

ASCB20230525-05

PRODUCT CATALOGUE

TO SUPPLY SUPERIOR EXCIPIENTS
FOR HUMAN HEALTH

ALPHA

Jiangxi Alpha Hi-Tech Pharmaceutical Co., Ltd.

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Glyceryl Monostearate	123-94-4	F20200000199	✓
Glyceryl Mono-and Distearate	1323-83-7	F20200000334	✓
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Oleyl Oleate	3687-45-4	F20210000350	USP
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◆ About us

Founded in 2009, Jiangxi Alpha Hi-tech Pharmaceutical Co., Ltd is specializing in R&D, manufacturing pharmaceutical excipients in China. The plant implement cGMP guideline, inspected by Provincial FDA every year. We adopt state-of-the-art production technology and our product quality strictly conforms to current CP/USP-NF/BP/EP/JP etc, Certificates are supported like GMP, ISO9001, ISO14001, ISO45001, HALAL, etc. Let's go hand in hand, mission-accomplish guarantee, to provide superior quality excipients for human health.

◆ Our service

- ✓ Customized excipients
- ✓ Technical services for drug development and conformance evaluation
- ✓ Strict quality control, conform to international standards, meet multiple applications
- ✓ Free samples
- ✓ Support site audit from customer and official

◆ Culture

- Goals: Safety, environmental, social responsibility, quality and efficiency.
- Alpha takes responsibilities for human beings and environment.
- Corporate benefits are social benefits.
- To supply superior excipients for human health.

◆ What we support:

- CP, EP, USP-NF, JP, BP
- Letter of authorization
- BSE/TSE/GMO-Free/Residual Solvents Statement/Elemental Impurity Statement
- GMP certificate/ISO9001/ISO14001/I-SO45001/HALAL

◆ Quality assurance system



◀ Croscarmellose Sodium



Appearance

White or off-white powder; hygroscopic. This product swells in water and forms a suspension. It is insoluble in absolute ethanol, ether, acetone or toluene.

Advantages

- ✓ Excellent hydration and rapid expansion
- ✓ Customized particle size based on requirements
- ✓ Excellent disintegrating effect, promoting drug dissolution

CODE	Specification	In-house specification
AG1301	CP/USP /EP/JP	Ethanol 0.5%;
		D10: 25um max; D50: 25-55um; D90: 60um max
AG1302	CP/USP /EP/JP	Ethanol 0.01%;
		D10: 25um max; D50: 25-55um; D90: 60um max

CAS No.: 74811-65-7
CDE REGISTRATION NO.: F20209990136
Quality Standard: CP2020, USP43-NF38,
EP10.0, JP
Packaging: 5kg/bag, 25kg/drum

Application

Examples

Highly effective disintegrants, commonly used in dispersible tablets

Finasteride Dispersible Tablets

Swelling materials, for pulse tablets

Triazolam Pulse Tablets

Others such as solid dispersion carriers, etc



◀ Sodium Stearyl Fumarate

Appearance

White to off-white powder or granule. Almost insoluble in water, slightly soluble in methanol, insoluble in acetone and anhydrous ethanol.

CAS No.: 4070-80-8

Quality Standard: CP2020; USP43-NF38; EP10.0.

CDE REGISTRATION NO.: F20190000009

Packaging: 1kg/bag, 5kg/carton, 20kg/drum.



Advantages

- ✓ Better flow aid
- ✓ Hydrophilic glidant, benefit for disintegration and dissolution
- ✓ Lower solvent residues such as toluene and acetone, better than imported similar products
- ✓ Suitable for tablets with more fat-soluble ingredients or limited to magnesium stearate

Application

- ✓ As lubricants for tablets and capsules with a concentration of 0.5 ~ 2.0% (w/w).
- ✓ It can form a protective coat film in effervescent tablets.
- ✓ As this product has one fatty chain less and one hydrophilic group more compared with magnesium stearate, so it can solve the slow dissolution of magnesium stearate as lubricant.
- ✓ Suitable for lubricants ofazole drugs, which are easy to react with magnesium stearate and cannot use magnesium stearate as lubricant.
- ✓ As a regulator and stabilizer, such as baked foods, floured thickened foods, baked potatoes and processed grains, with dosage for 0.2 %~ 1.0% of the food weight.

◆ Polyvinyl Alcohol

CAS No. : 9002-89-5
CDE REGISTRATION NO. : F20209990114
Quality Standard : CP2020; USP43-NF38;
EP10.0; JP17; GB31630-2014
Packaging: 1kg/bag, 5kg/carton, 25kg/drum

- ☑ White to yellowish powder or translucent granule.
- ☑ Medium soluble in ethanol, slightly soluble in acetone, almost insoluble in acetone.
- ☑ The solubility of PVA XY -88 model is good in hot and cold water.

Appearance

Product code:

AG0601	03-88 Granule	Viscosity 3.0-3.6
AG0602	03-88 Powder	Viscosity 3.0-3.6
AG0603	05-88 Granule	Viscosity 4.5-6.0
AG0604	05-88 Powder	Viscosity 4.5-6.0
AG0605	17-88 Granule	Viscosity 20-26
AG0606	17-88 Powder	Viscosity 20-26
AG0607	24-88 Granule	Viscosity 44-56
AG0608	24-88 Powder	Viscosity 44-56
AG0609	20-88 Granule	Viscosity 28-35
AG0614	04-88 Granule	Viscosity 3.7-4.5

Application

- ☑ As a film-forming material in coating agent/ spray agent/ film-coated agents
- ☑ As thickening agents, and suspending agents in eye drops
- ☑ As binder in tablets and granules
- ☑ As base material in gel dosage forms or emplastrum
- ☑ As emulsifiers/emulsification stabilizers in o/w emulsions due to its good suspending effect
- ☑ As a coating material for food additives



◆ Partially Neutralized Polyacrylate

White powder, almost insoluble in ethanol or ether, slowly dissolves into a thick liquid when dispersed with water.

Appearance

- ☑ High thermal stability, no decomposition when heated to 300 °C .
- ☑ Long term storage with low viscosity changes and less susceptibility to spoilage.

Advantages

CAS No. : 9033-79-8

Quality Standard: Enterprise Standard

Packaging: 5kg/drum, 20kg/drum

Application

Application Scene

Product

Drug formulations

Cataplasm Gel patch

Ibuprofen, flurbiprofen, lidocaine, piroxicam, indomethacin, lidocaine, loxoprofen, lidocaine, rivastigmine, diclofenac, propofol, etc.

Medical instruments

Pediatric fever patch

Quasi-drugs like cooling sheets and packs

Cosmetic Materials

Facial mask Cold compress

Used as thickeners in emulsions, creams, lotions, tonics, and other cosmetic products. We are able to formulate hydrous gels into sheet-shaped packs by combining different sodium polyacrylates and cross-linkers.

◆ Medium-chain Triglycerides

- ☑ This product is colorless or light yellow oily liquid, odorless, tasteless, freezing point is about 0°C.
- ☑ It can be miscible with methylene chloride, petroleum ether or soybean oil. It is easily soluble in methanol and almost insoluble in water.

Appearance

CDE REGISTRATION NO.: F20220000316

CAS No.: 73398-61-5(or85409-09-2)(or538-24-9)

Quality Standard: CP2020; CP2020; USP43-NF38; EP10.0; In-house specification

Packaging: 5kg/bottle, 4bottles/carton, 20kg/carton

Advantages

- ☑ Good solvent for fat soluble drugs, and is not easy to oxidize, good compatibility with drugs.
- ☑ Better spreading performance on the skin, does not affect the skin breathability;
- ☑ Good skin moisturizing effect, promote the penetration and release of drugs;
- ☑ High quality raw materials and excellent refining process, the product is colorless and transparent, stable and reliable quality.



Application

- ☑ In oral preparations, Medium-chain Triglycerides are used as a substrate for the preparation of oral emulsions, microemulsions, self-emulsifying systems, solutions or suspensions of drugs in unstable or insoluble media, such as alfalcalcidol. MCT can also be used as an intestinal absorption promoter or as a lubricant or anti-stick agent in common tablets.
- ☑ In topical pharmaceutical preparations, medium chain triglycerides can be used as oil-soluble substrates for ointments, creams and liquid emulsions.
- ☑ MCT is widely used in food, veterinary injection and cosmetics.

◆ Glycerol Dibehenate

CAS No.: 77538-19-3

CDE REGISTRATION NO.: F20209990110

Quality Standard: ChP2020; USP43-NF38; EP10.0; GB1886.65-2015

Packaging: 1kg/bag, 5kg/carton, 25kg/drum

Appearance

- ☑ White or off-white powder or hard wax block; it has a slight odor.
- ☑ Soluble in chloroform and almost insoluble in water or ethanol.

Benefits

- ☑ Spherical particles with good fluidity
- ☑ Very low acid value, conducive to preservation
- ☑ Stable and uniform sustained-release matrix materials and taste-masking materials
- ☑ Repeatable to granulate still with good performance

Application

Application	Dosage/%	Examples
Sustained release skeleton material	>10.0	Loratadine and Pseudoephedrine Sulfate Sustained Release Tablets
Fat-soluble coating material	>10.0	
Lubricants for tablets, etc	1.0-3.0	Captopril Tablets
Taste-masking agent		Amoxicillin Dry Suspension
Adhesives for tablets, etc	1.0-3.0	
Thickeners for gels, emulsions, etc	1.0-15.0	



Chlorobutanol Hemihydrate

CAS No. : 6001-64-5
CDE REGISTRATION NO. : F20209990112
Quality Standard : CP2020 ; USP43-NF38;
EP10.0; BP2017; JP17
Packaging: 1kg/bag, 5kg/bag, 25kg/drum



Appearance

White crystal powder; it has special odor resembling camphor; Easy to sublimate. Soluble in ethanol, chloroform, ether or volatile oil, slightly soluble in water.

Product code	Specification	Description
AG0401	Hemihydrate CP2020; USP43-NF38; EP9.0; BP2017; JP17	
AG0402	Hemihydrate EP10.0; BP2020	Low related substances Low residual solvents Low endotoxin control
AG0404	Anhydrous EP10.0; BP2020	

Application

- ☑ Used as a preservative in pharmaceuticals, the commonly used concentration is 0.5% (W/V).
- ☑ Widely used as preservatives in ointment, ophthalmic preparations and veterinary injections and especially suitable for non-aqueous preparations.
- ☑ Antifungal and antibacterial, effective against Gram-positive and Gram-negative bacteria and some fungi, such as *Candida albicans* and *Pseudomonas aeruginosa*.
- ☑ The antibacterial activity is bacteriostatic rather than bactericidal. When the pH is greater than 5.5, the activity decreases significantly.



Ethyl Oleate

- ☑ Colorless to pale yellow clear liquid.
- ☑ Almost insoluble in water, miscible with ethanol, dichloride methane or petroleum ether. It can be miscible with isopropanol in any proportion.

CAS No. : 111-62-6

CDE REGISTRATION NO.: F20209990135

Quality Standard: CP2020; EP10.0; USP43-NF38;
BP2020; GB 29938-2013

Packaging: 1kg/bottle, 5kg/drum, 20kg/drum, 180kg/drum

Application

- ☑ Used as a solvent, a transdermal absorption enhancer, a lubricant and a plasticizer in formulations.
- ☑ A suitable solvent for steroids and other lipophilic drugs. Widely used in veterinary injections such as Cefquinome sulfate, enrofloxacin. Its properties are similar to almond oil and peanut oil, and its viscosity is low, and it is easily absorbed by body tissues.
- ☑ Used as biodegradable microcapsules and microemulsions of cyclosporine implanted under the dermis.
- ☑ As the solvent of flavor oil, the carrier of essence fragrance in field of food additives.

Application	Examples
Veterinary drug injection	Cefquinome sulfate injection; Enrofloxacin injection; Avermectin injection
Transdermal absorption enhancer	Compound Estradiol Patch

◆ Polyethylene Oxide

CAS No.: 25322-68-3

CDE REGISTRATION NO.: F20220000511

- ☑ White to off-white, free-flowing powder; with a slight ammonia odor. Soluble in water and many common organic solvents, such as acetonitrile, chloroform, dichloromethane, insoluble in aliphatic hydrocarbons, ethylene glycol and ethanol.

Appearance

Advantages

- ☑ Wide range of molecular weights makes the formulation more flexible.
- ☑ Low toxicity when applied to various drug delivery routes.
- ☑ Hydrate quickly to form a gel when applied to hydrophilic matrix tablets.

Application

Dosage

Sustained release material

10-30%

Binder

1-10%

Alpha Code	Labeled average molecular weight	Dynamic viscosity (mPa · s) Polyethylene Oxide(g)/(Water+Isopropyl alcohol)(ml)
PEO-10	100 000	12—5030g/(570+125)
PEO-20	200 000	65—11530g/(570+125)
PEO-40	400 000	2250—4500(5% aqueous solution)
PEO-60	600 000	4500—8800(5% aqueous solution)
PEO-90	900 000	8800—17600(5% aqueous solution)
PEO-100	1 000 000	400—800(2% aqueous solution)
PEO-200	2 000 000	2000—400012g/(588+125)
PEO-400	4 000 000	1650—5500 (1% aqueous solution)
PEO-500	5 000 000	5500—75006g/(594+125)
PEO-700	7 000 000	7500—10 0006g/(594+125)

◆ Extended-release materials

Hydrogenated
Castor Oil

CAS No.: 8001-78-3

Hydrogenated
Soybean Oil

CAS No.: 8016-70-4

Hydrogenated
Vegetable Oil

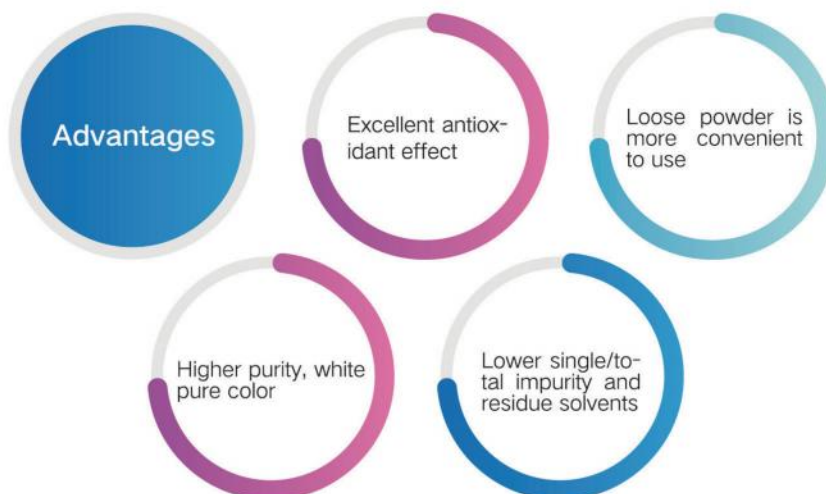
CAS No.: 68334-28-1

Glyceryl
Behenate

CAS No.: 30233-64-8

◆ Antioxidants

Butylated Hydroxytoluene;
Butylated Hydroxyanisole



◆ Antibacterial agent

Antibacterial agent

Chlorobutanol Hemihydrate	<ul style="list-style-type: none">✓ Low related substances✓ Very low residual solvents and endotoxin control✓ Conform to EP10.0/NF38/CP2020/JP17✓ Provide excipient grade and parenteral use model.
Benzyl Alcohol	<ul style="list-style-type: none">✓ Low related substances✓ Very low residual solvents and endotoxin control✓ Provide excipient grade and parenteral use model.✓ Conform to EP10.0/NF38/CP2020
Benzalkonium Chloride	<ul style="list-style-type: none">✓ Compounds, Conform to CPUSPEP✓ Component: C12 > 40%, C14 > 20%, C12+C14 > 70%✓ Low impurities: Benzyl Alcohol <0.5%, Benzaldehyde <0.15%, Benzyl Chloride <0.05%✓ Customized powder form
Thymol	
Methylparaben	
Propylparaben	

◆ Veterinary materials

☑ Preservative for injections use

Chlorobutanol Hemihydrate

☑ Solvent for injections use

Ethyl Oleate

☑ Suspending agent in injections, provide different content of Aluminum.

Aluminum Monostearate

◆ Food additives/Nutraceutical /Supplement use



Ethyl Oleate

Glyceryl Dibehenate

Polyvinyl Alcohol

Medium-Chain Triglycerides

◆ Cosmetic materials

Glyceryl Dibehenate

As Emulsifier.

Partially Neutralized Polyacrylate

As thickeners in emulsions, creams, lotions, tonics.

Medium-Chain Triglycerides

As oil-soluble substrates for ointments, creams and liquid emulsions.

• Contact us



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