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Pharmaceutical Grade Excipients Manual

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Excipients

Microcrystalline Cellulose

Powdered Cellulose

Microcrystalline Cellulose
and Carboxymethyl Cellulose Sodium

Magnesium Stearate

Povidone

Copovidone

Crospovidone

Croscarmellose Sodium EP/IP/BP/USP

Microcrystalline Cellulose

CAS No.: 9004-34-6 | Aditive: E-460 (i)

- **Appearance:** white or almost white, fine or granular, slightly hygroscopic powder.
- **Description:** white crystalline powder having fluidity, practically insoluble in water, in ethanol (95) and in Diethyl ether and swells with sodium hydroxide TS (JP).
- **Solubility:** practically insoluble in water, in acetone, in anhydrous ethanol, in toluene, in dilute acids and in a 50 g/l solution of sodium hydroxide.

Items	Specifications
Colour reaction	Red colour is produced
Identification Test-A	Infrared Absorption
Identification Test-B	Violet-blue colour should be produced
Identification Test-C	The degree of polymerization should be no more than 350
Total Aerobic Microbial count, CFU/g	NMT 1000
Total Combined Yeasts & Molds count, CFU/g	NMT 100
Escherichia coli/g	Should be absent
Pseudomonas aeruginosa/g	Should be absent
Staphylococcus aureus/g	Should be absent
Salmonella species/10g	Should be absent
Suspension test	The solids settles and a supernatant liquid appears
Starch and Dextrin	No Purplish to blue or blue colour should be produced
Assay, % cellulose (calculated on dried basis)	97.0 to 102.0
Conductivity, µS/cm	NMT 75
pH	5.0 to 7.5
Loss on Drying, %	NMT 7.0
Residue on Ignition/Sulphated Ash, %	NMT 0.1
Water Soluble Substances, %	NMT 0.25
Ether Soluble Substances, %	NMT 0.05
Carboxyl group, %	NMT 1
Heavy Metals, ppm	NMT 10
Arsenic, ppm	NMT 3
Lead, ppm	NMT 2
Mercury, ppm	NMT 0.1
Cadmium, ppm	NMT 1
Solubility in copper Tetramine	Should dissolve completely, leaving no residue

Microcrystalline Cellulose

CAS No.: 9004-34-6 | Aditive: E-460 (i)

Bulk density

Test	MCC 101	MCC 102	MCC 103	MCC 112	MCC 113	MCC 114
Loss on drying %	NMT 7.0	NMT 7.0	NMT 2.0	NMT 1.5	NMT 1.5	NMT 7.0
Bulk density g/ml	0.22 to 0.34	0.28 to 0.37	0.26 to 0.31	0.28 to 0.38	0.27 to 0.34	0.34 to 0.43
% retention on 60#	NMT 1	NMT 8	NMT 1	NMT 8	NMT 1	NMT 8
% retention on 200#	NMT 30	NTL 45	NMT 30	NTL 45	NMT 30	NLT 40/NMT 60

Test	MCC 1000	MCC 301	MCC 302	MCC 102 BD	MCC W	MCC WP
Loss on drying %	NMT 7.0	NMT 7.0	NMT 7.0	NMT 7.0	NMT 7.0	NMT 7.0
Bulk density g/ml	0.10 to 0.15	0.34 to 0.51	0.35 to 0.50	0.30 to 0.40	0.25 to 0.35	0.24 to 0.35
% retention on 60#	NMT 0.5	NMT 1	NMT 8	NMT 8	NMT 1	NMT 8
% retention on 200#	NMT 20	NMT 30	NTL 45	NTL 50	NMT 35	NMT 35

Test	MCC 12
Loss on drying %	NMT 7.0
Bulk density g/ml	0.25 to 0.37
% retention on 40#	NMT 1
% retention on 100#	NMT 50
% retention on 325#	NLT 70

Test	MCC 105	MCC 500	MCC 200
Loss on drying %	NMT 7.0	NMT 7.0	NMT 7.0
Bulk density g/ml	0.20 to 0.30	0.27 to 0.37	0.29 to 0.36
% retention on 40#		NTL 50	NTL 10
% retention on 100#			NTL 50
% retention on 400#	NMT 1		

Silicified Microcrystalline cellulose

Grade	Average Particle Size by Laser Diffraction (µm)	Bulk Density (g/mL)	Main application
MCC S-101	65	0.28-0.33	Formulas in which optimal compaction and decent flow is requiered.
MCC S-102	125	0.25-0.37	Formulas in which regular balance of flow and compactation is requiered.
MCC S-102 HD	125	0.38-0.50	Formulas in which optimal flow is required. This grade is for best desintegration times. * Low moisture grade available on request.
MCSS S-102 LM	125	0.25-0.37	Equivalent to quality of MICCEL S 102, but with lower moisture content (<3%).

Powdered Cellulose

CAS No.: 9004-34-6 | Aditive: E-460(ii)

- **Appearance:** white or almost white, fine or granular, slightly hygroscopic powder.
- **Description:** white or almost white, fine or granular powder.
- **Solubility:** (Ammonical Solution of copper Tetrammine) Should dissolved completely, leaving no residue.

Identification Test-A	Violet-blue colour should be produced
Identification Test-B (Degree of Polymerisation)	The degree of Polymerization is greater than 440
Identification Test-A(1)	Violet-blue colour should be produced.
Identification Test-A(2)	A white, opaque, bubble-free dispersion, which does not form a supernatant liquid at the surface, is obtained
Total Aerobic Microbial count, CFU/g	NMT 1000
Total Combined Yeasts & Molds count, CFU/g	NMT 100
Escherichia coli/g	Absence
Pseudomonas aeruginosa/g	Absence
Staphylococcus aureus/g	Absence
Salmonella species/10g	Absence
Ph	5.0 to 7.5
Loss on Drying, %	NMT 6.5
*Heavy Metals, ppm	Max. 10
*Bulk Density, g/L	330-410
Residue on Ignition, % (calculated on dried basis)	NMT 0.3
Water Soluble Substances, %	NMT 1.5
Ether Soluble Substances, %	MNT 0.15
*Particle Size Retained on Alpin Air jet > 90 µm (170 mesh), %	Max. 98.0
*Particle Size Retained on Alpin Air jet > 250 µm (60 mesh), %	Max. 55.0
*Particle Size Retained on Alpin Air jet > 400 µm (43 mesh), %	Max. 1.0

Microcrystalline Cellulose and Carboxymethyl Cellulose Sodium

Parameters	Specifications
Appearance	White or off-white, coarse or fine, Hygroscopic powder
Solubility	Dispersible in water producing a white, opaque colloidal dispersion. Practically insoluble in organic solvents and in dilute acids
Identification Test-A	A white, opaque, dispersion is produced that does not produce a supernatant
Identification Test-B	Each drop forms a white, opaque globule that does not disperse on standing
Identification Test-C	No blue or purplish blue colour is produced
Identification Test-D	It complies with the limits of the assay
Solubility in Ammonical solutión of Copper tetrammine	It dissolves completielu, leaving no residue
Sulfated Ash, %	Max. 7.4
Ph	6.0 to 8.0
Loss on Drying, % (1 g, at 105° C)	Max. 8.0
Total Aerobic Microbial count, CFU/g	NMT 1000
Total Combined Yeasts & Molds count, CFU/g	NMT 100
Escherichia coli/g	Should be absent
Pseudomonas aeruginosa/g	Should be absent
Staphylococcus aureus/g	Should be absent
Salmonella species/10g	Should be absent

CMC-501	
Assay, % (NLT 75 % and NMT 125 % of the labelled amount of Carboxymethycellulose Sodium, Calculate on dried basic)	7.1 to 11.9
Viscosity, cp (2.1 % solid)	Between 70 and 170
PSD, Weight % retained on 60 mesh	NMT 0.1 (IH)
PSD, Weight % retained on 200 mesh	NMT 40 (IH)

CMC-591	
Assay, % (NLT 75 % and NMT 125 % of the labelled amount of Carboxymethycellulose Sodium, Calculate on dried basic)	8.3 to 13.8
Viscosity, cp (1.2 % solid)	Between 40 and 95
PSD, Weight % retained on 60 mesh	NMT 0.1 (IH)
PSD, Weight % retained on 325 mesh	NMT 45 (IH)

CMC-611	
Viscosity, cp (2.5 % solid)	Between 50 and 120
PSD, Weight % retained on 60 mesh	NMT 0.1 (IH)
PSD, Weight % retained on 200 mesh	NMT 50 (IH)

CMC-581	
Assay, % (NLT 75 % and NMT 125 % of the labelled amount of Carboxymethycellulose Sodium, Calculate on dried basic)	8.3 to 13.8
Viscosity, cp (1.2 % solid)	Between 70 and 170
PSD, Weight % retained on 60 mesh	NMT 0.1 (IH)
PSD, Weight % retained on 200 mesh	NMT 35 (IH)

Magnesium Stearate

CAS No.: 557-04-0 | Aditive: E-470b

Magnesium Stearate is a fine, white, odourless powder is a magnesium salt of stearic acid. Our Magnesium Stearate is derived from 100% vegetable origin Stearic acid. Magnesium Stearate complies with the highest pharmaceutical standards, guaranteeing safety and efficacy. It's an essential ingredient in countless pharmaceutical and nutraceutical products.

Applications

- Essential for tablets, capsules, and granules: Guarantees uniformity, quality, and smooth compression, ensuring active ingredient release with lubrication.
- Acts as an emulsifier and soothing agent in creams, talcum powder, enhancing product texture and skin protection.
- Improves drug stability and shelf life, maintaining the integrity of medications.
- Acts as a thickening agent in dietary supplements.

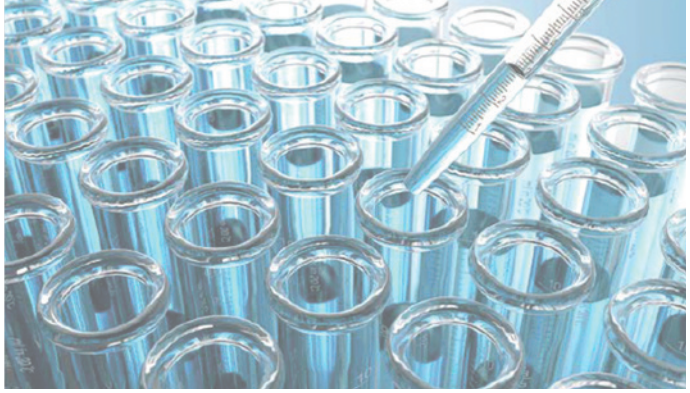
Characteristics

- **Appearance:** Very fine, light, white powder greasy to touch.
- **Odour:** With a characteristic odour of stearic acid; unctuous.
- **Solubility:** Practically Insoluble in water, alcohol, and ether.

Magnesium Stearate

CAS No.: 557-04-0 | Aditive: E-470b

Parameters	Specifications
Identification Test-A (freezing point), °C	NLT 53
Identification Test-B (acid value)	195 t 210
Identification Test-C	The 2 principal peaks in the chromatogram obtained with the test solution are similar in retention time to the 2 prinicipal peaks in the chromatogram obtained with the reference solution.
Identification Test-D	A white crystalline precipitate is formed.
Acidity or alkalinity	Not more than 0.05 mL of 0.1 M hydrochloric acid or 0.1 M sodium hydroxide is required to change the colour of the indicator.
Chlorides, %	Max. 0.1
Sulfates, %	Max. 1.0
Cadmiun, ppm	Max. 3
Lead, ppm	Max. 10
Nickel, ppm	Max. 5
Loss on drying, %	Max. 6.0
Assay	
Magnesium, % (dried substance)	4.0 to 5.0
Stearic acid, %	NLT 40.0
Sum of stearic acid and palmitic acid, %	NLT 90.0
Bulk density, g/cc	0.15 - 0.30 (IH)
Particle size distribution on 200 Mesh	NLT 95 % passing through (IH)
Particle size distribution on 325 Mesh	NLT 95 % passing through (IH)
Microbial contamination	
Total aerobic microbial count, CFU/g	NMT 1000
Total combined yeasts & molds counts, CFU/g	NMT 100
Staphylococcus aureus,/g	Should be absent.
Pseudomonas aeruginosa,/g	Should be absent.
Escherichia coli,/g	Should be absent.
Salmonella,/10 g	Should be absent.
Specific surface area, m^2/g	NLT 5.0



Povidone

CAS No.: 9003-39-8 | Aditive: E-1201

Characteristics

White free flouring hygroscopic powder, freely soluble in ethanol, methanol, slightly soluble in acetone. Because of its solubility in water and in many organic solvents, its high binding power and ability to form complexes, soluble polyvinylpyrrolidone occupies a special position among the synthetic colloids.

Applications

- Main application of Povidone K series: Tablets, capsules, granules.
- Bioavailability enhancement: Tablets, capsules, granules, pellets, suppositories, transdermal systems.
- Film formation: Ophthalmic solutions, tables, medical plastics.
- Solubilization: Oral, Parenteral and topical solutions.
- Stabilization of suspensions: Oral and parenteral suspensions, instant beverage powders and granules.
- Hydrophylization: Medical plastics, retard preparations, suspensions.
- Adhesives: Transdermal systems, adhesive gels.
- Drug stabilization: Enzymes in diagnostics.
- Toxicity reduction Tablets, capsules, granules: Injection preparations.

Specifications

- Povidone series meet the requirements of the latest USP/NF, PhEur, JP/JPE and CP.
- All grades of Povidone series are supplied in the form of an almost white, free-flowing powder. They have a slight characteristic odour and are practically tasteless.

Identification	K15	K17	K25	K30	K90
Colour (5 % in water) min.	BY6, B6	BY6, B6	BY6, B6	BY6, B6	BY6, B6
K value	12.8-17.3	15.3-18.4	22.5-27.0	27.0-32.4	81.0-97.2
Impurity A, ppm max	10	10	10	10	10
Impurity B, % max	3.0	3.0	3.0	3.0	3.0
Formic Acid. % max	0.5	0.5	0.5	0.5	0.5
Peroxides, ppm max	400	400	400	400	400
Aldehyde, ppm max	500	500	500	500	500
Hydrazine, ppm max	1	1	1	1	1

Copovidone

CAS No.: 25086-89-9 | Aditive: E-1209

Copovidone is a vinylpyrrolidone-vinyl acetate copolymer that is soluble both in water and in alcohols. It is used in the pharmaceutical industry as binders, granulating agents, retarding agents and film, Forming agents in drugs.

Characteristics

White or slightly yellowish, free-flowing powder with a faint characteristic odor and practically no taste. Copovidone readily dissolves in all hydrophilic solvents. Solutions of more than 10% concentration can be prepared in: water; ethanol; isopropanol; methylene chloride; glycerol; propylene glycol; it is less soluble in: ether; cyclic, aliphatic and alicyclic hydrocarbons.

Applications

Binder for tablets and granules	Is an excellent binder for tablets and granules.
Dry binder for direct compression Wet granulation	Between 2% and 5%, as a proportion of the final weight of the preparation, is usually used.
Film-coating	Forms films that are soluble at all Ph values.
Subcoating Sugar-coating Sprays Controlled-release preparations	Is used in sugar-coating to improve the adhesion of the coating to the surface of the tablet core and to increase the capacity of the coating solution for pigments and improve their dispersibility.

Specifications

Copovidone meets the requirements of the latest USP/NF, Ph.Eur. and JPE

Appearance of solution (10%)	By5, B5 min.	Heavy metals	20 ppm max
Aldehydes	500 ppm max.	Loss on drying	5.0% max
Peroxides	400 ppm max.	Sulphated ash	0.1% max
Hydrazine	1 ppm max.	K value	25.2-30.8
Monomers	0.1% max.	Ethenyl acetate	35.3%-42.0%
ImpurityA	0.5% max.	Nitrogen	7.0%-8.0%

Crospovidone

CAS No.: 9003-39-8 | Aditive: E-1202

Applications

Series posses a number of useful properties for pharmaceutical products:

- Improvement of tablet disintegration and therefore also of release and bioavailability of drugs through predictable swelling (disintegration effect).
- Improvement of release and bioavailability of drugs through complexation.
- Selective adsorption of polyphenols by complexation.
- Stabilization of suspension by HC as a hydrophilic polymer.
- Adsorption of water.

Specifications

Series meet the requirements of the latest USP, PhEur.
Crospovidone are supplie as fine white prowders. They have a slight characteristic odour and are practically tasteless. They are insoluble in all the usual solvents.

Identification	Type A	Type B
Particle size, ≤63 microns	85 % max.	85 % min.
Particle size, >63 microns	15 % min.	15 % max.
Water, % max	5.0	5.0
Sulphate ash, % max	0.1	0.1
Water-soluble substances, % max	1.5	1.5
Heavy metals, ppm max.	10	10
Vinylpyrroldione, ppm max.	10	10
Peroxides (as H2O2), ppm max.	400	1000
Nitrogen, %	11.0-12.8	11.0-12.8

Croscarmellose Sodium EP/IP/BP/USP

CAS No.: 74811-65-7

Test	Specifications
Description/Appearance	1. A white or greyish-white powder as IP 2. White or greyish-white hygroscopic powder as EP/BP 3. White, free-flowing powder as USP
Solubility	1. Partially in water; insoluble in alcohol, in ether, and in other organic solvents as IP/USP 2. Practically insoluble in acetone, in anhydrous ethanol and in toluene as EP/BP
Identification Test-A	1. Settles as a blue, fibrous mass as IP/BP 2. Croscarmellose Sodium absorbs the methylene blue and settles as a blue, fibrous mass
Identification Test-B	A reddish-violet color develops at the interface as EP/IP/BP/USP
Identification Test-C	A dense white precipitate is formed as EP/IP/BP/USP
Ph	Between 5.0-7.0 as EP/IP/BP/USP
Sodium chloride & sodium glycolate	NMT 0.5 % as EP/IP/BP/USP. Water
Soluble substances	NMT 10.0 % as EP/IP/BP/USP
Loss on drying	NMT 10.0 % as EP/IP/BP/USP
Sulphated ash/Residue on Ignition	14.0 % to 28.0 % as EP/IP/BP/USP
Settling volume	10.0 ml-30.0 ml as EP/IP/BP/USP
Degree of substitution	0.60 to 0.85 as IP/USP, 0.65 to 0.85 as EP/BP
Heavy metals	NMT 20 ppm as IP
Micro biological Analysis	
Total Aerobic Microbial count, CFU/g	NMT 1000
Total Combined Yeasts & Molds count, CFU/g	NMT 100
Staphylococcus aureus/g	Should be absent
Pseudomonas aeruginosa/g	Should be absent
Escherichia coli/g	Should be absent
Salmonella /10g	Should be absent

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Your reference partner

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