

Statement on Hypromellose Quality

Capsugel® empty hypromellose-based capsule products

Related to the quality of HydroxyPropyl Methyl Cellulose (HPMC, hypromellose) raw material applied in the manufacture of Capsugel® empty HPMC-based capsules, we inform you that it meets the most current requirements of the following regulatory references and subsequent amendments:

- European Pharmacopoeia (Ph. Eur.)
- United States Pharmacopoeia / National Formulary (USP/NF)
- Japanese Pharmacopoeia
- Commission Regulation (EU) No 231/2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008

As a source of information, the table below shows the values for the HPMC specifications used by Lonza and the requirements mentioned in the European and United States Pharmacopoeia.

Parameter	Lonza Specification	Current version Ph. Eur.			Current version USP/NF	
Identification	Positive	Positive			Positive	
Loss on drying	≤ 5.0%	≤ 5.0%			≤ 5.0%	
Assay	Conform to content specification for specific substitution type used	Substitution type	Methoxy (%)	Hydroxypropoxy (%)	Methoxy (%)	Hydroxypropoxy (%)
		1828	16.5 to 20.0	23.0 to 32.0	16.5 to 20.0	23.0 to 32.0
		2208	19.0 to 24.0	4.0 to 12.0	19.0 to 24.0	4.0 to 12.0
		2906	27.0 to 30.0	4.0 to 7.5	27.0 to 30.0	4.0 to 7.5
		2910	28.0 to 30.0	7.0 to 12.0	28.0 to 30.0	7.0 to 12.0
Residue on ignition	≤ 1.0%	≤ 1.5%			≤ 1.5%	
Appearance of solution	Conform	Conform			Conform	
Viscosity	Conform	Conform			Conform	
Heavy metals	≤ 10 ppm	N/A			N/A	
pH	5.0 – 8.0	5.0 – 8.0			5.0 – 8.0	
Total Aerobic Microbial Count	≤ 100 cfu/g	≤ 10 ³ cfu/g			≤ 10 ³ cfu/g	
Total Yeasts and Moulds Count	≤ 50 cfu/g	≤ 100 cfu/g			≤ 100 cfu/g	

Parameter	Lonza Specification	Current version Ph. Eur.	Current version USP/NF
Salmonella	Absent in 10 g	Absent in 10 g	Absent in 10 g
E. Coli	Absent in 1 g	Absent in 1 g	Absent in 1 g
Arsenic	≤ 0.1 ppm	N/A	N/A
Lead	≤ 0.1 ppm	N/A	N/A
Mercury	≤ 0.1 ppm	N/A	N/A
Cadmium	≤ 0.1 ppm	N/A	N/A

The information contained herein corresponds to Lonza's knowledge on the subject at the date of publication and is, to the best of our knowledge, accurate. However, Lonza refuses any liability for the application and use of further processed material containing our products. According to the relevant regulations, the manufacturer of the final product is solely responsible for the use and commercialization of the Lonza product and the information contained herein.

For further information, please contact your Lonza account representative.

Products: DRcaps®, Vcaps®, Vcaps® Plus

Sites: Colmar FRANCE, Greenwood USA, Puebla MEXICO, Sagami-hara JAPAN, Suzhou CHINA

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