PHARMATRANS SANAQ AG
PHARMACEUTICALS

SOLID DOSAGE FORMS EXCIPIENTS

MCC SANAQ® (Microcrystalline Cellulose)
For tablet and capsule formulations

SSG SANAQ® (Sodium Starch Glycolate)
A disintegrant and super for tablets, capsules and granules

MCC SILICIFIED SANAQ®
Mixture of microcrystalline cellulose and colloidal silicon dioxide

LUBRISANAQ® (Sodium Stearyl Fumarate)
High quality lubricant for tablet and capsule formulations

DICOM SANAQ® (Direct compression able mixture of Excipients)
High compressibility, superior dilution and desired disintegration time

PVP SANAQ® (Polyvinylpyrrolidone)
Binder for tablet and capsule formulations

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MCC SANAQ®

Microcrystalline Cellulose

Definition:

Microcrystalline Cellulose MCC SANAQ® is a purified and partially depolymerized α-cellulose. High standards in the selection of the raw material and the ingredients for the production of MCC SANAQ® and strict observation of the manufacturing guarantee a steady quality.

Applications :

MCC SANAQ® is mainly used as filling, binding and blasting material for tableting (direct tableting), as well as for dry and wet granulation and as filling material for hard gelatine capsules.

MCC SANAQ® fine grade types have an enormous swelling power to be used as stabilizers for suspensions.

MCC SANAQ® is used as filter material in separation technology.

MCC SANAQ® is suitable for cosmetics, as stabilizer for emulsions, as absorption and turbidity material and as viscosity regulator.

Characteristics

MCC SANAQ® is pure microcrystalline cellulose, which chemical and physical identities meet the international standards (Pharm Eur., USP/NF, JP, Kosher).

MCC SANAQ® has excellent compressibility. The outstanding plasticity enables to produce tablets with high temper and ultimate strength. At the same time the tablets have very short disintegration times. Its good flowing properties guarantee high production rates. High microbial purity, colour stability and excellent absorption properties of MCC SANAQ® lead to success in all tableting processes.

MCC SANAQ® is a nonreactive substance with homogenous particle size. This makes it ideal as filter Material in separation technology to guarantee results of high quality.

Standard Types :

MCC SANAQ® 101	standard grade and most widely used, especially for wet granulation
MCC SANAQ® 102	better flowability than 101, suited for direct compression
MCC SANAQ® 200	bigger particle size and better flowability than 102, suited for dirct compression

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SPECIFICATIONS

Microcrystalline Cellulose MCC SANAQ®

(USP-NF / Ph. EUR)

Type	101	102	102 HBD	103	112	113	200	1000	Test method
Description	Microcrystalline Cellulose is purified, partially depolymerized cellulose prepared by treating alpha cellulose, obtained as a pulp from fibrous plant material, with mineral acids.								
Appearance	White to almost white, fine or granular powder								
Odour	odourless								
Solubility	Practical insoluble in water, absolute ethanol, acetone and toluene								Ph. Eur.
Iodinated zink chloride solution (Ident. A)	passes								USP-NF/Ph. Eur.
Degree of Polymerization (Ident. B)	n.m.t. 350 DP units								USP-NF/Ph. Eur.
Particle Size									
+ 60 mesh	n.m.t. 1.0 %	n.m.t. 8 %	n.m.t. 8 %	n.m.t. 1.0%	n.m.t. 8.0%	n.m.t. 8.0%	n.l.t. 10.0%	n.m.t. 0.5%	
+ 100 mesh							n.l.t. 50.0%		
+ 200 mesh	n.m.t 30.0%	n.l.t. 45.0 %	n.l.t. 50.0 %	n.m.t. 30.0%	n.l.t. 45%	n.l.t. 45%		n.m.t. 20.0%	
Bulk density g/cm3	0.22 - 0.34	0.28 - 0.37	0.30 - 0.40	0.26 - 0.37	0.28 - 0.38	0.28 - 0.38	0.29 - 0.36	0.10 - 0.15	USP-NF
Loss on drying	n.m.t. 7.0 %	n.m.t. 7.0 %	n.m.t. 7.0 %	n.m.t. 2.0 %	n.m.t. 1.5 %	n.m.t. 1.5 %	n.m.t. 7.0 %	n.m.t. 7.0 %	USP-NF
pH value	5.0 - 7.5								USP-NF/Ph. Eur.
Conductivity	n.m.t. 75 µ S								USP-NF
Sulphate Ash /Residue on ignition	n.m.t. 0.1 %								USP-NF
Water soluble substances	n.m.t 0.25 %								USP-NF/Ph. Eur.
Ether soluble substances	n.m.t. 0.05 %								USP-NF/Ph. Eur.

The MCC SANAQ® has not come into contact with any organic solvents during the production, storage and delivery.

Microbiological Parameters		
Total aerobic count	n.m.t. 1000 CFU/g	USP-NF / Ph. Eur.
Moulds and yeasts	n.m.t. 100 CFU/g	USP-NF / Ph. Eur.
E. coli, Pseudomonas aeruginosa	negative in 10 g sample	USP/Ph. Eur.
St. Aureus, Salmonella species	negative in 10 g sample	USP/Ph. Eur.

Wet Granulation
Direct Compression
High Bulk Density Grade
Low Moisture Grade
Direct Compression & Superior Flow
High Dose Formulation & Reduced Tablet Size

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SSG SANAQ® Type A

Sodium Starch Glycolate

Definition

Disintegrant, Super Disintegrant

Applications

Swallowable tablet- Orally Dispersible tablet- Hard capsules

Characteristics

SSG is the sodium salt of cross-linked carboxymethyl starch. SSG is derived from starch with two chemical modifications

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PHARMACEUTICALS

SPECIFICATION

SSG SANAQ® Type A

Sodium Starch Glycolate

(USP/NF / Ph. EUR / JPE)

Appearance	A white or almost white, fine, free-flowing powder, very hygroscopic
Examined under microscope	Conformed to the test.
Solubility	Practically insoluble in methylene chloride. Atranslucent suspension in water
Identifications	
A. pH	Between 5.5 and 7.0
B. Suspension test	Suspension forms settles after standing.
C. Iodine test	The solution becomes blue to violet.
D. Sodium test	Dense white precipitate is formed.
Appearance of solution S1 Clear	The opalescence is not morepronounced than reference suspension I.
Colorless	Not more intensely colored than reference solution B9.
Sodium chloride	≤ 7.0 %
Sodium glycolate	≤ 2.0 %
Iron	≤ 20 ppm
Loss on drying	≤ 10.0 %
Microbial contamination	2.8 % ~ 4.2 % of sodium
Assay	400
Residual solvent (Methanol)	≤ 3000 ppm

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MCC SILICIFIED SANAQ®

Microcrystalline cellulose and silicone dioxide

Definition:

Combination of microcrystalline cellulose (MCC) and colloidal silicon dioxide (CSD).

Applications :

Tablets, film coated tablets,Oral dispersable tablets

Characteristics:

Co Processed mix developed to reduce some weakness of conventional binders including: low bulk density, poor flow, loss of compatibility, stickiness issues, and sensitivity to lubricants. When used for direct compression can significantly reduce the number of required excipients and formulations producing cost effective tablets.

Standard Types:

MCC SANAQ S 101
MCC SANAQ S 102
MCC SANAQ S 112

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SPECIFICATIONS

MCC SANAQ® S

Silicified Microcrystalline Cellulose

Type	101	102	112	Test method
Description	White or almost white, very fine to moderataly finde powder. It is a free-flowing material.			
Solubility	Slightly soluble in sodium hydroxide solution (1 in 20); practically insoluble in water, in acetone, in ethanol, in toluene, and in diluted acid.			
Identification				
Test-A (IR Absorption)	Should be comply			
Test-B	The substance tatkes on a violet-blue color should be produced			
Test-C	A deep Yellow color is produced			
Test-D (Silica dispersion uniformity test)	NMT 0.02			
Impurities				
Heavy Metals, µ/g	NMT 10			USP-NF
Specific Tests				
Residue on Ignition %	1.8 - 2.2			USP-NF
Particle Size				
+ 60 mesh	n.m.t. 1.0 %	n.m.t. 8 %	n.m.t. 8.0%	
+ 200 mesh	n.m.t 30.0%	n.l.t. 45.0 %	n.l.t. 45%	
Bulk density g/ml	0.28 - 0.33	0.25 - 0.37	0.25 - 0.37	USP-NF
Loss on drying	n.m.t. 7.0 %	n.m.t. 7.0 %	n.m.t. 1.5 %	USP-NF
pH value	5.0 - 7.5			USP-NF
Conductivity	n.m.t. 75 µ S			USP-NF
Sulphate Ash /Residue on ignition	n.m.t. 0.1 %			USP-NF
Water soluble substances	n.m.t 0.25 %			USP-NF
Ether soluble substances	n.m.t. 0.05 %			USP-NF
Microbiological Parameters				
Total aerobic count	n.m.t. 1000 CFU/g			USP-NF
Moulds and yeasts	n.m.t. 100 CFU/g			USP-NF
E. coli, Pseudomonas aeruginosa	absent			USP-NF
St. Aureus, Salmonella species	absent			USP-NF

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LubriSANAQ®

Sodium Stearyl Fumarate

Definition:

Tablet lubricant

Applications :

Designed for formulations in which other lubricants (i.e. Mg Stearate) lead to formulation and/or manufacturing challenges examples in effervescent tablets or granules solutions

Characteristics:

Designed to accelerate product development in particluarly for high-speed direct compression of tablets.

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SPECIFICATION

LubriSANAQ®

Sodium Stearyl Fumarate

(USP/NF / Ph. EUR / JPE)

Description	A white or almost white, fine powder
Identification	IR spectrum matches with reference standard
Solubility	Practically insoluble in water, slightly soluble in methanol, practically insoluble in acetone and in ethanol.
Water (By Karl Fischer)	N.M.T. 5.0 %
Saponification value	142.20 – 146.00, calculated on the dried basis
Impurity (TLC)	The solution becomes blue to violet.
Limit of sodium stearyl maleate	N.M.T. 0.25 %
Limit of stearyl alcohol	N.M.T. 0.5 %
Lead	N.M.T. 0.001 %
Heavy Metals	N.M.T. 0.002 %
Assay	99.00 % - 101.50 % calculated on the anhydrous basis
Related substances any impurity	N.M.T. 0.50 %
Loss on drying	≤ 10.0 %
Total Impurities	N.M.T. 0.50 %
Residual solvent	
Acetone	N.M.T 300ppm
Ethyl Acetate	N.M.T 300ppm
Toluene	N.M.T 300ppm
Methanol	N.M.T 300ppm

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DICOM SANAQ®

Co processed excipient Mix

Definition:

Combination of two or more compendial or non-compendial excipients designed to physically modify their properties without chemical change not leading to the formation of covalent bonds. The combination and selction of ingredients is designed to maximize performance their functionality.

Applications :

Tablets,oral dispersable tablets and film coated tablets. Indicated to aid processing during manufacture, enhance the stability and effectiveness during manufacturing product process.

Characteristics :

Mixtures with high compressibility,superior diluition properties and fast disitegrating time. The purpose of the excipient is to aid processing during manufacture, enhance stability or bioavailability.

Standard Types :

SANAQ® ML 011	Microcrystalline Cellulose + Lactose anhydrous
SANAQ® SL 004	Co processed of Starch +Lactose anhydrous
SANAQ® SP 204	Co Processed for traditional tablet formulation
SANAQ® SP 205	Co Processed for traditional tablet formulation
SANAQ® SP 206	Co Processed for traditional tablet formulation
SANAQ® SR 300	Co Processed for slow release formulation

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PHARMACEUTICALS

SPECIFICATIONS

DICOM SANAQ®

solutions for direct compression formulations

(USP/NF / JP / Ph. EUR)

Type	LS 004	ML 011	SP 204	SP 205	SP 206	SR 300
Composition	Lactose - Starch	MCC - Lactose	MCC - MgO2 -Starch - Pregelatizend starch - Sodium starch glycolate	MCC - Colloidal Silicon dioxide - Povidone K30 - Crosspovidone	MCC - Colloidal silicon dioxide - Polyvinyl pyrrolidone - Sodium starch glycolate	Hydroxypropyl Methylcellulose EC - MCC - HPC - Starch - Colloidal Silicon dioxide - Talcum - Mg Stearate"
Functionality	Diluent - Disintegrant	Diluent - Binder	Diluent and dry binder	Diluent	Diluent	Matrix type of tablets
Description	Off white free flowing granules	Off white free flowing granules	Off white free flowing granules	Off white free flowing granules	Off white free flowing granules	Off white free flowing granules
Particle Size	NMT 5.0% w/w Retained on 20# NLT 65.0% w/w Retained on 100# NMT 35.0% w/w Retained on 100#	NMT 5.0% w/w Retained on 20# NLT 65.0% w/w Retained on 100# NMT 35.0% w/w Retained on 100#	NMT 5.0% w/w Retained on 20# NLT 65.0% w/w Retained on 100# NMT 35.0% w/w Retained on 100#	NMT 5.0% w/w Retained on 20 # NLT 65% w/w Retained on 100 # NMT 35% w/w Passed through 100 #	NMT 5.0% w/w Retained on 20 # NLT 65% w/w Retained on 100 # NMT 35% w/w Passed through 100 #	NMT 5.0% w/w Retained on 20 # NLT 65% w/w Retained on 100 # NMT 35% w/w Passed through 100 #
Loss on drying	NMT 3.0%	NMT 3.0%	NMT 3.0 %	NMT 3.0 %	NMT 3.0 %	NMT 5.0 %
Bulk Density	0.5 – 1.0 g/mL	0.5 - 1.0 g/mL	0.5 – 1.0 g/mL	0.75 g/mL	0.75 g/mL	0.35-0.60 g/mL
Repose Angle		NMT 35°	NMT 35°			
pH (2% aq susp)	4.0 – 8.0	4.0 - 8.0	10.0 – 12.0	4.0 – 8.0	4.0 – 8.0	4.0 – 8.0
TAMC	< 1000 CFU/g	< 1000 CFU/g	< 1000 CFU/g	< 1000 CFU/g	< 1000 CFU/g	< 1000 CFU/g
TYMC	< 100 CFU/g	< 100 CFU/g	< 100 CFU/g	< 100 CFU/g	< 100 CFU/g	< 100 CFU/g
E. coli, Pseudomonas aeruginosa	negative in 10 g sample	negative in 10 g sample	negative in 10 g sample	negative in 10 g sample	negative in 10 g sample	negative in 10 g sample
St. Aureus, Salmonella species	negative in 10 g sample	negative in 10 g sample	negative in 10 g sample	negative in 10 g sample	negative in 10 g sample	negative in 10 g sample

Application fields

LS 004	Diluent - Disintegrant
ML 011	Diluent - Binder
SP 204	Designed for moisture sensitive APIs and where alkaline conditions are needed for stability purpose
SP 205	Designed for moisture sensitive and low bulk density and fluffy API's formulations.
SP 206	Designed for moisture sensitive and low bulk density and fluffy API's formulations
SR 300	Designed for modified release, matrix type of tablets

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PVP SANAQ®

Polvinylpyrrolidone

Definition:

Polyvinylpyrrolidone has the molecular formula of (C6H9NO)n and appears as a white to slightly off-white powder.

Applications :

It has multiple uses,as a binder for tablets,chewable tablets and capsules, a film former for ophthalmic solutions and as an adhesive for transdermal systems.

Characteristics:

Polyvinylpyrrolidone formulations are widely used in the pharmaceutical industry due to their ability to dissolve in both water.The k number refers to the mean molecular weight of the povidone.

Standard Types :

PVP SANAQ® K15
PVP SANAQ® K17
PVP SANAQ® K30
PVP SANAQ® K90

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SPECIFICATION

PVP SANAQ®

Polyvinylpyrrolidone

(USP/NF / Ph. EUR)

Type	K17	K25	K30	K90
Appearance	White or off white powder			
Solubility	Freely soluble in water in ethanol (96%) and in methanol, very slightly soluble acetone			
Appearance of Solution	Clearly and not more intensely colored than reference solution B6, BY6 or R6			
Identifications	Meet Requirements			
K value	15.3 - 18.4	22.5 - 27.0	27.0 - 32.4	81.0 - 97.2
Vinylpyrrolidone (Impurity A)	0.1			
	10			
Moisture % Max	5			
Solid content % Min	95			
pH value (5% n aqueours solution	3.0 - 5.0	3.0 - 5.0	3.0 - 5.0	4.0 - 7.0
Sulphate Ash % max	0.1			
Nitorgen content %	11.5 - 12.80			
2-Pyrrolidone (Impurity B) % max	3			
Aldehyde (as acetaldehyde) ppm max	500			
Heavy Metals ppm max	10			
Hydrazine ppm max	1			
Formic Acid % max	0.5			
Peroxidwe (As H2O2). ppm max	400			

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