Intelligent manufacturing of
ecomaterials to serve human health.

For more detailed product information,
please pay attention to the public account of
"Well Pharmaceutical Material Technology Service".

Nanjing Well Pharmaceutical Group Co., Ltd

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南京威尔药业集团股份有限公司
Nanjing Well Pharmaceutical Group Co., Ltd

Introduction of Nanjing Well Pharmaceutical Group Co., Ltd.

Nanjing Well Pharmaceutical Group Co., Ltd. (stock code: 603351) was established in 2000. The company adheres to 70 years of fine chemical synthesis technology experience and is committed to R&D and manufacture of pharmaceutical materials, base oils of advanced synthetic lubricant, new pesticide additives, animal health care, etc. With professional customization, continuous innovation, benefiting mankind, and pursuit of excellence as the corporate mission, we have been making great efforts to build a technology brand of our own. The group has 10 subsidiaries, which are distributed in Nanjing, Yangzhou and other cities in China.

Nanjing Well Pharmaceutical Technology Co., Ltd. is a wholly-owned subsidiary of the Group, and it is a new R&D and manufacture center for pharmaceutical excipients and APIs of the Well Group. The project is located in Nanjing Jiangbei New Material Science and Technology Park, covering an area of about 134 acres, with more than 200 employees, and a total investment of over RMB 700 million. From the initial design, construction to brought into operation, the project thoroughly implements the concepts of automation, efficiency, safety, reliability and environmental friendliness. It aims to build a world-class full-process automation factory and is committed to providing customers with high-quality, safe and reliable products. 15 synthetic production lines and 7 GMP clean packaging lines have been built, which can achieve an annual output of more than 20,000 tons of pharmaceutical excipients and APIs.

We have passed ISO9001/14001/45001 certifications, and develop pharmaceutical excipients and API in accordance with GMP Guidelines, Quality Management Practices for Pharmaceutical Excipients, and IPEC-PQG Guidelines for Pharmaceutical Excipients, carrying out manufacture quality management of pharmaceutical excipients and APIs to ensure the stability and controllability of quality.

We are committed to the technical research and standard improvement of pharmaceutical excipients and APIs. Especially the research on excipients for injection has been positioned at the forefront of the industry, making positive contributions to the quality improvement of pharmaceutical excipients and the realization of safety, effectiveness and quality controllability of pharmaceutical excipients.

We will continue to drive development ideas with innovation, pay attention to the demand of customers, implement the corporate philosophy of "considering for you, helping you succeed", provide you with high-quality and safe pharmaceutical excipients and technical services, and strive to become an "well-known brand of pharmaceutical excipients abroad", "Top brand of excipients for injection in China".

Introduction of WELL R&D Institute

The R&D Institute of Nanjing Well Pharmaceutical Group located in the Nanjing Jiangbei New Material Science and Technology Park, focuses on the R&D and application research of new materials such as pharmaceutical excipients, APIs, lubricating materials, vaccine adjuvants and synthetic biological products, etc. The R&D Institute has successively undertaken a number of national and provincial research projects, and participated in drafting and revising the specifications of several excipients in the CHP and USP.

The R&D institute actively promoted the concept of innovative development, established co-operate laboratories with famous universities or authoritative drug control institutes. Research platforms such as NMPA Key Laboratory for Research and Evaluation of Pharmaceutical Preparations and Excipients, Joint Innovation Center of Jiangsu Industrial Technology Research Institute, Provincial Engineering Technology Research Center, Foreign Expert Studio, CNAS Analysis Laboratory, etc. have been established. The R&D Institute provide powerful support for product development, quality improvement and pharmaceutical application research, etc. We do our best to assist customers in new drug application (NDA), abbreviated new drug application (ANDA) and Consistency Evaluation of Generic Drug. We are dedicated to deliver better customer service and wish to bring maximum benefits for all of our clients.

18+Million USD
Research Investment of Recent 3 Years

15000+m²
Area of Research Laboratories

130+
Number of Researchers

57
Number of excipients registered

30+
Projects under development

91/50
Number of Patents Applied /Authorized

CONTENTS

CONTENTS

EXCIPIENTS
FOR INJECTION

Excipients for Injection

01 | Polysorbate 80（For Injection）

CAS number: 9005-65-6
CDE registration number: F20190001857（A）
FDA DMF: 35699
CEP: R0-CEP2020-419-Rev 00
Pharmacopoeia specification compliance: USP/EP/JP/ChP
Storage: In an airtight container, protected from light.

一、Properties and Benefits

- Comply with the specifications of current EP, USP and JP.
- Using high-purity raw materials derived from plants, product can withstand terminal sterilization, and the product has good batch-to-batch repeatability.
- Lower acid value, peroxide value and water content compared with non-injectable grade.
- Bacterial endotoxins and micro-organisms or sterility are strictly controlled, meet the requirements of parenteral dosage forms.

二、Applications

- Nonionic surfactant, solubilizer, wetting agent, plasticizer. It also can be used as oil-in-water emulsifier.

三、Safety Evaluation

- Compared with non-injectable polysorbate 80, polysorbate 80 (For Injection) did not show hemolysis and erythrocyte aggregation at the final concentration of 0.5mg/mL in the test system.
- Polysorbate 80 (For Injection) simulated the highest clinical concentration, and after injection into the ear vein of New Zealand rabbits, no obvious pathological changes appeared, which proves that the product is not irritating to blood vessels.
- Compared with non-injectable polysorbate 80, in the guinea pig active allergy test, the polysorbate 80 (For Injection) administration group had no abnormal reaction symptoms, and no toxicological significance change of hematology, coagulation, blood biochemical and other indicators.
- The maximum tolerated dose (MTD) of polysorbate 80 (For Injection) was significantly higher than that of non-injectable polysorbate 80.
- The above research conclusions come from a safety evaluation center with GLP qualification.

02 | Polysorbate 20（For Injection）

CAS number: 9005-64-5
CDE registration number: F20190001866（A）
FDA DMF: 36565
Pharmacopoeia specification compliance: USP/EP/ChP
Storage: In an airtight container, protected from light.

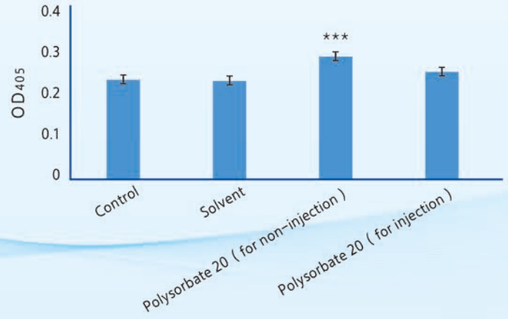
一、Properties and Benefits

- Comply with the specifications of the current EP and USP.
- With the precise polymerization technology and high-efficiency directional esterification technology, the composition is stable and the batch-to-batch variability is reduced.
- Compared with non-injectable grade, the acid value, peroxide value and water content are even lower.
- Compared with non-injection grade, it significantly improves safety and reduces the incidence of allergic reactions (see the figure below).

二、Applications

- Nonionic surfactants, solubilizers, wetting agents.
- Widely used as an emulsifier for oil-in-water pharmaceutical emulsions.

Evaluation of the allergic reaction of polysorbate 20 in zebrafish



03 | Sorbitan Trioleate（Span 85）

CAS number: 26266-58-0
CDE registration number: F20180000112
Pharmacopoeia specification compliance: USP/EP/ChP
Storage: In an airtight container, protected from moisture.

一、Properties and Benefits

- By high-efficiency directional esterification technology, the composition is stable and the batch-to-batch variability is reduced.
- Low peroxide value, good storage stability.
- Bacterial endotoxins and micro-organisms are strictly controlled, meet the requirements of parenteral dosage forms.

二、Applications

- Emulsifier, liquid water-in-oil emulsifier and oil-in-water emulsion stabilizer.
- Non-ionic surfactant and emulsifier, can be used in biological products, such as a component of vaccine adjuvant MF59.

04 | Polyoxyl（35）Castor Oil（For Injection）

CAS number: 61791-12-6
CDE registration number: F20190001865（A）
Pharmacopoeia specification compliance: USP/EP/ChP
Storage: In an airtight container, protected from light.

一、Properties and Benefits

- The raw material is refined castor oil, with light color and high purity.
- Narrow molecular weight distribution, good batch-to-batch repeatability.
- Low impurities content to ensure product application safety. Hemolysis and allergic reactions are rare.
- Bacterial endotoxins and micro-organisms are strictly controlled, meet the requirements of parenteral dosage forms.

二、Applications

- Nonionic surfactants, emulsifiers, solubilizers, particularly suitable for liquid preparations.
- It can be used effectively in self-emulsifying drug delivery systems (SEDDS), enhance solubility and bioavailability of APIs.

05 | Polyoxyl 15 Hydroxystearate

CAS number: 70142-34-6
CDE registration number: F20180000588
Pharmacopoeia specification compliance: USP/EP
Storage: In an airtight container.

一、Properties and Benefits

- Comply with the specifications of the current USP and EP.
- Low impurities content, e.g. ehtylene oxide, dioxane, ethylene glycol, diethylene glycol, etc.
- Good product stability and can withstand terminal sterilization to ensure application safety.
- Bacterial endotoxins and micro-organisms are strictly controlled, meet the requirements of parenteral dosage forms.

二、Applications

- Non-ionic solubilizer, emulsifier, potent surfactant.
- Safe and Suitable for parenteral and ophthalmic drugs.

06 Oleic Acid（For Injection）

CAS number: 112-80-1
CDE registration number: F20190001867（A）
Pharmacopoeia specification compliance: USP/EP
Storage: In an airtight container, protected from light, at 4 ~ 8 ℃.

一、Properties and Benefits

- The raw material is of plant origin, with good safety.
- High purity, low impurities content, and good batch-to-batch repeatability.
- Bacterial endotoxins and micro-organisms are strictly controlled, meet the requirements of parenteral dosage forms.

二、Applications

- As a co-emulsifier in lipid emulsions, it can improve the emulsification effect and enhance the stability of the emulsion.
- It can also be used as an emulsifier and transdermal penetration enhancer in topical preparations.

07 Sodium Oleate（For Injection）

CAS number: 143-19-1
CDE registration number: F20190001870（A）
Pharmacopoeia specification compliance: ChP
Storage: In an airtight container, protected from light, in a cool place.

一、Properties and Benefits

- The raw material is of plant origin, with good safety.
- The product has high purity, low impurities content, and good batch-to-batch repeatability.
- Bacterial endotoxins and micro-organisms are strictly controlled, meet the requirements of parenteral dosage forms.

二、Applications

- As a co-emulsifier in lipid emulsions, it can improve the emulsification effect and enhance the stability of the emulsion.

08 Egg Yolk Lecithin（For Injection）

This product is a mixture of phospholipids, the main components are phosphatidylcholine (PC), phosphatidylethanolamine (PE) and phosphatidylinositol (PI), etc. The product can be classified into several types according to the content of PC and PE, such as EPC 70, EPC 80, EPC 90 and EPC 96.

CAS number: 93685-90-6.97281-44-2

CDE registration number: F20190001473（A）

Pharmacopoeia specification compliance: USP/EP/ChP

Storage: In an airtight container, protected from light, at −18 ℃ or below.

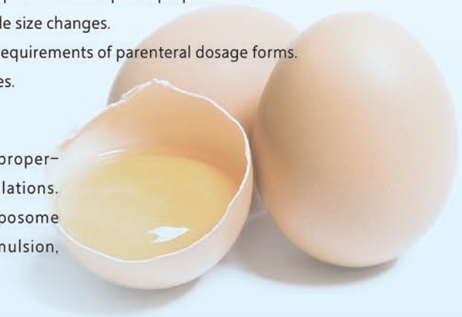
Product type	Content of PC	Content of PE
EPC 70	About 70%	NMT 20%
EPC 80	About 80%	NMT 10%
EPC 90	About 90%	NMT 1.0%
EPC 96	NLT 96%	NMT 0.4%

一、Properties and Benefits

- The appearance is almost white or light yellow powder or waxy solid, can be dispersed completely and dissolved quickly.
- Using high efficient extraction technology, the composition is stable and has low batch-to-batch variability.
- Provide high-purity grade product, with PC content up to 96%, meet the requirements of special preparations.
- The prepared emulsion can withstand terminal sterilization with little particle size changes.
- Bacterial endotoxins and micro-organisms are strictly controlled, meet the requirements of parenteral dosage forms.
- Products can be customized according to customers' needs and preferences.

二、Applications

- As a mainly constituent of fat emulsions, with excellent emulsifying properties, suitable either for parenteral nutrition or drug-containing formulations.
- Good biocompatibility, can be used as emulsifier, solubilizer and liposome membrane material in pharmaceutical preparations such as fat emulsion, lipid microspheres, mixed micelles, liposomes, etc.



09 Soy Lecithin（For Injection）

This product is a mixture of phospholipids, the main components are phosphatidylcholine (PC), phosphatidylethanolamine (PE) and phosphatidylinositol (PI), etc. The product can be classified into several types according to the content of PC and PE, such as SPC 70, SPC 90 and SPC 95.

CAS number: 8030-76-0

CDE registration number: F20190001869（A）

Pharmacopoeia specification compliance: EP/ChP

Storage: In an airtight container, protected from light, at −18 ℃ or below.

Product type	Content of PC	Content of PE
SPC 70	NLT 45.0%	NMT 30.0%
SPC 90	NLT 88%	NMT 5%
SPC 95	NLT 95%	NMT 0.4%

一、Properties and Benefits

- The appearance is yellow or brown, semi-solid or mass, can be dispersed completely and dissolved quickly.
- Raw materials of non-GMO sources are guaranteed.
- Using high efficient extraction technology, the composition is stable and has low batch-to-batch variability.
- Provide high-purity grade product, with PC content up to 95%, meet the requirements of special preparations.
- The prepared emulsion can withstand terminal sterilization with little particle size changes.
- Bacterial endotoxins and micro-organisms are strictly controlled, meet the requirements of parenteral dosage forms.
- Products can be customized according to customers' needs and preferences.

二、Applications

- Natural emulsifier, non-toxic, with potent emulsifying property, is widely applied in fat emulsion injection and mixed micellar preparations. Meanwhile, it can also enhance the cellular immune function of the human body.

10 Polyethylene Glycol 300 (For Injection)
Polyethylene Glycol 400 (For Injection)

CAS number: 25322-68-3
Storage: In an airtight container.

Product name	CDE registration number	Pharmacopoeia specification compliance
PEG 300 (For Injection)	F20190001874 (A)	USP/EP/ChP
PEG 400 (For Injection)	F20190001859 (A)	USP/EP/JP/ChP

一、Properties and Benefits

- Using precise polymerization technology, good process control ensures stable polymerization degree of the product.
- Advanced refining technologies can guarantee excellent batch-to-batch repeatability.
- Low impurities content, strictly control on potential mutagenic or toxic impurities such as ethylene glycol, diethylene glycol, and triethylene glycol in the product to ensure the safety of parenteral formulations.
- Low peroxide value helps to improve the stability of the preparation.
- Bacterial endotoxins and micro-organisms are strictly controlled, meet the requirements of parenteral dosage forms.

二、Applications

- Widely used as a solvent for injections and ophthalmic preparations.
- As suspending agent, thickener and plasticizer in liquid and semi-solid preparations to maintain the physical properties and improve the stability of the preparations.

11 Polyethylene Glycol 4000 (For Injection)

CAS number: 25322-68-3
CDE registration number: F20180000448
Pharmacopoeia specification compliance: USP/EP/JP/ChP
Storage: In an airtight container.

一、Properties and Benefits

- Using precise polymerization technology, good process control ensures stable polymerization degree of the product.
- Advanced refining technologies can guarantee excellent batch-to-batch repeatability.
- Compared with non-injectable grade, the impurities content is lower, and potential mutagenic or toxic impurities such as ethylene glycol, diethylene glycol, and triethylene glycol in the product are strictly controlled to ensure the safety of parenteral formulations.
- Bacterial endotoxins and micro-organisms are strictly controlled, meet the requirements of parenteral dosage forms.

二、Applications

- It is often used as a thickener and suspending agent for suspension injection.
- As bulking agent in lyophilized prepations.

12 | Propylene Glycol（For Injection）

CAS number: 57-55-6
CDE registration number: F20190001855（A）
Pharmacopoeia specification compliance: USP/EP/JP/ChP
Storage: In an airtight container, protected from light and moisture.

一、Properties and Benefits

- Selecting high-purity raw materials, and the product is colorless and clear liquid.
- With low peroxide value and good storage stability.
- The purity of the product is greater than 99.5%, and according to customers requirements, products with lower impurities content than the specifications of USP/EP/JP/ChP can be customized.
- Bacterial endotoxins and micro-organisms are strictly controlled, meet the requirements of parenteral dosage forms.

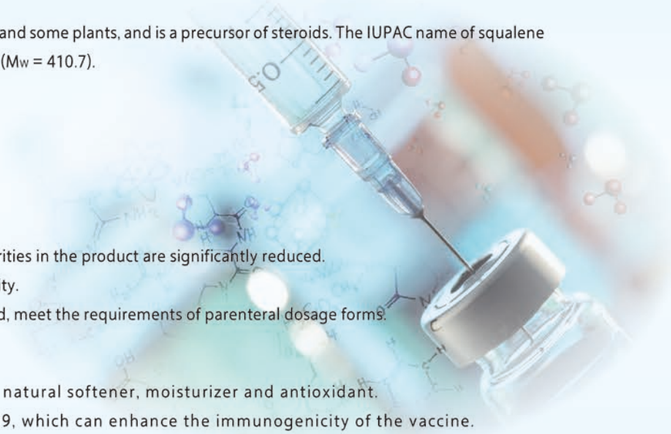
二、Applications

- Widely used as a solvent, co-solvent and stabilizer for injections.

13 | Squalene

Squalene ($C_{30}H_{50}$) is an unsaturated hydrocarbon found in animals and some plants, and is a precursor of steroids. The IUPAC name of squalene is 2,6,10,15,19,23-hexamethyl-2,6,10,14,18,22-tetracosahexaene (M_W = 410.7).

CAS number: 111-02-4
CDE registration number: F20180000667
Pharmacopoeia specification compliance: EP
Storage: In an airtight container, protected from light, at 2 ~ 8 ℃.

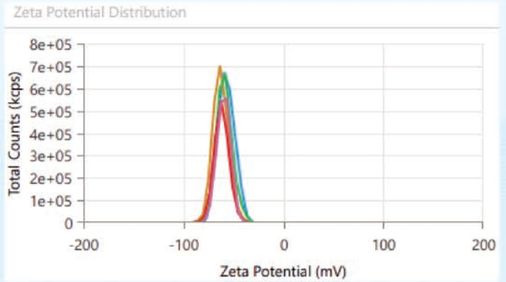


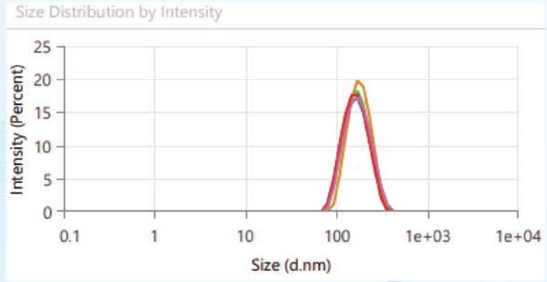
一、Properties and Benefits

- Using advanced refining and purification technology, the impurities in the product are significantly reduced.
- Low peroxide value and acid value, provide good storage stability.
- Bacterial endotoxins and micro-organisms are strictly controlled, meet the requirements of parenteral dosage forms.

二、Applications

- Main component of skin surface polyunsaturated lipids, natural softener, moisturizer and antioxidant.
- Squalene is the core ingredient in vaccine adjuvant MF59, which can enhance the immunogenicity of the vaccine.
- The MF59 emulsion was prepared with squalene, polysorbate 80 (For Injection), sorbitan trioleate, etc. through high-speed shearing and high-pressure homogenization, the product obtained has the same particle size as the RLD product and shows good accelerated and long-term stability.





14 Castor Oil

CAS number: 8001-79-4
CDE registration number: F20180000671
Pharmacopoeia specification compliance: USP/EP/JP
Storage: In an airtight container, protected from light, in a cool place.

一、Properties and Benefits

- Advanced refining technologies can guarantee excellent batch-to-batch repeatability.
- Low peroxide value and acid value, provide good storage stability.
- Low impurities content (e,g, free fatty acid), to ensure the safety of parenteral formulations.
- Bacterial endotoxins and micro-organisms are strictly controlled, meet the requirements of parenteral dosage forms.

二、Applications

- Mainly used as an oily solvent for injections.

15 Benzyl Alcohol

CAS number: 100-51-6
CDE registration number: F20180000658
Pharmacopoeia specification compliance: USP/EP/JP/ChP
Storage: In a well-closed container, protected from light.

一、Properties and Benefits

- Advanced refining technologies provides product with high purity and thus low impurities content. The impurity benzaldehyde is NMT 0.05%, cyclohexylmethanol is NMT 0.10%, other individual impurities are NMT 0.02%, and the total amount of impurities whose relative retention time is greater than benzyl alcohol is NMT 0.2%.
- Bacterial endotoxins and micro-organisms are strictly controlled, meet the requirements of parenteral dosage forms.

二、Applications

- It can be used as a solvent and preservative for oral liquid, topical formulations, intravenous injection, ophthalmic preparations, etc.

16 | Lactose Monohydrate（For Injection）

CAS number: 5989-81-1
CDE registration number: F20190001474（A）
Pharmacopoeia specification compliance: USP/EP/JP/ChP
Storage: In a well-closed container.

一、Properties and Benefits

- As an excellent bulking agent with relative high Critical Temperature (Tc), it is widely used in lyophilized preparations.
- Extremely low residual protein levels（α-lactalbumin, β-lactoglobulin and β-casein each NMT 0.05ppm) can effectively reduce the risk of allergic reactions.
- Low content of impurities such as reducing sugar.
- Bacterial endotoxins and micro-organisms are strictly controlled, meet the requirements of parenteral and inhalation dosage forms.

二、Applications

- Lactose for injection with low residual protein and low endotoxin can be used as a carrier/diluent in inhalation and lyophilized preparations.

17 | Trehalose（For Injection）（Trehalose dihydrate）

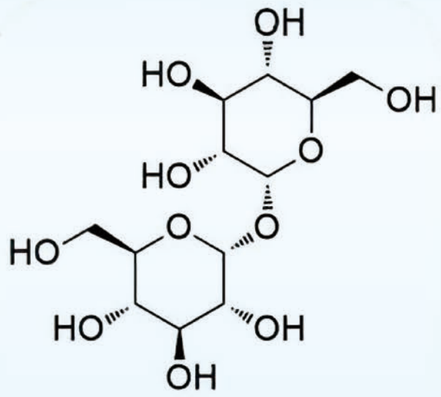
CAS number: 6138-23-4
CDE registration number: F20180000662
Pharmacopoeia specification compliance: USP/EP/JP/ChP
Storage: In an airtight container, protected from moisture.

一、Properties and Benefits

- Low content of impurities such as reducing sugar.
- Strictly control the elemental impurities, comply with the guidelines of ICH Q3D.
- Bacterial endotoxins and micro-organisms are strictly controlled, meet the requirements of parenteral and inhalation dosage forms.

二、Applications

- Stabilizer for liposomes during drying.
- Protectant of protein formulations.
- It can keep the activity of the enzyme in the solution even in the lyophilized condition;



Trehalose

18 Poly(lactide-co-glycolide) series（For Injection）PLGA

CAS number: 26780-50-7

CDE registration number: F20190001476（A）

Pharmacopoeia specification compliance: ChP/USP

Storage: In an airtight container, in a freezer or a refrigerator (-20 ~ 8 ℃), maintain the product's temperature close to the room temperature before the seal is removed to decrease the degradation caused by the condensation water.

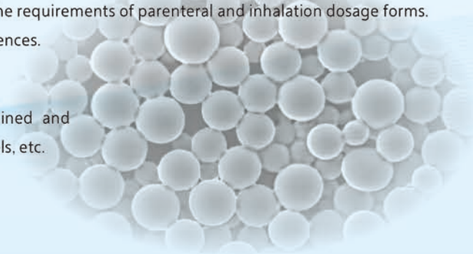
Product name		Intrinsic Viscosity
PLGA5050 (Lactide:Glycolide 50:50)	PLGA5050-20H	15~25 mL/g
	PLGA5050-30H	25~35 mL/g
	PLGA5050-40H	35~45 mL/g
PLGA7525 (Lactide:Glycolide 75:25)	PLGA7525-25H	20~30 mL/g
	PLGA7525-35H	30~40 mL/g
	PLGA7525-45H	40~50 mL/g
PLGA 8515 (Lactide:Glycolide 85:15)	PLGA8515-20H	15~25 mL/g
	PLGA8515-30H	25~35 mL/g
	PLGA8515-60H	50~60 mL/g

一、Properties and Benefits

- Degradable organic compound with high molecular weight, with good biocompatibility, film-forming and vesicle-forming properties.
- Advanced polymerization and refining technologies can guarantee excellent batch-to-batch repeatability.
- Low impurities and monomer residues, low residual catalyst content, can be used for sensitive API to ensure the stability of the preparations.
- Bacterial endotoxins and micro-organisms are strictly controlled, meet the requirements of parenteral and inhalation dosage forms.
- Products can be customized according to customers' needs and preferences.

二、Applications

- As a degradable carrier material, PLGA can be employed for sustained and controlled release dosage forms, such as microspheres, nanocapsules, gels, etc.



Excipients for oral and topical applications

01 Sorbitan Fatty Acid Esters (Span series)

Pharmacopoeia specification compliance: USP/EP/ChP

Storage: In a well-closed container.

Product name	CAS number	CDE registration number	Application
Sorbitan Laurate (Span 20)	1338-39-2	F20180000589 (A)	W/O Emulsifier
Sorbitan Stearate (Span 60)	1338-41-6	F20180000495	W/O Emulsifier
Sorbitan Oleate (Span 80)	1338-43-8	F20190001868 (A)	W/O Emulsifier

一、Properties and Benefits

- Strictly control the composition of sorbitan to ensure batch-to-batch repeatability.
- Low acid value, low peroxide value, good storage stability.
- Using the high-efficiency directional esterification technology, products have light color and stable composition.
- With less inclined to crystallize at low temperature and carbonization at high temperature.

二、Applications

- Water-in-oil emulsifier, oil-in-water emulsion stabilizer and co-emulsifier, widely used in oral and external preparations.

02 Polysorbate series (Tween series)

Pharmacopoeia specification compliance: USP/EP/ChP

Storage: In an airtight container, protected from light.

Product name	CAS number	CDE registration number	Application
Polysorbate 20 (Tween 20)	9005-64-5	F20190001871 (A)	O/W Emulsifier
Polysorbate 60 (Tween 60)	9005-67-8	To be registered	O/W Emulsifier
Polysorbate 80 (Tween 80)	9005-65-6	F20190001856 (A)	O/W Emulsifier

一、Properties and Benefits

- Comply with the specifications of current USP and EP.
- With the precise polymerization technology and high-efficiency directional esterification technology, the composition is stable and the batch-to-batch variability is reduced.
- Low impurity residue, good product stability.

二、Applications

- Non-ionic surfactants and oil-in-water emulsifiers, solubilizers, wetting agents, suspension stabilizers.
- It can be used for solubilization and emulsification of oral preparations and external preparations.

03 Polyoxyl（35）Castor Oil

CAS number: 61791-12-6
CDE registration number: F20190001472（A）
Pharmacopoeia specification compliance: USP/EP/ChP
Storage: In an airtight container, protected from light.

一、Properties and Benefits

- The raw material is refined castor oil, with light color and high purity.
- Using precision polymerization technology to obtain narrow molecular distribution and good batch-to-batch repeatability.
- Low acid value, free fatty acid and peroxide value to ensure good stability of preparations.

二、Applications

- Nonionic surfactant, HLB value is about 12-14.
- It can be used effectively in self-emulsifying drug delivery systems (SEDDS) and enhance solubility and bioavailability of APIs, especially suitable for solution dosage forms containing volatile oils, fat-soluble and other hydrophobic drugs.

04 Polyoxyl (n) Hydrogenated Castor Oil

Pharmacopoeia specification compliance: USP/EP/ChP
Storage: In a well-closed container, protected from light.

Product name	CAS number	CDE registration number	HLB value	Abbreviation
Polyoxyl (40) Hydrogenated Castor Oil	61788-85-0	F20220000193	14 ~ 16	HEL40 RH40
Polyoxyl (60) Hydrogenated Castor Oil	61788-85-0	F20180000473	15 ~ 17	HEL60

一、Properties and Benefits

- The raw material is refined castor oil, with light color and high purity.
- Using precision polymerization technology to obtain narrow molecular distribution and good batch-to-batch repeatability.
- Low acid value, free fatty acid and peroxide value to ensure good stability of preparations.

二、Applications

- Nonionic surfactants, solubilizers, emulsifiers.
- It can increase the solubility of poorly soluble drugs and is almost tasteless, so it can be used preferentially in oral preparations.
- It can be used effectively in self-emulsifying drug delivery systems (SEDDS), enhance solubility and bioavailability of APIs.

05 Polyoxyl (40) stearate

CAS number: 9004-99-3
CDE registration number: F20190001864 (A)
Pharmacopoeia specification compliance: USP/EP/JP/ChP
Storage: In a well-closed container, protected from moisture.

一、Properties and Benefits

- Using precision polymerization technology to obtain narrow molecular distribution and good batch-to-batch repeatability.
- Low water and impurities content to ensure the good stability of preparations.
- Good compatibility with human skin and has been widely used in topical preparations.

二、Applications

- Emulsifier, solubilizer, wetting agent, often used as emulsifier of oil-in-water cream and lotion.

06 Poloxamer 188 / Poloxamer 407

CAS number: 9003-11-6
Pharmacopoeia specification compliance: USP/EP/ChP
Storage: In a well-closed container, protected from light.

Product name	CDE registration number	MW	Weight % oxyethylene
Poloxamer 188	F20190001853 (A)	7680~9510	79.9%~83.7%
Poloxamer 407	To be registered	9840~14600	71.5%~74.9%

一、Properties and Benefits

- Using precision polymerization technology to obtain narrow molecular distribution and good batch-to-batch repeatability.
- Low unsaturation, good product storage stability.
- Low impurities content to ensure product application safety.

二、Applications

- Emulsifier, solubilizer, wetting agent and suspension stabilizer for liquid oral and topical preparations.
- Can be used as a coating plasticizer for oral solid preparations.
- As gel base for liquid or semi-solid formulations.

07 Pegoxol-7 Stearate (Polyoxylethylene stearates)

Pegoxol-7 stearate is a Mixture of Macrogol-6 stearate, Ethylene glycol monopalmitostearate and Macrogol-32 stearate.

CAS number: 9004-99-3

CDE registration number: F20180000669

Pharmacopoeia specification compliance: In-house specification

Storage: In a well-closed container, protected from moisture, in a cool place.

一、Properties and Benefits

- Using precise polymerization technology and high-efficiency directional esterification technology, the composition is stable and the batch-to-batch variability is reduced.
- Low impurities content, low moisture and acid value to ensure good stability of preparations.
- Excellent compatibility with the skin.

二、Applications

- Non-ionic oil-in-water emulsifier for topical preparations, which can improve the stability of emulsions.

08 Polyoxyl 25 Cetostearyl Ether（Peregal O-25）

CAS number: 68439-49-6

CDE registration number: F20180000675

Pharmacopoeia specification compliance: USP/EP

Storage: In an airtight container.

一、Properties and Benefits

- Narrow molecular distribution by using precision polymerization technology.
- Advanced refining technologies can guarantee excellent batch-to-batch repeatability.
- Low impurities content to ensure product application safety.

二、Applications

- It is non-ionic surfactants which is widely used in topical formulations, mainly as emulsifiers for water-in-oil and oil-in-water emulsions.

09 Cetomacrogol 1000（Polyoxyl 20 Cetostearyl Ether）

CAS number: 9004-95-9
CDE registration number: F20180000665
Pharmacopoeia specification compliance: USP/EP
Storage: In an airtight container.

一、Properties and Benefits

- Narrow molecular distribution by using precision polymerization technology.
- Advanced refining technologies can guarantee excellent batch-to-batch repeatability.
- Low impurities content to ensure product application safety.

二、Applications

- Oil-in-water emulsifier, which can be used for topical preparations such as emulsions and creams.
- It can also be used as a solubilizer to improve drug solubility and has excellent pH stability.

10 Propylene Glycol

CAS number: 57-55-6
CDE registration number: F20190001854（A）
Pharmacopoeia specification compliance: USP/EP/JP/ChP
Storage: In an airtight container, protected from light and moisture.

一、Properties and Benefits

- Selecting high-purity raw materials, and the product is colorless and clear liquid.
- The purity of the product is greater than 99.5%, and according to customers requirements, products with lower impurities content than the specifications of USP/EP/JP/ChP can be customized.
- With low peroxide value and good storage stability.

二、Applications

- Solvent, moisturizer, and skin penetration enhancer for external preparations. It also has antibacterial effect.
- Filler for soft capsules.
- Plasticizer for film coating materials.

11 | Butylene Glycol

CAS number: 107-88-0
CDE registration number: F20180000471
Pharmacopoeia specification compliance: USP
Storage: In an airtight container, protected from light and moisture.

一、Properties and Benefits

- By using advanced refining process, products with high purity and low impurities content and shows excellent batch-to-batch repeatability.
- Low toxicity, good hygroscopicity and water solubility.

二、Applications

- Solvent, moisturizer and softener.
- Good antibacterial effect.
- Can be used in creams, gels, etc. It is also commonly used as a moisturizer in cosmetics.

12 | Polyethylene Glycol 400/Polyethylene Glycol 600

CAS number: 25322-68-3
Storage: In an airtight container.

Product name	CDE registration number	Pharmacopoeia specification compliance
Polyethylene Glycol 400	F20190001858 (A)	USP/EP/JP/ChP
Polyethylene Glycol 600	F20190001468 (A)	USP/EP/ChP

一、Properties and Benefits

- Using precise polymerization technology, good process control ensures stable polymerization degree of the product.
- Advanced refining technologies can guarantee excellent batch-to-batch repeatability.
- Low impurities content, strictly control on potential mutagenic or toxic impurities such as ethylene glycol, diethylene glycol, and triethylene glycol in the product to ensure the safety of formulations.
- Low peroxide value helps to improve the stability of the preparation.

二、Applications

- Solvent for oral solutions.
- Filler and plasticizer for gels, ointments and soft capsules.

13 Polyethylene Glycol 1000/1500/3350/4000/6000

CAS number: 25322-68-3
Storage: In a well-closed container.

Product type	CDE registration number	Pharmacopoeia specification compliance	Appearance
Polyethylene Glycol 1000	F20190001860 (A)	USP/EP/ChP	White waxy solid
Polyethylene Glycol 1500	F20190001861 (A)	USP/EP/JP/ChP	White flakes
Polyethylene Glycol 3350	F20220000429	USP/EP	White flakes or powder
Polyethylene Glycol 4000	F20190001862 (A)	USP/EP/JP/ChP	White flakes or powder
Polyethylene Glycol 6000	F20190001863 (A)	USP/EP/JP/ChP	White flakes or powder

一、Properties and Benefits

- Using precise polymerization technology, good process control ensures stable polymerization degree of the product.
- Advanced refining technologies can guarantee excellent batch-to-batch repeatability.
- Low impurity content, low peroxide, to ensure product application safety and formulations stability.
- Different molecular distribution of PEGs can be customized to meet the requirements of different preparations.

二、Applications

- In the preparation of liquids and semi-solids, it is used as a multifunctional excipient for solvents and solubilizers of APIs.
- It can also be used as a suppository/ointment base and moisturizer, and has excellent compatibility with the skin.
- PEG 3350/4000/6000 can be used as a thickener to increase the viscosity of the formulation, and can be used as a coating plasticizer for oral solid preparations.
- Adhesives and lubricants for oral solid preparations.

14 Sorbitol Sorbitan Solution

CAS number: 98201-93-5 & 8007-43-0
CDE registration number: F20180000493
Pharmacopoeia specification compliance: USP/ChP
Storage: In an airtight container.

一、Properties and Benefits

- Advanced sorbitol dehydration and refining technologies, with low impurities content and good batch-to-batch repeatability.
- Enhance the capsule finish gloss for a premium appearance, prevent leakage and help to maintain a proper moisture balance within the capsule shell.
- Remarkable compatibility with gelatin that ensures no migration, prevent leaching into the filler media or at the surface of the soft capsules.

二、Applications

- It is often used as a plasticizer for soft capsules, and has good compatibility with gelatin. The surface of the prepared soft capsules is smooth and shiny, which can keep the capsule shell with proper moisture and is not easy to deform.
- It can also be used in orally dissolving film preparations.

15 Triethyl Citrate

CAS number: 77-93-0
CDE registration number: F20190001475（A）
Pharmacopoeia specification compliance: USP/EP/ChP
Storage: In an airtight container.

一、Properties and Benefits

- High product purity and each impurity NMT 0.2%, total impurities content NMT 0.5%.
- Perfect substitutes for phthalate esters.
- Safe and non-toxic plasticizer with low volatility.
- Good compatibility with polar polymers (acrylates and cellulose derivatives, etc.).

二、Applications

- Plasticizers commonly used in oral solid preparations, such as tablets, pills, granules and other coating formulations.
- It can also be used as a surfactant, a flavoring agent, etc.

Active Pharmaceutical Ingredients

01 Polidocanol （Lauromacrogol 400）

CAS number: 3055-99-0
CDE registration number: Y20210000529（A）
Pharmacopoeia specification compliance: EP/JP
Storage conditions: In an airtight container, protected from light, at 2 ~ 8 ℃.

一、Properties and Benefits

- First registration in China.
- Meet the specifications of EP and JP.
- Using precise polymerization technology to ensure the high repeatability of structural characteristics such as the average chain length of the product and the average polymerization degree of ethylene oxide.
- Strictly control the impurity level of starting raw materials, and adopt advanced refining and processing technology to ensure that the impurities content of the product meets the requirements of the ICH guidelines for APIs.
- Complete evaluation, research and control of mutagenic impurities to ensure drug safety.
- Investigate and control elemental impurities according to ICH Q3D guidelines.
- The accelerated and long-term stability tests indicated good stability of the products.

二、Applications

- Active pharmaceutical ingredients, Sclerosing Agents.

02 Polyethylene Glycol 3350 API / Polyethylene Glycol 4000 API

CAS number: 25322-68-3
Storage conditions: In an airtight container.

Product type	CDE registration number	Pharmacopoeia specification compliance
Polyethylene Glycol 3350	Y20230000383	USP/EP
Polyethylene Glycol 4000	Y20220000602	USP/EP/JP/ChP

一、Properties and Benefits

- By precise polymerization technology and advanced refining post-processing technology to ensure batch-to-batch repeatability.
- Spray granulation process gives good flowability, and the particle size can be customized according to the requirements of clients.
- The product quality meets the domestic and foreign pharmacopoeia specifications.
- Comprehensive research and control on process by-products and degradation impurities.
- Complete evaluation, research and control of mutagenic impurities to ensure drug safety.
- Investigate and control elemental impurities according to ICH Q3D guidelines.
- The accelerated and long-term stability tests indicated good stability of the products

二、Applications

- Active pharmaceutical ingredients, osmotic laxatives, laxatives, enema.