

CERTIFICATE OF ANALYSIS

Hydroxypropylmethylcellulose Hart Kapseln - Leerkapseln (verschlossen) - Bio-Kompatibel
 Artikelnummer Nummer.: HPMC00TRVE - Charge: 387-380 - Größe: 00 - Farbe: transparent
 Produktionsdatum: 08.2018 - MHD: 08.2023
 Halal-Status: Halal-zertifiziert. - Kosher-Status: Kosher-zertifiziert - Stat. Warennummer: 39234090

PHYSICAL Specification	MEASURE UNIT	Method	Specifications	Results
Average Weight	mg	DCC - MI - P003- / USP <2091>	132,0 - 146,0	139,3
Loss of drying	%	DCC - MA - P027	4,0 - 8,0	5,6
Identification of HPMC	x	DCC - MA - P073- / USP	Positiv	Passes
Disintegration	min	DCC - MA - P063- / USP <701>	*N.M.T. 15	Passes
ANALYTICAL Specification				
Arsenic*	ppm	External	*N.M.T. 0,8	Passes
Chromium*	ppm	External	*N.M.T. 2,0	Passes
Cadmium*	ppm	External	*N.M.T. 0,5	Passes
Cobalt*	ppm	External	*N.M.T. 0,8	Passes
Nickel*	ppm	External	*N.M.T. 20,0	Passes
Mercury*	ppm	External	*N.M.T. 0,1	Passes
Lead*	ppm	External	*N.M.T. 1,0	Passes
Vanadium*	ppm	External	*N.M.T. 0,5	Passes
Total Yeasts and Molds Count	cfu/g	DCC-MA-P031 / USP<61>	< 1000	10
Total viable aerobic count: bacteria	cfu/g	DCC-MA-P031 / USP<61>	< 1000	10
Total Coliforms		DCC-MA-P036 / USP<62>	absence / 10 g	Absence
Salmonella		DCC-MA-P039 / USP<62>	absence / 10 g	Absence
Escherichia Coli		DCC-MA-P036 / USP<62>	absence / 10 g	Absence
Staphylococcus Aureus		DCC-MA-P037 / USP<62>	absence / 10 g	Absence
Pseudomona Aeruginosa		DCC-MA-P033 / USP<62>	absence / 10 g	Absence
Yeast and Mold, in cfu/g		DCC-MA-P040 / USP<61>	N.M.T. 100	< 10

* Reduced frequency testing

* N.M.T. = Not more than

Lagerhinweis: 15 – 25 °C / 35 – 65% relative Luftfeuchtigkeit.
 Beutel vor starker Hitze und Kälte schützen.



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Quality Assurance Statement

The “Organic” labelling of finished hard capsule products, which are made using our Organ Caps , is conform with the Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 and COMMISSION REGULATION (EC) No 889/2008 of 5 September 2008 laying down detailed rules for the implementation of Council Regulation (EC) No 834/2007 on organic production and labelling of organic products with regard to organic production, labelling and control.

To finally label a finished product as “Organic” all ingredients have to comply with the up mentioned regulations.

Empty hard capsules themselves cannot be certified “Organic”, because they are not a finished product for a daily intake. Only the final finished product can be indicated “Organic”.

The ingredients of our Organ Caps are to be found in the list of the regulation 889/2008 and are therefore suitable for “Organic” products.

Ingredients

- E 464 Hydroxypropylmethylcellulose
- Water

Process aids (are used only during the hard capsule production)

- E 422 Glycerin
- E 551 Silicon dioxide

We hope that this information is helpful for you and stay at your disposal in case of any further questions.

This Conformation is valid without signiture

Homayoun Azizi

SPECIFICATION

Hydroxypropylmethylcellulose Capsule, empty (Lock Type) for organic use

Description:

Two-piece Hard Capsules made from all natural plant derived raw materials with typical, almost neutral taste and odour. Hypromellose (Hydroxy-propyl-methyl cellulose, HPMC) is a polymer of cellulose ethers, derived from wood cellulose fibres. The capsules are preservative-free and meet all established requirements of the Ph.Eur. (EP, European Pharmacopoeia) and USP (United States Pharmacopoeia).

Colour (Cap / Body): transparent 1-0K / transparent 1-0K

Size [minims]	00 el	00	0 el	0
Article No.:	#	56-000145	#	56-000144
Weight [mg]	145,00	139,00	121,00	109,00
Tolerance [± mg]	6,00	7,00	6,00	6,00
Length Cap [mm]	13,00	11,80	11,73	10,85
Tolerance [± mm]	0,35	0,35	0,35	0,35
Length Body [mm]	22,35	20,10	20,00	18,35
Tolerance [± mm]	0,35	0,35	0,35	0,35
Length closed [mm]	25,30	23,40	23,20	21,60
Tolerance [± mm]	0,30	0,30	0,30	0,30
External Diameter [mm]				
Cap	8,58	8,56	7,65	7,65
Body	8,25	8,23	7,35	7,35

Size [minims]	1	2	3	4
Article No.:	56-000143	#	#	#
Weight [mg]	80,00	63,00	50,00	40,00
Tolerance [± mg]	5,00	4,00	3,00	3,00
Length Cap [mm]	9,85	8,80	8,00	7,20
Tolerance [± mm]	0,35	0,35	0,35	0,35
Length Body [mm]	16,40	15,15	13,45	12,10
Tolerance [± mm]	0,35	0,35	0,35	0,35
Length closed [mm]	19,40	17,60	15,70	14,30
Tolerance [± mm]	0,30	0,30	0,30	0,30
External Diameter [mm]				
Cap	6,96	6,39	5,85	5,33
Body	6,63	6,12	5,60	5,08

* The body represents approximately 60 % of the capsule weight the cap approximately 40 %.

SPECIFICATION

Hydroxypropylmethylcellulose Capsule, empty (Lock Type) for organic use

Parameter	Specification	Method
<u>Moisture [%]:</u>	4.0 - 8.0	DCC - MA - P027
<u>Disintegration [min]:</u>	≤ 15	DCC - MA - P063 / USP <701>
<u>Heavy metals [ppm]*:</u>		
Arsenic	≤ 0.8	
Chromium	≤ 2.0	
Cadmium	≤ 0.5	
Lead	≤ 0.5	
Mercury	≤ 0.1	
Cobalt	≤ 5.0	
Vanadium	≤ 10.0	
Nickel	≤ 20.0	
* Reduced frequency testing on a quaterly basis		
<u>Microbiology [CFU/g]:</u>		
Total aerobic microbial counts	≤ 1 x 10 ³	DCC - MA - P031 / USP <61>
Total combined Yeast and Mould counts	≤ 1 x 10 ²	DCC - MA - P040 / USP <61>
Total Coliforms	negativ / 1	DCC - MA - P036 / USP <62>
E. coli	negativ / 1	DCC - MA - P036 / USP <62>
Salmonella	negativ / 10	DCC - MA - P039 / USP <62>
Staphylococcus Aureus	negativ / 1	DCC - MA - P037 / USP <62>
Pseudomonas Aeruginosa	negativ / 1	DCC - MA - P033 / USP <62>
<u>AQL-defect rate [%]:</u>	<u>Unprinted Capsules</u>	<u>Printed Capsules</u>
Critical	0.010	0.010
Major	0.040	0.065
Minor	0.250	1.500

Durability

In the original packaging five years.

Transport / Storage:

A regulated cool transportation between 4-7°C is uncritical for the product quality. Storage conditions: cool (15-30°C), dry (35-70% rel. humidity) and light protected. An acclimatization period of 1-2 days after transport and before production is recommended.

GMO-Status:

The product is in accordance with Regulations (EC) No. 1829/2003 and No. 1830/2003. A labelling regarding presence of genetically modified organisms (GMO) is therefore not necessary.

BSE-Status

The product fulfils the BSE-safety requirements of the European Community (Commission decision 2000/418/EC, and alteration 2001/233/EC).

Halal-Status:

The product is Halal-certified.

Kosher-Status:

The product is Kosher- certified.

GRAS-Status:

Hyromellose is GRAS listed by American authority FDA which means, it is considered "generally recognised as safe".