



# SUNHERE

Pharmaceutical Excipients

**ANHUI SUNHERE PHARMACEUTICAL EXCIPIENTS CO.,LTD.**

CHINA • ANHUI



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# Company profile



SUNHERE

ANHUI SUNHERE PHARMACEUTICAL EXCIPIENTS CO., LTD. is the large and professional pharmaceutical excipients manufacturer in China, the national R&D base of the new type pharmaceutical excipients and the high-tech corporation. It has obtained the "Innovation Fund for Science & Technology" awarded by the Ministry of State Science & Technology. It is the executive director of China Association of Pharmaceutical Excipients, participates in editing Chinese Pharmacopoeia 2010. It is located in biological & pharmaceutical garden, economic & technological developing zone, Huainan city.

The main products of the corporation are pharmaceutical excipients and food additives etc. The production of the corporation strictly follows the requirement of GMP and performs the management of GMP. The products are sold all over more than thirty provinces in China and exported to Europe, America, and South- East Asia etc.



## Low-Substituted Hydroxypropyl Cellulose (Hydroxypropylcellulose, Low-Substituted/L-HPC)

**Comply with USP, BP, EP, CP**

Item	USP/BP/EP	CP
Identification	Conforms	
Loss on drying (%)	≤5.0	≤8.0
Residue on ignition/Sulfated ash (%)	≤0.5/0.8	≤1.0
Chlorides (%)	≤0.36	≤0.2
Heavy metals (%)	≤0.001	≤0.002
Assay (%)	5.0-16.0	
pH	5.0-7.5	
Iron (%)	---	≤0.010
Arsenic (%)	---	≤0.0002
Microbial limit	Conforms	

**Cas No.** 78214-41-2      **H. S.** 39129000

**Main Purpose:** Tablet binders and disintegrants.

**Package:** 20kg/kraft bag or 20kg/fiber drum

**Packing Size:** 1.8cbm/mt (bag) or D37cm\*H53cm (drum)

**G. W.** 20.2kg (bag) or 22.5kg (drum)

## Carboxymethylcellulose Sodium (CMC-Na)

**Comply with USP, CP**

Item	USP	CP
Identification	Conforms	
Assay(Na) (%)	6.5-9.5	
Heavy metals(ppm)	≤20	≤10
Viscosity (mPa. s)	600-3000 3000-5000 5000-15000 (Brookfield, 2%, 25°C)	75-140% (NDJ-1, 2%, 25°C)
pH	6.5-8.5	6.5-8.0
Clarity & colour of solution	---	Conforms
Loss on drying (%)	≤10.0	
Chloride (%)	---	≤1.0
Sulfate (%)	---	≤0.5
Silicate (%)	---	≤0.5
Iron (%)	---	≤0.016
Arsenic (%)	---	≤0.0003
Sodium glycolate (%)	---	≤0.4
Microbial limit	Conforms	

**Cas No.** 9004-32-4

**H. S.** 39123100

**Main Purpose:** Tablet binders and disintegrants.

**Package:** 25kg/kraft bag

**Packing Size:** 1.9cbm/mt

**G. W.** 25.2kg



## Croscarmellose Sodium

Comply with USP, BP, EP, CP

Item	USP/BP/EP	CP
Identification	Conforms	
pH	5.0-7.0	
Loss on drying (%)	≤10.0	
Na-chloride & Na-glycolate (%)	≤0.50	
Residue on ignition/Sulfated ash (%)	14.0-28.0	
Heavy metal (ppm)	≤10 / 20	
Degree of Substitution	0.60-0.85	
Content of Water-soluble Material (%)	≤10.0	
Settling Volume (ml)	10.0-30.0	
Particle size distribution	Conforms	---
Microbial limits	Conforms	

**Cas No.** 74811-65-7 **H.S.** 39129000

**Main Purpose:** Tablet and capsule disintegrant.

**Package:** 25kg/fiber drum

**Packing Size:** D37cm\*H53cm

**G.W.** 27.5kg



## Microcrystalline Cellulose (MCC-101)

Comply with USP, BP, EP, CP

Item	USP/BP/EP	CP
Identification	Conforms	
Solubility	Conforms	
pH	5.0-7.5	
Ether-soluble Substances (%)	≤0.05	≤0.05
Water-soluble Substances (%)	≤0.25	≤0.2
Heavy metal (ppm)	≤10	
Residue on Ignition/ Sulfated ash (%)	≤0.1	≤0.1
Loss on drying (%)	≤7.0	≤7.0
Bulk Density (g/cm <sup>3</sup> )	0.32-0.42	— —
Conductivity (μS/cm)	≤75	≤75
Chlorides (%)	— —	≤0.03
Starch	— —	Conforms
Arsenic (%)	— —	≤0.0002
Particle Size: Retained 60 mesh (250microns) (%) Retained 200 mesh (74 microns) (%)	≤1.0 ≤30.0	— —
Microbial limit	Conforms	

Cas No. 9004-34-6 H.S. 39129000

**Main Purpose:** Tablet and capsule diluent; tablet disintegrant.

**Package:** 20kg/kraft bag or 20kg/fiber drum

**Packing Size:** 2.2cbm/mt(bag) or D37cm\*H53cm(drum)

**G.W.** 20.2kg (bag) or 22.5kg (drum)



## Microcrystalline Cellulose (MCC-102)

Comply with USP, BP, EP, CP

Item	USP/BP/EP	CP
Identification	Conforms	
pH	5.0-7.5	
Ether-soluble Matter (%)	≤0.05	≤0.05
Water-soluble Matter (%)	≤0.25	≤0.2
Heavy metal (ppm)	≤10	
Residue on Ignition/ Sulfated ash (%)	≤0.1	≤0.1
Loss on drying (%)	≤7.0	≤7.0
Bulk Density (g/cm <sup>3</sup> )	0.32-0.42	— — —
Conductivity (uS/cm)	≤75	≤75
Chlorides (%)	— — —	≤0.03
Starch	— — —	Conforms
Arsenic (%)	— — —	≤0.0002
Particle Size: Retained 60 mesh (250microns)(%) Retained 200 mesh (74 microns)(%)	≤8.0 ≥45.0	— — —
Microbial limit	Conforms	

**Cas No.** 9004-34-6 **H.S.** 39129000

**Main Purpose:** Tablet and capsule diluent; tablet disintegrant.

**Package:** 20kg/kraft bag or 20kg/fiber drum

**Packing Size:** 2.2cbm/mt (bag) or D37cm\*H53cm(drum)

**G.W.** 20.2kg (bag) or 22.5kg (drum)



## Silicon Dioxide

Comply with USP, CP

Item	USP	CP
Identification	Conforms	
Particle Size (120mesh) (%)	---	≥85.0
Sulfate (%)	≤0.5	
pH	4.0-8.0	5.0-7.5
Loss on Drying (%)	≤5.0	
Assay (%)	≥99.0	
Chloride (%)	≤0.1	
Loss on Ignition (%)	≤8.5	
Heavy metal (ppm)	≤30	
Arsenic (%)	≤0.0003	
Iron (%)	---	≥0.015
Microbial limit	Conforms	

Cas No. 14464-46-1 H.S. 28112210

Main Purpose: Glidant; emulsion stabilizer; anticaking agent.

Package: 10kg/plastic woven bag

Packing Size: 5.0cbm/mt

G.W. 10.2kg

## Colloidal Silicon Dioxide/Silica, Colloidal Anhydrous

Comply with USP, BP, EP, CP

Item	USP	BP/EP	CP
Identification	Conforms	Conforms	Conforms
Apparent Volume (ml)	---	---	≥35
pH	3.5-5.5	3.5-5.5	3.5-5.5
Chlorides	---	≤250ppm	≤0.011%
Loss on Drying (%)	≤2.5	---	≤2.5
Assay (%)	99.0-100.5	99.0-100.5	99.0-100.5
Loss on Ignition (%)	≤2.0	≤5.0	≤2.0
Calcium	---	---	Conforms
Aluminum	---	---	Conforms
Iron (%)	---	---	≤0.015
Heavy Metals (ppm)	---	≤25	≤25
Arsenic (ppm)	≤8	---	≤3
Microbial limit	Conforms	Conforms	Conforms

Cas No. 7631-86-9 H.S. 28112210

Main Purpose: Glidant; emulsion stabilizer; viscosity-increasing agent; anticaking agent.

Package: 10kg/kraft bag with pallet or 10kg/carton

Packing Size: 15cbm/mt (bag) or D117cm\*W56cm\*H31cm (carton)

G.W. 10.3kg(bag) or 13kg(carton)



## Magnesium Stearate

Comply with USP, BP, EP, CP

Item	USP/BP/EP	CP
Identification	Conforms	
Acidity or Alkalinity	Conforms	
Loss on Drying (%)	≤6.0	≤5.0
Chloride (%)	≤0.1	≤0.10
Sulfate (%)	≤1.0	≤0.6
Lead (ppm)	≤10	---
Cadmium(ppm)	≤3	---
Nickel(ppm)	≤5	---
Relative Content of Stearic Acid and Palmitic Acid (%)	≥40.0 ≥90.0	
Assay (Mg)(%)	4.0-5.0	
Iron (%)	---	≤0.01
Heavy metals(ppm)	---	≤15
Microbial limit	Conforms	

**Cas No.** 557-04-0 **HS Code:** 29157090

**Main Purpose:** Lubricants, Anti-adhesive, Glidant.

**Package:** 10kg/kraft bag or 15kg/kraft bag; 10kg/fiber drum or 15kg/fiber drum

**Packing Size:** 2.8cbm/mt (bag) or D38cm\*H53cm (drum)

**G.W.** 10.2kg/15.2kg (bag) or 12.5kg/17.5kg (drum)

## Sodium Stearyl Fumarate

Comply with USP, BP, EP

Item	USP/BP/EP
Identification	Conforms
Water (%)	≤5.0
Lead (ppm)	≤10
Heavy metals(ppm)	≤20
Saponification Value(anhydrous basis)	142.2-146.0
Sodium Stearyl Maleate(%)	≤0.25
Stearyl Alcohol (%)	≤0.5
Assay (%)	99.0-101.5
Any impurity(%)	≤0.5
Total impurity(%)	≤5.0
Microbial limit	Conforms

**Cas No.** 4070-80-8 **HS Code:** 2917190090

**Main Purpose:** Enteric coating material.

**Package:** 25kg/fiber drum

**Packing Size:** D40cm\*H67cm

**G.W.** 28.5kg





## Maize Starch/Corn Starch

Comply with USP, BP, EP, CP

Item	USP/BP/EP	CP
Identification	Conforms	
pH	4.0-7.0	4.5-7.0
Loss on drying (%)	≤15	≤14
Residue on ignition /Sulfated ash (%)	≤0.6	≤0.2
Iron (%)	≤0.001	≤0.002
Oxidizing substances (%)	≤0.002	≤0.002
Sulfur dioxide (%)	≤0.005	≤0.004
Microbial limit	Conforms	

**Cas No.** 9005-25-8 **H.S.** 35051000

**Main Purpose:** Tablet and capsule diluent; tablet and capsule disintegrant; tablet binder.

**Package:** 25kg/kraft bag or 25kg/fiber drum

**Packing Size:** 1.8cbm/mt (bag) or D37cm\*H53cm (drum)

**G.W.** 25.2kg (bag) or 27.5kg (drum)

## Dextrin

Comply with USP, BP, EP, CP

Item	USP/BP/EP	CP
Identification	Conforms	
Acidity/pH	Conforms/2.0-8.0	Conforms
Reducing sugars (%)	≤10	≤0.2g
Loss on drying (%)	≤13.0	≤10.0
Residue on ignition /Sulfated ash(%)	≤0.5	≤0.5
Particle-size distribution	Conforms	—
Powder flow	Conforms	—
Apparent viscosity(mPa.s)	100-350	—
Chloride and sulfate /Chlorides(%)	≤0.2	—
Protein(%)	≤1.0	—
Heavy metals (ppm)	≤20	≤20
Iron (%)	—	≤0.005
Microbial limit	Conforms	

**Cas No.** 9004-53-9 **H.S:**35051000

**Main Purpose:** Tablet binders and fillers.

**Package:** 25kg/kraft bag

**Packing Size:** 1.7cbm/mt

**G.W.** 25.2kg



## Sodium Starch Glycolate

Comply with USP, BP, EP, CP

Item	USP/BP/EP	CP
Identification	Conforms	
pH	5.5-7.5(Type A) 3.0-5.0(Type B)	5.5-7.5
Sodium chloride (%)	≤7.0	≤6.0
Sodium glycolate (%)	≤2.0	≤2.0
Iron (%)	≤0.002	≤0.002
Heavy metals (ppm)	≤20	≤20
Loss on drying (%)	≤10.0	≤10.0
Assay(Na)(%)	2.8-4.2(Type A) 2.0-3.4(Type B)	2.0-4.0
Microbial limit	Conforms	

**Cas No.** 9063-38-1 **H.S.**35051000

**Main Purpose:** Tablet disintegrants.

**Package:** 25kg/kraft bag or 25kg/fiber drum

**Packing Size:** 1.7cbm/mt (bag) or D35cm\*H42cm (drum)

**G.W.** 25.2kg (bag) or 27.5kg (drum)

## Pregelatinized Starch (Pregelatinised Starch/Starch,Pregelatinised)

Comply with USP, BP, EP, CP

Item	USP/BP/EP	CP
Identification	Conforms	
pH	4.5-7.0	
Loss on drying (%)	≤14.0/ ≤15.0	≤14.0
Residue on ignition /Sulfated ash(%)	≤0.5/ ≤0.6	≤0.3
Iron (%)	≤0.002	
Sulfur Dioxide (%)	≤0.008/ ≤50ppm	≤0.004
Oxidizing substances/Oxidising substances (%)	Conforms	≤0.002
Foreign matter	Conforms	—
Cold-water-soluble matter	Conforms	—
Particle-size distribution	Conforms	—
Powder flow	Conforms	—
Particle size	—	Conforms
Microbial limit	Conforms	

**Cas No.** 9005-25-8 **H.S.**35051000

**Main Purpose:** Tablet binders, disintegrants and diluents.

**Package:** 25kg/kraft bag or 25kg/fiber drum

**Packing Size:** 1.7cbm/mt (bag) or D35cm\*H42cm (drum)

**G.W.** 25.2kg (bag) or 27.5kg (drum)



## Betadex

Comply with USP,BP,EP,CP

Item	USP/BP/EP	CP
Identification	Conforms	
Assay(%)	98-102/98.0-101.0	98.0-102.0
Specific rotation/Specific optical rotation	+160°~+164°/+160~+164	+159°~+164°
Light-absorbing impurities	$\leq 0.10(230-350\text{nm})$ $\leq 0.05(350-750\text{nm})$	
Related substances	Conforms	---
Color and clarity of solution/Appearance of solution	Conforms	
Water/Loss on drying (%)	$\leq 14.0/ \leq 16.0$	$\leq 14.0$
Residue on ignition/Sulfated ash (%)	$\leq 0.1$	$\leq 0.1$
Chloride (%)	---	$\leq 0.018$
Heavy metals (ppm)	$\leq 5/ \leq 10$	$\leq 10$
Reducing sugars (%)	$\leq 0.2$	$\leq 1.0$
pH	5.0-8.0	5.0-8.0
Related compounds(%)	$\leq 0.5$	---
Microbial limit	Conforms	

Cas No. 7585-39-9 H.S.35051000

Main Purpose: Solubilizing agents and stabilizers.

Package: 25kg/ fiber drum

Packing Size:D36cm\*H43cm

G.W. 27.5kg

## Soluble Starch

Comply with CP

Item	CP
Loss on drying (%)	$\leq 13.0$
Residue on ignition (%)	$\leq 0.5$
Iron (%)	$\leq 0.001$
Arsenic(%)	$\leq 0.0002$
pH	6.0-7.5
Reducing substance(%)	$\leq 5.0$
Oxidizing substance(%)	$\leq 0.002$
Chloride (%)	$\leq 0.15$
Heavy metals (ppm)	$\leq 20$
Ash(%)	$\leq 0.5$
Clarify of solution	Conforms
Sulfur dioxide	$\leq 0.004$
Microbial limit	Conforms

Cas No. 9005-84-9 H.S:35051000

Main Purpose: Tablet fillers,thickeners and stabilizers.

Package: 25kg/kraft bag

Packing Size:1.7cbm/mt

G.W. 25.2kg



## Povidone (PVP K30)

Comply with USP, BP, EP, CP

Item	USP / BP / EP	CP
Identification	Conforms	
pH	3.0-5.0	3.0-7.0
Water (%)	≤5.0	
Residue on ignition / Sulfated ash (%)	≤0.1	
Heavy metals (as Lead) (ppm)	≤10	
Aldehydes	≤0.05% / 500ppm	≤9.1ml
2-Pyrrolidone(%)	≤3.0	---
Vinylpyrrolidinone (%)	≤0.001	≤3.6ml
K-value	27-32	
Nitrogen content (%)	11.5-12.8	
Peroxides(ppm)	≤400	---
Formic Acid(%)	≤0.5	---
Hydrazine(ppm)	≤1	---
Microbial limit	Conforms	

Cas No.9003-39-8 HS Code: 39059900

Main Purpose: Disintegrant; Dissolution enhancer; suspending agent, tablet binder.

Package: 25kg/fiber drum

Packing Size: D38cm\*H53cm

G.W.27.5kg



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## Povidone (PVP K90)

Comply with USP,BP,EP

Item	USP/BP/EP
Identification	Conforms
pH	4.0-7.0
Water (%)	≤5.0
Residue on ignition/Sulfated ash (%)	≤0.1
Heavy metals (as Lead ) (ppm)	≤10
Aldehydes	≤0.05% / 500ppm
2-Pyrrolidone(%)	≤3.0
Vinylpyrrolidinone (%)	≤0.001
K-value	81-97.2
Nitrogen content (%)	11.5-12.8
Peroxides(ppm)	≤400
Formic Acid(%)	≤0.5
Hydrazine(ppm)	≤1
Microbial limit	Conforms

**Cas No. 9003-39-8 HS Code: 3905990000**

**Main Purpose:** Disintegrant; Dissolution enhancer; suspending agent, tablet binder.

**Package:** 25kg/fiber drum

**Packing Size:** D38cm\*H53cm

**G.W.27.5kg**



## Crospovidone(PVPP)

Comply with USP,BP,EP,CP

Item	USP/BP/USP	CP
Identification	Conforms	
pH	---	5.0-8.0
Loss on drying (%)	≤5.0	
Residue on ignition Sulfated ash(%)	≤0.1	
Heavy metals (ppm)	≤10	
Water-soluble substances (%)	≤1.5 / 1.0	≤1.0
Vinylpyrrolidinone (Impurity A)	≤10ppm	≤0.001%
Nitrogen content (%)	11.0-12.8	
Peroxides	≤400ppm	≤0.04%
Arsenic	---	≤0.0002
Microbial limit	Conforms	

Cas No. 9003-39-8 HS Code: 39059900

Main Purpose: Tablets, Granules, Pills, Disintegrants and fillers

Package: 20kg/fiber drum

Packing Size: D38cm\*H55cm

G.W.22.5kg

## Sugar Spheres

Comply with USP,BP,EP,CP

Item	USP/BP/EP	CP
Identification	Conforms	Conforms
Fineness	Conforms	---
Heavy metals (ppm/ ug/g)	≤5	≤5
Loss on drying (%)	≤4.0 / 5.0	≤4.0
Residue on ignition/ Sulfated ash (%)	≤0.25 / 0.2	≤0.2
Assay(sucrose content) (%)	62.5-91.5 / ≤92	Conforms
Particle size distribution	Conforms	Conforms
Specific rotation	+41°to +61°	---
Microbial limit	Conforms	

H.S:3824909990

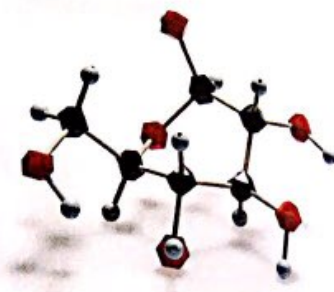
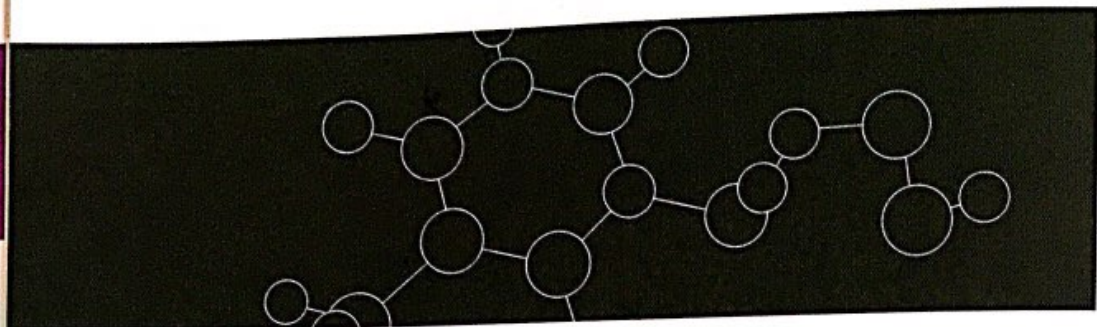
Main Purpose: Necessary stripping masterbatch to produce skeleton type pellets.

Package: 5kg/fiber drum or 25kg/fiber drum

Packing Size: D30cm\*H33cm or D35cm\*H42cm

G.W. 6kg or 27kg





## Polyacrylic Resin II / III (Methacrylic Acid Copolymer)

Comply with CP

Item	CP (Polyacrylic Resin II)	CP (Polyacrylic Resin III)
Character	White strip or powder , caked easily in ethanol.	
Solubility	Dissolved in warm ethanol within 1h, and insoluble in water. (Strip off the growth of about 1cm, powder is not grind.)	
Viscosity(mPa.s,25°C)	≤50	
Acid value	300-330	210-240
Identification	Conforms	
pH	4.0-6.0	
Loss on drying (%)	≤10.0	
Heavy metals(ppm)	≤30	
Arsenic(%)	≤0.0002	
Microbial limit	Conforms	

H.S.3906909090

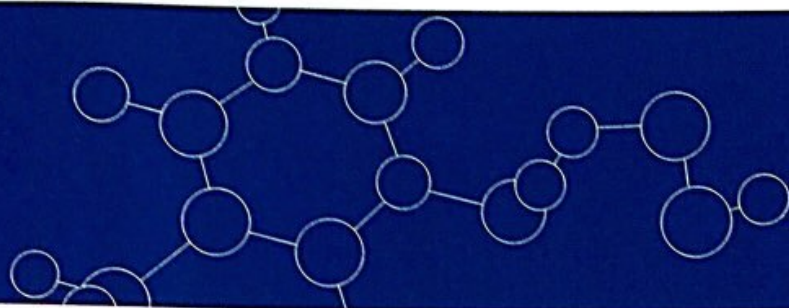
**Main Purpose:** Enteric soluble coating material.

**Package:** 5kg/kraft bag

**Packing Size:** 6cbm/mt

**G.W.** 5.2kg





## Polyacrylic Resin IV (Methacrylic Acid Copolymer)

### Comply with CP

Item	CP
Character	Light yellow granular or flaky solid ; special smell.
Solubility	Dissolved in warm ethanol within 1h, Slightly soluble in hydrochloric acid solution(9→1000) within 1h, and insoluble in water.
Relative density	0.810-0.820
Refractive index	1.380-1.395
Viscosity(mPa.s, 30℃, NDJ-79 Viscosimeter)	5-20
Alkalinity value	162.0-198.0
Identification	Conforms
Color of the solution	≤0.20
Loss on drying(%)	≤4.0
Residue on ignition(%)	≤0.2
Heavy metals(%)	≤0.001
Arsenic(%)	≤0.0002
Microbial limit	Conforms

**H.S.3906909090**

**Main Purpose:** Gastric soluble coating material.

**Package:** 10kg/fiber drum

**Packing Size:** D35cm\*H42cm

**G.W.** 12.5kg





**Polyethylene Glycol 6000 (PEG 6000)**
**Comply with USP,CP**

Item	USP	CP
Appearance(25°C)	Flakes or fine powder	White waxy and flake solid or granular powder, a little special slight smelling.
Identification	Conforms	
Average Molecular Weight	5400-6600	5400-7800
Residue on ignition (%)	≤0.10	≤0.1
Kinematic Viscosity ( mm <sup>2</sup> /S )	---	10.5-16.5
pH(5%)	4.5-7.5	4.0-7.0
Color and Clarity of solution	---	Colorless and clear
Freezing Point (°C)	---	53-58
Hydroxyl Value ( mgKOH/g)	---	16-22
Moisture(%)	---	≤1.0
EO (%)	---	≤0.0001
Dioxane (%)	---	≤0.001
Formaldehyde (%)	---	≤0.003
Heavy Metals (ppm)	---	≤5
Free Ethylene Oxide (ug/g)	≤10	---
1,4-Dioxane (ug/g)	≤10	---
Completeness and Color of Solution	Conforms	---
Viscosity (mPa.s, 98.9±0.3°C, mm <sup>2</sup> /s)	250-390	
Microbial limit	Conforms	

**H.S. 3404200000**
**Main Purpose:** The matrix of ointment and suppository, lubricant of tablet and capsules.

**Package:** 25kg/fiber drum

**Packing Size:** D35cm\*H46cm

**G.W. 27.5kg**
