

浙江一新制药股份有限公司 Zhejiang Yixin Pharmaceutical Co., Ltd.

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HEALTHY TODAY, BE BRILLIANT IN FUTURE!



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Profile



Zhejiang Yixin Pharmaceutical Co., Ltd, set up in 1989, is a high-tech enterprise specializing in the development, production and sales of Traditional Chinese Medicine, natural API, health products, herbal extracts and carbohydrates.

At present, Yixin has herbal extracts workshop, oral solid workshop, oral solution workshop, preparation workshop for external use, natural API workshop and carbohydrates (Jiang nan) workshop.

浙江一新制药股份有限公司成立于 1989 年,是一家 专业从事中西药制剂、保健食品、原料药、植物提取物、糖 化产品的高科技现代化企业。

目前一新拥有植物提取车间、口服固体车间、口服液 体车间、外用制剂车间、天然原料药车间及糖化车间。

With 35 years of experience in Traditional Chinese Medicine and herbal extracts, Yixin presents top quality products and services under rigid GMP system and international regulations. All production sites are subjected to regular inspections by authorities and customers alike.

As an open and dynamic enterprise, Yixin pays close attention to the quality of customer service, Yixin streamlined and efficient organization structure fully support us in providing the best quality-focused service. Welcome customers from all over the world to join hands in creating prosperity together for the health of all human beings.





Oral preparation workshop 口服制剂车间

植物提取/原料药车间

Facilities

一新制药,在中药和植物提取领域深耕细作三十 五年,严格执行国际和国内药品生产质量管理规范, 提供优质产品。所有产品的生产线均接受官方和客户 的日常审计。

一新制药,具有高效流畅的组织架构,充分满足 客户需求,提供优质服务。欢迎世界各地的客户与我 们携手,共创未来。





Carbohydrates workshop 糖化学车间



05

History

carbohydrates facility (updated 2019) 糖化车间通过 NSF 认证 Yixin Carbohydrates Facility was inspected and classified as acceptable Obtained Drug Manufacturing by US.FDA for Dietary Supplement Certificate for API, dosage form and herbal extracts (Zhiyuan Road) 糖化车间接受并通过美国 FDA 对 获得原料药和制剂(含提取物)的 膳食补充剂成分生产企业现场检查 药品生产许可证 2023 2015 2024 Administration & Drug manufacturing facilities moved to Zhiyuan Road, Jiangnan Industrial park 行政和药品生产设施整体搬迁至江南 高新工业园致远路

Quality System

Ouality Assurance

From raw materials, intermediates to finished products, GMP system has been established and improved for over 20 years to ensure the traceability and consistence. For herbal extraction, API from herbs and Traditional Chinese Medicine facilities, CFDA GMP Certificates have been obtained since 2002, updated 2015 and 2018 respectively, they are under strict surveillance of CFDA. For carbohydrates facility, ISO certificate has been obtained since 2013, updated 2020. In 2006, 2011, 2015, Yixin herbal API facility and carbohydrate facility were inspected respectively by US FDA and classified as acceptable.

Quality Control

Yixin Quality Control Building is equipped with the first class testing instruments such as HPLC, GC, IR, AAS and etc. To secure the accuracy and consistency of data, data integrity system with audit trailing has been established since 2016. Fully trained lab technicians perform chemical analysis and testing on raw materials and finished products by validated scientific methods that allow you to offer your clients the reliable products.

质量方针

求实创新, 敬业诚信, 质量第一, 规范经营。

质量目标

以满足顾客需求为已任,确保出厂产品合格率、产品市场 抽检合格率达到100%。规范管理,持续改进,实现过程产品一 次交验合格率99%以上。努力发展高起点、高技术、高质量的产 品,确保公司在行业中的技术优势、质量优势,提高市场竞争 力。



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Drug Manufacturing License



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ISO9001:2015 Certificate

US FDA Inspection for Carbohydrates

Certificates

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Plant-derived

D-Galacose 植物来源 D-半乳糖

D-Galactose is an aldohexose that occurs naturally in the body. It is commonly found in dairy products, sugar beets, certain gums and mucilages.

D-Galacose is a basic ingredient usually used for creating brain senescence in animal models, increasing glycoproteins production through adding to cell culture medium. As one of primary monosaccharides. D-Galactose can be acted as a basic start material for synthesis of many important intermediates. Certain medications contain galactose as excipient.

Plant derived, low endotoxin D-galactose is specifically for biopharmaceutical use, It can serve as a key, chemically defined component to optimize protein production while reducing lactate and ammonia formation.

Application

Targeted drug development Biochemical reagent Culture medium Food additive Starting material for synthesis Drug formulation excipient

Product Information



D-半乳糖是一种体内能自然生成的己醛醣,它通常存在于在 奶制品、甜菜、某些树胶和植物粘液中。

D-半乳糖是一种基本成分,通常用于创建脑衰老的动物模型,加入细胞培养基来增进糖蛋白的生成。作为一种基本的单糖,D-半 乳糖是合成许多重要中间体的基本起始原料。某些药物含有半乳糖 作为辅料。

植物来源、低内毒素的 D-半乳糖尤其适用于生物制药。它是一 种关键的、化学明确的成分,用于优化蛋白的生产,同时能降低乳糖 和氨基酸的形成。

Carbohydrates

Advantages

Plant-derived. NAD

Yixin' s plant derived D-galactose (NAD) is completely from nature tree, non GMO source, developed specifically for biopharmaceutical use.

Low Endotoxin

Yixin plant derived D-galactose controls Endotoxin at the very low level to ensure the highest quality in biopharmaceutical products. It can meet special requirement less than 5 EU/g or more stricter requirement.

GMP System

Yixin plant derived D-galactose is produced under GMP system to ensure the traceability and consistent supply. For carbohydrates facility, NSF GMP certificate has been obtained since 2015, In 2015 Yixin carbohydrate facility was inspected and concluded by US FDA to meet the related requirements.



Plant-derived **L-Arabinose** 植物来源 L-阿拉伯糖

L-Arabinose is a naturally occurring pentose with a sweet taste and is widely distributed as a component of complex non-starch polysaccharides in plant cell walls and plant gums.

As a low-calorie sugar-substituting sweetener, the relative sweetness of L-Arabinose equals to half of the Sucrose's. Some research suggested that L-Arabinose selectively inhibit sucrose absorption and then inhibit the increase of blood sugar.

Furthermore, L-Arabinose is an intermediate in flavor industry for producing flavors, the derivates of L-Arabinose can be used in the development of antiviral agents such as nucleoside.

Application

Intermediate for nucleoside derivates synthesis Intermediate for flavors synthesis Ingredient in function food Food additive in foods, drinks

Product Information

Cas No.	5328-37-0
EINECS	226-214-6
Synonyms	L-(+)-Arabinose, L-Arabinopyranose
Chemical Structure	HO OH OH
Molecular Formula	C5H10O5
Molecular Weight	150.13
Purity	NLT 99.0%
Solubility	Easily soluble in water, slight soluble in alcohol
Specific Rotation	101°- 105 °

L-阿拉伯糖是一种天然的戊糖,带有甜味,作为复合非淀粉多糖的一种成分广泛存在于植物细胞壁和植物胶中。

作为一种低热量的代糖,L-阿拉伯糖的甜味是蔗糖的一半,研 究表明L-阿拉伯糖能选择性地抑制蔗糖的吸收,进而抑制血糖的 提高。

此外,在香料工业上,L-阿拉伯糖是生产香料的中间体,L-阿 拉伯糖的衍生物能用于开发核苷类抗病毒药物。

Carbohydrates

Advantages

Plant-derived, 100% Non-GMO Source

Yixin's plant derived L-Arabinose is completely from nature tree, non GMO source. It does NOT have any GMO risk, neither Yixin nor any of Yixin suppliers of raw materials has used Genetically Modified Organisms in this product.

Clean Technology

Yixin plant derived L-arabinose is produced by clean technology, during the whole production process, only water is used as extraction solvent to ensure the environmental sustainability and the process safety.

Low Impurity Profile

Yixin plant derived L-arabinose is produced under GMP system, every batch is tested for its chemical impurities and chiral impurity to meet the quality requirements both in pharmaceutical and food industry.

D-Mannose

D-mannose, is a sugar monomer of the aldohexose series of carbohydrates, existing in many kinds of fruits and plants, it is important in human metabolism especially in the glycosylation of certain proteins.

As a natural bioactive monosaccharide, D-mannose is a popular nutritional and health beneficial food supplement, especially used as a dietary supplement influencing glyconutrient contribution on human health. The particular components in D-mannose and its method of absorption in the body make it effective in treating or preventing infections in the bladder and urinary tract.

Now D-mannose is widely used as food additive, dietary supplement ingredient, cosmetic ingredient and starting material for pharmaceutical industry.

D- 甘露糖是己醛糖中的一种单糖,存在于多种水 果和植物中,它对人体代谢尤其是某些蛋白的糖基化来 说非常重要。

作为一种天然的生物活性单糖,D-甘露糖是一种 流行的具有营养和健康价值的食品补充剂,尤其是用 于膳食补充剂来改善影响人体健康的醣质营养素分布。 D-甘露糖独特的成分及其被人体吸收的方式使得它具 有治疗和预防膀胱及尿路感染的效果。

Product Information



目前 D- 甘露糖已被广泛用作食品添加剂、膳食补充剂成分、 化妆品成分,以及制药工业的起始原料。

Application

Food additive, Dietary supplement ingredient, Cosmetic ingredient Agriculture(Poultry), Start material for synthesis, Reagent





Carbohydrates

Advantages

Non-GMO Source

Yixin's cD-mannose is sourced from D-glucose, neither Yixin nor any of Yixin suppliers of raw materials has used Genetically Modified Organisms in this product.

Clean Technology

Our D-mannose is produced by clean technology, during the whole production process, only safe solvents for food industry are used to ensure the environmental sustainability and the process safety.

GMP System

Our D-mannose is produced under GMP system to ensure the traceability and consistent supply. As a major dietary supplement ingredient, Yixin D-mannose facility was assessed by NSF to meet GMP requirement for dietary supplement ingredient.



Natural Galantamine HBr. ^{植物来源氢溴酸加兰他敏}

Galanthamine Hydrobromide is a strong (reversible) cholinesterase inhibitor that increases the susceptibility of an organism to acetylcholine, and is an effective treatment for mild to moderate dementia of the Alzheimer's type.

氢溴酸加兰他敏是一种高度选择性的竞争性乙酰胆碱 酯酶抑制剂,通过与烟碱性受体变构位点结合而提高乙酰 胆碱的内在作用,对轻度至中度阿尔茨海默型痴呆症状有 效。我公司是目前国内少数同时拥有原料药批文和GMP证 书且能正常供货的厂家之一。

Product Information



Certificates



Registration

GMP Certificate No. in China	ZJ20180020
DMF No. in USA	17972

Herbal Extracts

Advantages

Natural Product

Yixin Galantamine is isolated from natural herb, non GMO source; it is produced on basis of extraction and purification process, 100% from nature.

GMP System

Yixin Galantamine facility was inspected and classified as acceptable by US FDA in 2006, 2011, GMP certificate from CFDA has been obtained since 2005, updated 2018.

Cultivation

To ensure the stable supply of Galantamine HBr, a large area of herbs has been cultivated and advanced technology has been adopted to enhance the yield and consistent quality.





Usnea Extract

(+)-Usnic Acid & its salt form 松萝酸及其钠盐

Usnic acid is uniquely found in lichens, It is a potent antibiotic effective against Gram-positive bacterias and other bacterias. It also exhibits antiviral, antiprotozoal, antimitotic, anti-inflammatory and analgesic activity. Other characteristics, like ultraviolet absorption, preserving properties, antigrowth, antiherbivore and anti-insect properties, have also been demonstrated.

Sodium usnic acid is the salt form of usnic acid for better water solubility.

松萝酸在地衣中发现的一种 天然抗菌成分,对革兰氏阳性菌 以及其他多种菌有着很强的抗菌 效果。松萝酸钠是松萝酸的钠 盐,具有更好的水溶性。



Name	Usnic Acid
CAS No.	7562-61-0
Origin	Usnea
Molecular Formula	C18H16O7
Molecular Weight	344.32
Apperance	Yellow crystalline substance
Purity	NLT 98%



Herbal Extracts

Advantages

Natural Product

Yixin Usnic Acid is extracted from Usnea, Usnea looks like long, fuzzy strings hanging from forest trees and rocks without any contamination. In the whole production process, only extraction and purification are involved, it is 100% from nature.

Stronger Anti-bacteria with Lower Toxicity

Against certain bacteria, Usnic acid is stronger than antibiotic penicillin. Yixin natural Usnic Acid demonstrates stronger anti-bacteria effect in comparison with synthetic source, in the meantime, gave excellent lower results of cytotoxicity.

GMP System

Yixin Usnic acid facility follows GMP guidelines to ensure the traceability and consistence. It has been frequently audited by international companies, DMF is available.

Application

Creams, powers, toothpaste, mouthwash, deodorants hair shampoos and sunscreen products.



(-)-Epigallocatechin gallate (EGCG)

EGCG is a kind of component extracted from Chinese green tea. It is the primary active and water-soluble component of green tea, which has the highest content among the the tea catechins. It accounts for 9-13% of green tea in net weight.

By virtue of its peculiar stereochemical structure, EGCG possesses much stronger anti-oxidant activities and plays an important role in preventing cancer and cardiovascular diseases

In addition, it is potent as the reversal agent of MDR (Multidrug Resistance). As such, it may improve the sensitivity of cancer cells to chemotherapy drugs and reduce toxicity on the heart.

CAS No. 989-51-5

01101101	
M.F.	C22H18O11
M.W.	458.37
Purity	90% - 99%

Application

Medicine, Health food, Food, Cosmetics and Beverage, etc.

Epicatechin (EC)



Epigallocatechin (EGC)











Tea polyphenol Tea polyphenol (TP), a kind of polyphenol, mainly contains tea catechin, with concentrations of 8%-20% in the tea leaves. TP is an important chemical with health promoting benefits found in Tea.

Tea catechin They are stronger active materials formed with catechin as the main structure combined with gallic acid group. Those of them exist in green tea are mainly (-)-epigallocatechin gallate (EGCG), (-)-epigallocatechin (EGC), (-)-epicatechin gallate (ECG), epicatechin (EC), (-)-gallocatechin gallate (GCG), and (+)-catechin ...



(+)-Catechin





Reference



Contract Manufacturing

Yixin has GMP production lines for herbal extracts and dosage forms including tablets, capsules, granules, syrups, ointment, solution (external use), mixture(oral solution), and ointment(cream)_n Yixin also has GMP certificate from NSF international for dietary supplement (ingredient).

All facilities are under rigid GMP system and international regulations. All analytical chromatography instruments have been updated with audit trailing system, data integrity system has been established since 2016.

Welcome companies all over the world to contact us for contract manufacturing.

一新拥有符合GMP标准的植物提取、糖浆剂、合剂、片剂、胶囊剂、颗粒剂、软膏剂、乳膏剂和外用溶液剂等多条生产线,并获得了膳食补充剂(原料)的NSF认证。

所有的生产设施都按GMP体系和国际法规严格管理,2016年建立了数据完整性系统,分析仪器均具备审计 追踪功能。

欢迎各位联系洽谈植物提取和制剂的合同加工事宜!





Herbal Medicines 中成药品种(部分)



No.	Product Name
1	Beidening [®] Children' Cough Syrup 贝得宁牌儿童咳液
2	Andaping [®] Strong Loquat Syrup 安达平牌强力枇杷露
3	Jiaoer [®] Children Appetite Syrup 娇儿牌小儿喜食糖浆
4	Qichang [®] Qinglin Grannules 齐畅牌清淋颗粒
5	Xuezhongyu [®] Blood Replenishing Angelica Syrup 雪中玉牌补血当归精



Application

Special applicable to children cough, asthma and yellow phlegm.

Applicable to bronchitis, coughs.

Special applicable to children indigestion, loss of appetite and diarrhea caused by indigestion.

Applicable to stranguria, hernia closure caused by damp-heat in the urinary bladder.

Applicable to dizziness, anemia, physical weakness, women's irregular menstruation, postpartum blood deficiency.

更多信息请访问 http://www.yixinpharm.com

Herbal Extracts ^{植物提取物目录}

No.	Product Name	Specification	CAS No.	Test method
1	Galantamine Hydrobromide 氢溴酸加兰他敏	USP/EP/CP	1953-04-4	HPLC
2	Usnic Acid 松萝酸	98%	7562-61-0	HPLC
	Sodium Usnic Acid 松萝酸钠	98%	34769-44-3	UV
3	(+)-Catechin 儿茶精	98%	154-23-4	HPLC
	EGCG 表没食子儿茶素没食子酸酯	90%, 95%, 98%, 99%	989-51-5	HPLC
	EC 表儿茶素	90%, 95%, 98%	490-46-0	HPLC
	ECG 表儿茶素没食子酸酯	98%	1257-08-5	HPLC
	EGC 表没食子儿茶素	98%	970-74-1	HPLC
	GCG 没食子儿茶素没食子酸酯	98%	4233-96-9	HPLC
4	Gossypol Acetate 醋酸棉酚	98%	12542-36-8	HPLC
5	Camptothecin 喜树碱	99%	7689-03-4	HPLC

Carbohydrates ^{糖化学产品目录}

No.	Product Name	Specification	CAS Number	Test method
1	D-Galactose, plant derived 植物来源D-半乳糖	USP/EP	59-23-4	HPLC
2	D-Mannose D─甘露糖	99%	3458-28-4	HPLC
3	L-Arabinose。 plant derived 植物来源L−阿拉伯糖	99%	5328-37-0	HPLC
4	β-D-Galactose Pentaacetate β −D−半乳糖五乙酸酯	99%	4163-60-4	GC
5	β-D-Glucose Pentaacetate β −D−葡萄糖五乙酸酯	99%	604-69-3	GC
6	Methy-α-D-Mannopyranoside 甲基−α-D-吡喃甘露糖苷	99%	617-04-9	HPLC
7	Methy-α-D-Galactopyranoside 甲基−α−D−吡喃半乳糖苷	99%	3396-99-4	HPLC
8	Methy-β-D-Galactopyranoside 甲基−β−D−吡喃半乳糖苷	99%	1824-94-8	HPLC
9	D-Tagatose D−塔格糖	99%	87-81-0	HPLC

Product Catalog