup> edges, of the separated cap and body are cut flat without any visible roughness.
- K-CAPS<sup>®</sup> there are easy separation on the high-speed capsules filling machines.
- K-CAPS<sup>®</sup> are more clear and brighter than the competition.
- K-CAPS<sup>®</sup> are soluble in water.
- K-CAPS<sup>®</sup> disintegrate in less than 15 minutes.
- K-CAPS<sup>®</sup> moisture content is kept between 4% and 8%
- K-CAPS<sup>®</sup> weights vary  $\pm 5$ mg. Variances in weight are due to the moisture level and accepted fluctuations in capsule dimensions.
- K-CAPS<sup>®</sup> visual quality is based on Military Standard 105E, using simple sampling with level II of General Inspection.
- K-CAPS<sup>®</sup> retain all their characteristics and requirements provided they are stored and handled in their original packing, in places with temperatures between 59°F (15°C) and 86°F (30°C), and relative humidity levels between 35% and 70%.

**TABLE N°. 1 EMPTY CAPSULES WEIGHT**

SIZE	CAPSULE WEIGHT (mg)
00E	143.0 $\pm$ 5
00	136.0 $\pm$ 7
0	105.0 $\pm$ 6
1	79.0 $\pm$ 5
2	63.0 $\pm$ 4
3	50.0 $\pm$ 3
4	40.0 $\pm$ 3

**TABLE N°. 2 INDIVIDUAL LENGTHS**

SIZE	CAP		BODY	
	(mm)	(inches)	(mm)	(inches)
00E	13.00 $\pm$ 0.35	0.510 $\pm$ 0.014	22.35 $\pm$ 0.35	0.879 $\pm$ 0.014
00	11.80 $\pm$ 0.35	0.464 $\pm$ 0.014	20.10 $\pm$ 0.35	0.791 $\pm$ 0.014
0	10.85 $\pm$ 0.35	0.427 $\pm$ 0.014	18.35 $\pm$ 0.35	0.722 $\pm$ 0.014
1	9.85 $\pm$ 0.35	0.388 $\pm$ 0.014	16.40 $\pm$ 0.35	0.645 $\pm$ 0.014
2	8.80 $\pm$ 0.35	0.346 $\pm$ 0.014	15.15 $\pm$ 0.35	0.596 $\pm$ 0.014
3	8.00 $\pm$ 0.35	0.315 $\pm$ 0.014	13.45 $\pm$ 0.35	0.529 $\pm$ 0.014
4	7.20 $\pm$ 0.35	0.283 $\pm$ 0.014	12.10 $\pm$ 0.35	0.476 $\pm$ 0.014

1889 SW THIRD STREET POMPANO BEACH, FL 33069  
TELEPHONE (954) 975-6618 FAX (954) 979-1370

CALLE 79B 78C-21 BARRANQUILLA COLOMBIA  
TELEPHONE (575) 3304100 FAX (57-5) 330-4105



**TABLE N°. 3 JOINING LENGTH OF THE CLOSED CAPSULES**

SIZE	CLOSED CAPSULE	
	(mm)	(inches)
00E	25.30 ± 0.30	1.000 ± 0.012
00	23.40 ± 0.30	0.921 ± 0.012
0	21.60 ± 0.30	0.850 ± 0.012
1	19.40 ± 0.30	0.764 ± 0.012
2	17.60 ± 0.30	0.693 ± 0.012
3	15.70 ± 0.30	0.618 ± 0.012
4	14.30 ± 0.30	0.563 ± 0.012

**TABLE N°. 4 EXTERNAL DIAMETERS**

SIZE	CAP		BODY	
	(mm)	(inches)	(mm)	(inches)
00E	8.58	0.338	8.25	0.325
00	8.56	0.337	8.23	0.324
0	7.65	0.301	7.35	0.289
1	6.96	0.274	6.63	0.261
2	6.39	0.252	6.12	0.241
3	5.85	0.230	5.60	0.220
4	5.33	0.210	5.08	0.200

**TABLE N°. 5 APPROXIMATE CONTENT OF A FILLED AND CLOSED CAPSULE, (In mg)**

SIZE	DENSITY OF DOSING POWDER			
	0.6 g/ml	0.8 g/ml	1.0 g/ml	1.2 g/ml
00E	612	816	1.020	1.224
00	570	760	950	1.140
0	408	544	680	816
1	288	384	480	576
2	216	288	360	432
3	162	216	270	324
4	120	160	200	240

**TABLE N°. 6. MICROBIOLOGICAL QUALITY OF THE CAPSULE**

PARAMETER	SPECIFICATION
Total aerobic microbial count	<1000 CFU/gram
Salmonella Species	Negative
Escherichia Coli	Negative
Pseudomonas Aeruginosa	Negative
Staphylococcus Aureus	Negative
Yeast and Mold	NMT 100/gram

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**TABLE N° 7. VISIBLE DEFECTS ON UNPRINTED CAPSULES**

<b>CRITICAL</b>	<b>MAJOR</b>	<b>MINOR</b>
Foreign capsule	Dirty capsule	Bubbles
Hole	Punched end	Spot
Closed capsule	Chipped cap or body (major)	Chipped cap or body (minor)
Cracked	Thin spot	Inside dirty end
Sticking capsule	String (major)	Wrinkle
Trim	Double cap	Star end
Double dip	Loose piece	String (minor)
Short body	Bad dip	Line in end
Uncut	Rough cut (major)	Vegetable clot
Mashed capsule	Bad join	Scraping
Long cap or body	Lateral corrugation	Collect pinch
	Short cap	Particle inside the capsule
	Long joining	Black speck
		Uneven cut
		Rough cut (minor)

**TABLE N° 8. VISIBLE DEFECTS ON PRINTED CAPSULES**

<b>CRITICAL</b>	<b>MAJOR</b>	<b>MINOR</b>
Foreign material	Imprint Smeared (legible)	Ink spot (minor)
Unprinted	Partial Imprint (missing or cut off)	Off-center misplaced (minor)
Imprint Smeared (not legible)	Off-center (misplaced printing)	Partial imprint (minor)
		Roller mark
		Poor ink cover-up
		Print line
		Multiple print (Legible)
		Light and Dark imprint

**TABLE N° 9. ACCEPTABLE QUALITY LEVELS (AQL)**

<b>TYPE OF DEFECT</b>	<b>UNPRINTED CAPSULES ( AQL)</b>	<b>PRINTED CAPSULES ( AQL)</b>
CRITICAL	0.010	0.010
MAJOR	0.040	0.065
MINOR	0.250	0.650

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**TABLE N°10. ACCEPTANCE-REJECTION LEVELS (AQL)**

TYPE OF DEFECT	SIZE OF THE CAPSULE SAMPLE	UNPRINTED CAPSULES		PRINTED CAPSULES	
		# Acceptance	#Rejection	# Acceptance	#Rejection
CRITICAL	1250	0	1	0	1
MAJOR	1250	1	2	2	3
MINOR	1250	7	8	14	15

**TABLE N°. 11. SHIPMENTS STANDARDS FOR EMPTY HARD CAPSULES OF VEGETABLE ORIGIN**

SIZE	QUANTITY (CAPSULES / BOX)
00E	65.000
00	75.000
0	100.000
1	125.000
2	175.000
3	200.000
4	250.000

Name and position: **Odalis Vergara D. / Quality Assurance Manager**

Certificate code: V024-07

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