

QUALITÄTSMANAGEMENT

SPECIFICATION

LIGAMED MF-2-V

BSW: 31400521

version: 3 / 05.01.2009

appearance: White powder

composition: Magnesium salt of vegetable fatty acids consisting mainly of stearic acid and palmetic acid.

properties: Magnesium Stearate for special applications in Pharma-, food- and cosmeticindustries. The product is in accordance with the USP32/NF27/BP2007/Ph.Eur 6th ed./DAB10/ JP 15th. ed./FCC 6th. ed./ CP2005

parameter	unit	methode	specification limit			
			lower	target	upper	
Identification A	øC	Ph.Eur	53			
Identification A	metal reaction	USP/NF		passes test		
Identification B	retention time GC	USP/NF		retentions match		
Acidity or	ml 0,01N HCl	Ph.Eur			0,5	
Alkalinity	ml 0.01 N NaOH	Ph.Eur			0,5	
Heavy metals as Pb	ppm	JP			15	
Heavy metals as Pb	ppm	CP			15	
Lead	ppm	BAE 300-B			5	
Cadmium	ppm	BAE 300-B			3	
Nickel	ppm	BAE 300-B			5	
Iron content	ppm	BAE 300-B			100	
Chloride	ppm	BAE-627			100	
Sulphate	%	Ph.Eur			0,5	
Acid value of the fatty acid	mg KOH/g	Ph.Eur	195		210	
Relative content of stearic acid	%	USP/NF	40			
Rel. cont. of stearic and palmetic acid	%	USP/NF	90			
Aerobic microbial count	cfu/g	USP/NF			1000	
Molds & Yeasts	cfu/g	USP/NF			100	
Escherichia coli	cfu/10g	USP/NF		absent		
Salmonella Species	cfu/10g	USP/NF		absent		
Residual Solvents		USP/NF		meets USP/NF		
Loss on drying	%	BAE 600			4	
Magnesium content	%	BAE 200 o	4,2		4,5	
Free fatty acid	%	BAE 400			2	
Sieve residue at 200 mesh	%	BAE 605			1	
Bulk density tapped	g/ml	BAE 611a	0,27		0,37	
specific surface area BET	m2/g	USP/NF	6		10	

The information and datas given in this sheet represent our best knowledge but are not a guarantee for any properties or performance of the products including patent infringement and legislation of other countries. They don't release the customer from making his own assessment under his own assessment under his own conditions and requirements.



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parameter	unit	methode	specification limit		
			lower	target	upper
Contamination		BAE 601		in accordance	

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