



Pharmaceutical Adjuvant

Pharmaceutical & Health Care
Product Guide

Small enough to care, Big enough to deliver

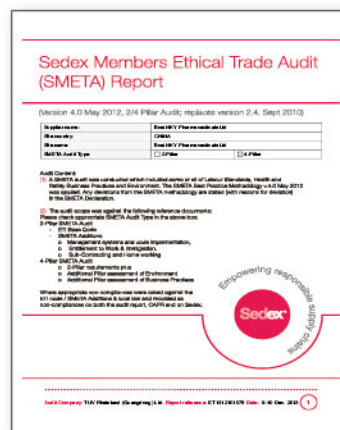


ENVIRONMENTAL RESPONSIBILITY

- Fully compliant with government requirements and regulations
- Real time monitoring of waste streams
- 100% recycling of processing water
- Complete conversion from coal to natural gas
- Focus on developing green production processes

CUSTOMER and TECHNICAL SERVICE

- Technical Research Center to assist our customer with formulation development
- New R&D center commissioned in 2018 having integrated R&D and pilot manufacturing
- Customer partnering to develop new opportunities
- Strong customer and quality management services to assist our customers



NKY® is the registered trademark of Boai NKY Pharmaceuticals Ltd (NKY). KoVidone®, PolyKoVidone® and, OraRez® are the trademark names of NKY.

THE COMPANY

- Publicly traded company on the Shenzhen stock exchange (stock code 300109)
- First domestic company to develop and manufacture PVP and PVM/MA products
- 3rd Largest Global PVP manufacturer
- 2nd Largest Global PVM/MA manufacturer
- International subsidiaries in China, Europe and Japan
- Global distribution network

OUR PRODUCTS

- KoVidone® and PolyKoVidone® line of products representing Povidone, Crospovidone and Copovidone pharmaceutical excipients.
- OraRez® line of PVM/MA copolymer and derivatives representing functional polymers for bioadhesive/mucoadhesive applications.
- KoVidone®-I (PVP-I) broad spectrum biocidal, antifungal and antiviral agent.
- Pharmaceutical solvents and intermediates.

QUALITY

- First Chinese manufacturer to be EXCiPACT™ GMP certified
- All pharmaceutical products manufactured under strict cGMP guidelines
- All pharma products handled and packaged in class D cleanrooms
- State of the art manufacturing facility (commissioned 2013)
- QC equipment and test methods fully validated and fully audit trail compliant

KoVidone® and PolyKoVidone® polyvinylpyrrolidone (PVP) series products of NKY are widely used in the pharmaceutical field as excipients, suitable for a broad range of dosage forms.

Solid dosage forms

Product	Solid Dispersions	Tablet	Capsule	Coating	Sustained release	Granulation
KoVidone® K 12 / 17		+	+		+	
KoVidone® K 25 / 30	+	+	+	+	+	+
KoVidone® K 90	+	+	+		+	+
KoVidone® VA64	+	+	+	+	+	+
PolyKoVidone® XL / XL-10	+	+	+			+

Liquid dosage forms & Semisolid dosage forms

Product	Injection	Eye drops	Oral solution	Suspensions	External uses	Transdermal system	Spray
KoVidone® K 12 / 17	+	+					
KoVidone® K 25 / 30		+	+	+	+	+	
KoVidone® K 90			+	+	+	+	
KoVidone® VA64							+
PolyKoVidone® XL / XL-10				+		+	

+* Pyrogen free products

NKY's PVP products comply with all required pharmacopoeias (USP/NF, EP, JP, KP, IP, BP and FCC, etc.) to meet the needs and expectations of our global customers.



NKY PHARMA

Boai NKY KoVidone® and PolyKoVidone® polymers are an essential ingredient to formulating highly effective pharmaceutical products. The polymers are produced in a state of the art manufacturing facility operating under full cGMP compliance. In addition, all physical handling and packaging of powders is conducted in class-D clean rooms with specific attention placed on reducing the risk of any potential particulate/foreign matter contamination.

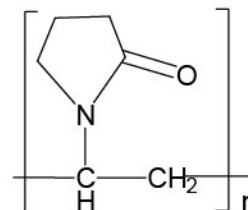
POLYMERS FOR PHARMACEUTICAL

KoVidone® K

Product name KoVidone® K Povidone
USP/EP name Povidone, povidonum
INCI/CTFA Polyvinylpyrrolidone(PVP)
CAS NO. 9003-39-8

Properties Nontoxic; Non-irritant; Hygroscopic; Freely soluble in water, alcohol and most other organic solvents; Very slightly soluble in acetone; Excellent solubility; Film-forming; Chemical stability; Physiologically inert; Complexation and binding property.

Specification Based on the polymer molecular weight and viscosity in water, the current series products are classified based on their K-values.



Product	K-value*	Mv**	Main application
K12	10.2 - 13.8	3,000 - 7,000	Used as a solubilizer, dispersant and anti-crystallization agent in liquid dosage applications.
K15	12.75 - 17.25	8,000 - 12,000	
K17	15.3 - 18.36	10,000 - 16,000	
K25	22.5 - 27.0	30,000 - 40,000	Used as a binder, film-forming agent, solubilizer, suspension stabilizer and dispersant in dosage form applications.
K30	27 - 32.4	45,000 - 58,000	
K60	54 - 64.8	270,000 - 400,000	Used as a binder, thickener or suspension stabilizer in dosage form applications.
K90	81 - 97.2	1,000,000 - 1,500,000	

*K-value is calculated by determining the polymer relative viscosity in water and applying the results to the Fikentscher equation.

**Mv is viscosity-average molecular weight.

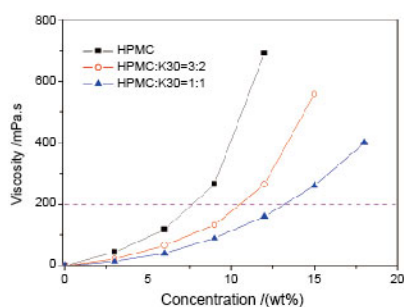
Applications

KoVidone® K series products possess excellent binding, film-forming, dispersing and thickening properties and are widely used in the following dosage forms:

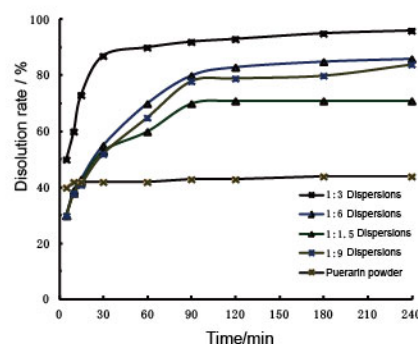
- Binder: suitable for wet and dry granulation and direct compression in tableting, improves particle compressibility and can be added to powder blends in dry or granulated forms by the addition of water, alcohol or hydro-alcoholic solutions.
- Solubilizer: suitable for oral and parenteral formulations, enhancing the solubility of poorly soluble drugs in solid dispersion forms.
- Coating agent or binder: coating of active pharmaceutical ingredients on a support structure.
- Suspending, stabilizing or viscosity-modifying agent: suitable for topical and oral suspension and solution applications. The solubility of poorly soluble drugs may be enhanced by combining with KoVidone.

Viscosity modifier in tablet coatings

The addition of KoVidone® K30 to HPMC film coating solutions can effectively reduce the viscosity of the HPMC solution while not affecting the resultant hydration profile of the resultant film.



Puerarin povidone solid dispersions dissolution curve



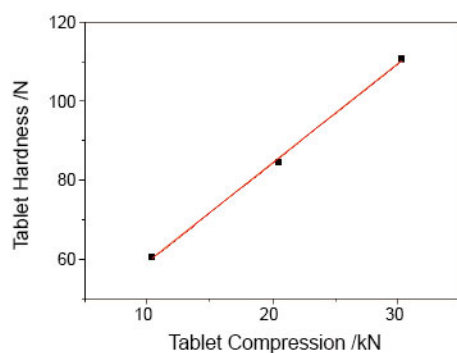
Puerarin - KoVidone® K30 solid dispersions can accelerate the dissolution of puerarin rate significantly.

KoVidone® K30 applied in high content nutraceutical products prescription tablets.

In the case of poor compressible powders containing high content nutraceutical products, KoVidone® K30 can be used as an efficient binder. The addition of a small amount of KoVidone® K30 significantly improves the compressibility of the resultant powder.

Component	Content
Extract Powder	90%
KoVidone® K30	2%
PolyKoVidone® XL	4%
SiO ₂	3%
Magnesium stearate	1%

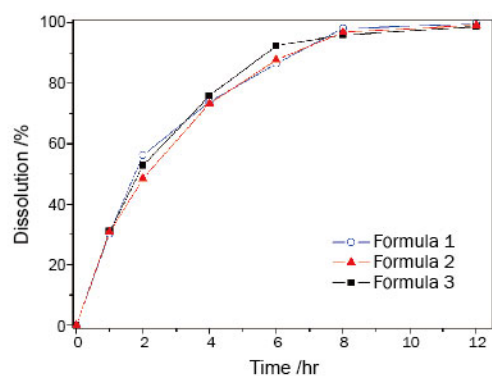
Compression KN	Hardness N
10.4	60.58
20.5	84.63
30.3	110.56

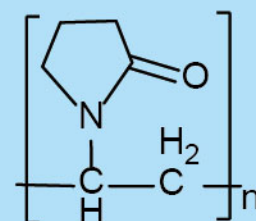


KoVidone® K90 can be used to modify the release rates of drugs in controlled release dosage forms.

Component	Formu1	Formu2	Formu3
metformin HCL	55%	55%	55%
KoVidone® K90	20%	10%	-
HPMC 50cp	-	10%	20%
MCC	23%	23%	23%
Talc	1%	1%	1%
Magnesium stearate	0.5%	0.5%	0.5%
Aerosil	0.5%	0.5%	0.5%

	Formu1	Formu2	Formu3
Hardness N	45	38	33
Friability %	0.05	0.25	0.25

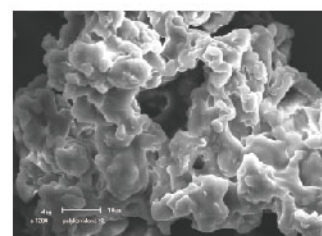




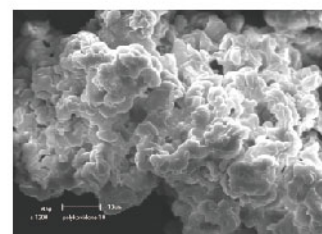
PolyKoVidone®

Product name:	PolyKoVidone® Crosspovidone
USP/EP name:	Crospovidonum, crospovidone
INCI/CTFA:	Insoluble PVP
CAS NO.:	25249-54-1
Properties:	Hygroscopic; Insoluble in water, acid, alkaline and all other common solvents; Swells rapidly in water without gel formation; Improves flowability and plasticity; Strong particle compressibility; Non-ionic; Chemically inert; Low Peroxide content
Special Type:	Based on the distribution of particle size the material is classified as either type A or B:

The particle size of crospovidone (PVPP) strongly influences the disintegration profile of tablets.



PolyKoVidone® XL (A) 50-300µm



PolyKoVidone® XL-10 (B) 10-50µm

Applications

PolyKoVidone® possesses dual binding and disintegration properties while enhancing active solubilization. The product is used in the following applications:

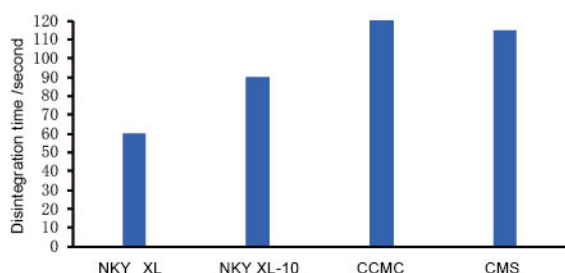
- Super disintegrant; due to its excellent swelling characteristics in water, PolyKoVidone® can be used as water insoluble disintegrant for wet and dry granulation processes. The material can be added either before or after granulation in direct compression tableting processes. It exhibits high capillary activity and pronounced hydration capacity, without the formation of gel.
- Solubility enhancer; PolyKovidone® increasing the solubility of poorly soluble drugs via co-evaporation processes.
- Suspension stabilizer; PolyKoVidone® increasing the viscosity and improves the dispersion properties to reduce the sedimentation rate of drugs, meanwhile increasing the re-dispersibility of said sediment. Suitable for liquid and instant oral preparations.
- Complexing agent of drug ingredients; PolyKoVidone® stabilizes active ingredients in pharmaceutical products, improving drug solubility and bioavailability.



Comparison of compressibility and disintegration times of various disintegrants.

Component	Ratio
Disintegrant	99%
Mg-stearate	1%

Compression KN	Hardness N
25	>60

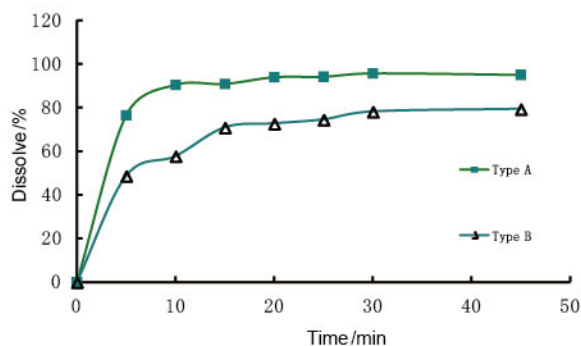


Dry mixing of ingredients followed by direct compression at 25 KN results in PolyKoVidone® tablets showing improved compressibility.

PolyKoVidone® quick and efficient swelling in water provides unparalleled disintegration profiles for tablet formulation.

Effect of different particle size PolyKoVidone® on nimodipine release

Dissolution rates of nimodipine solid dispersions can be effectively adjusted by using varying particle size PolyKoVidone® PVPP in the formulation.

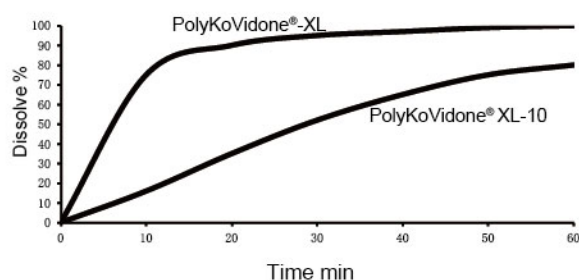


PolyKoVidone® particle size has a strong influence on nimodipine release rates. Particle sizes that are either too small or too large both have the effect of decreasing drug release rates. Thus, depending on the type PolyKoVidone® used in the formulation, drug release rates can be tailored to meet specific release profiles.

Comparison of Indometacin tablet dissolution curves with different PolyKoVidone® types.

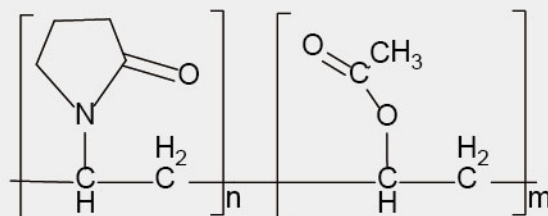
Component	Ratio
Indometacin	15%
Lactose	25%
MCC	15%
Starch	20%
KoVidone® K30	3%
Disintegrant	4%
Mg-stearate	1%
Talc	1%

Compression KN	Hardness N
22	>60



Even when applied in insoluble drug dosage forms, PolyKoVidone® still possesses excellent swelling characteristics that effectively enhance the rate of drug release to improve drug bioavailability.





KoVidone® VA64

Product name	KoVidone® VA64 Copovidone
USP/EP name	Copovidone, Copovidonum
INCI/CTFA	VP/VA copolymer 60/40
CAS NO.	25086-89-9
K value	25.2-30.8 (Copovidone 28), 27.0-33.0 (Copovidone 30)
Properties	Hygroscopic capacity lower than KoVidone® K30; Soluble in water, alcohol and many other organic solvents; Glass transition temperature (Tg) lower than KoVidone® K30; Forms transparent, water removable films.

The content of vinyl acetate 35.3-41.0%

Applications

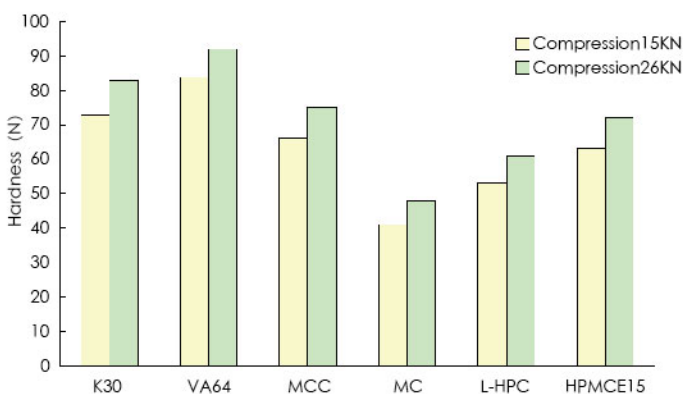
KoVidone® VA64 possesses excellent powder and film properties for broad application in the pharmaceutical field:

- Water soluble tablet binder; suitable for wet or dry granulation and direct compression processes, improves particle compressibility.
- Film-former; permeable film coating for tablet and sugar coatings to protect against splitting, decrease moisture sensitivity and provide good film adhesiveness, elasticity, and hardness.
- Porogenic agent; for use in taste-masking and component of the matrix material used in controlled-release formulation.
- Solubilizing agents; for solid dispersion processes to enhancing bioavailability and improve drug solubility.





Comparison of binder compressibility



KoVidone® VA64 is suitable for deformation processing to improve formulation plasticity and is an excellent binder for dry granulation and direct compression processing.

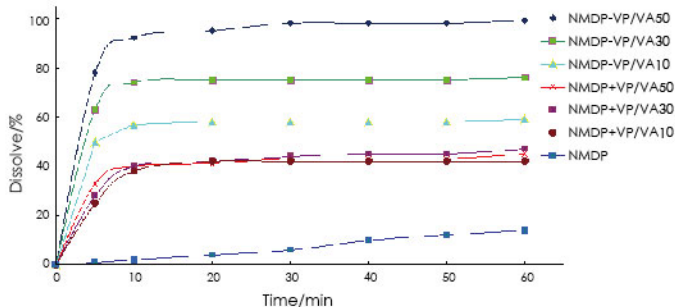
Nimodipine- KoVidone® VA64 solid dispersion HME process

Due to its lower glass transition temperature T_g , KoVidone® VA64 is especially suited for developing solid dispersion drug systems via hot melt extrusion processing.

Hot melt extrusion (HME) technology is a new technique to prepare pharmaceutical dosage forms. HME shows unique advantages and is used to: improve the dissolution rate of poorly soluble drugs and prepare slow or controlled release dosage forms for both tablet and topical applications.

HME uses no solvent in the production process, the drug in hot melt extruded with a suitable polymer carrier. The extrusion process converts crystalline drugs to their amorphous form that helps to improve both drug solubility and bioavailability and increase the stability of the finished dosage form.

HME technology can also be used to prepare solid dispersion dosage forms. The highly efficient mixing of the solid dispersion in the molten polymer matrix improves the quality of the drug dispersion to enhance drug dissolution in the finished dosage form.

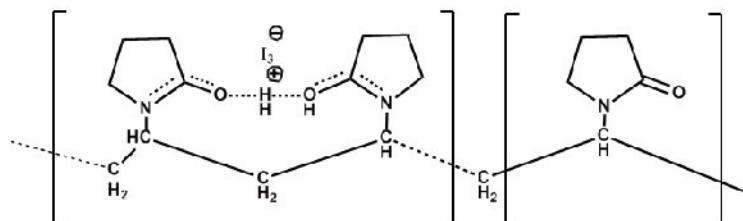


NMDP-VP/VA: HME process

NMDP+VP/VA: Physical mixture

Value indicates % VP/VA in the formulation

KoVidone® - I



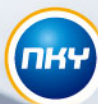
Product name	KoVidone® - I
USP name	Povidone - Iodine
EP name	Povidone Iodinated (Povidonum Iodinatum)
INCI/CTFA	PVP-Iodine
CAS NO.	25655-41-8
Properties	Broad spectrum biocide; Soluble in water, ethyl alcohol, isopropyl alcohol, glycols, glycerin, acetone and polyethylene glycol; Film-forming; Stable complex; Less irritating to the skin and mucosa; Non-selective germicidal action; No known tendency for the development of resistant microorganisms.
Effective Iodine	9.0-12.0 %



Applications

KoVidone® -I is a broad spectrum biocidal, antifungal and antiviral agent with extremely low risk of promoting microorganism resistance. Applications include:

- Used as an antiseptic agent against broad spectrum of disease causing microorganisms.
- Widely used in pharmaceutical, veterinarian, agricultural and consumer good applications.
- Used for the disinfecting of skin and equipment before injection or surgery.
- Used for the treatment of: oral, vaginal, skin and hair infections.
- Highly effective at inactivating human and avian influenza viruses.
- Disinfectant used in the foodstuff, aquaculture and veterinarian industries to control pathogenic bacteria, reduce the infection of fish and fish eggs and prevent and cure animal diseases.



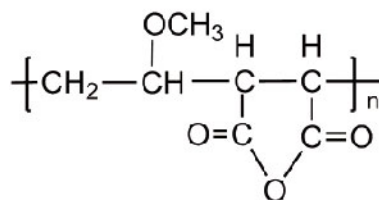
With the customers' concern in mind, BOAI NKY OraRez® polymers explored a novel PVM/MA synthesis process with proprietary intellectual property rights. Unlike competitor PVM/MA manufacturers, no benzene or toluene solvents are employed in any OraRez® process, therefore completely eliminating the safety and health concerns of residual aromatic solvents in the final product. For this reason, OraRez® is especially suited for oral care application and pharmaceutical applications. In addition, our green process is significantly more environmentally friendly than traditional manufacturing processes.

POLYMERS FOR PHARMACEUTICAL

OraRez® AN (PVM/MA)

CAS: [9011-16-9]

(methylvinylether/maleic anhydride copolymer)



Properties

- 100% Free of benzene and aromatic solvents
- Broad molecular weight/viscosity range
- Water insoluble polymer having a reactive anhydride ring
- Perfectly alternating –ABAB– structure

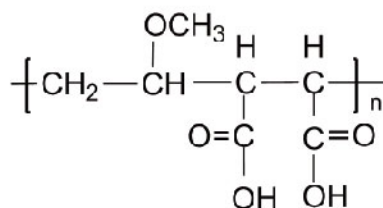
Applications

OraRez® AN copolymers are the safest PVM/MA material on the market today. They offer unique formulation and product development opportunities. Applications include:

- “Direct use” pharmaceutical applications
- Versatile reactive polymer for generating new derivatives
- Controlled release of bioactives
- Generation of hydrolysable linkages for prolonged drug release systems
- Generation of pH sensitive systems
- Hydrogel preparation

OraRez[®] W

(PVM/MA – Diacid)



CAS: [25153-40-6]

(methylvinylether/maleic acid copolymer)

Properties

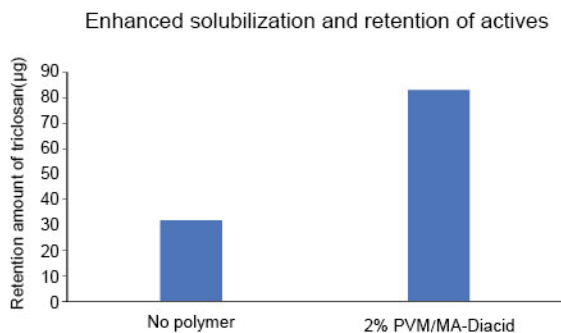
- Biocompatible water-soluble film former
- Excellent bioadhesive/mucoadhesive properties
- Excellent chelating properties
- Enhances solubilization and retention of actives and drugs
- Broad molecular weight range and tunable rheological
- Polyanion having two distinct pKa's

Applications

OraRez[®] W is an outstanding mucoadhesing showing the ability to complex, solubilize and retain actives on the mucosal tissue. The material's bioadhesive properties' and unique structure makes it an invaluable component to pharmaceutical products. Applications include:

- Retention of drugs on mucosal tissue
- Water-soluble, pain-free adhesive applications (e.g. ostomy bags, buccal patches)
- Solubilization/retention of actives in the oral cavity
- PVM/MA-polymer or PVM/MA-drug complex systems for controlled release
- Enteric coatings and systems
- Hydrogel dressing

NKY OraRez[®] W polymers can improve solubilization and retention of actives on mucosal tissue.





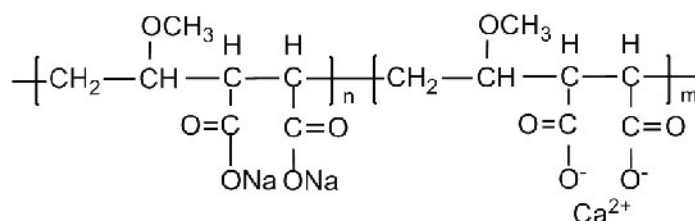
NKY PHARMA

POLYMERS FOR PHARMACEUTICAL

OraRez[®] MS (PVM/MA – MS)

CAS: [62386-95-2]

(methylvinylether/maleic acid mixed sodium/calcium salt)



Properties

- Biocompatible water-soluble polymer
- Excellent bioadhesive/mucoadhesive properties
- Calcium salt bridges enhance cohesive properties

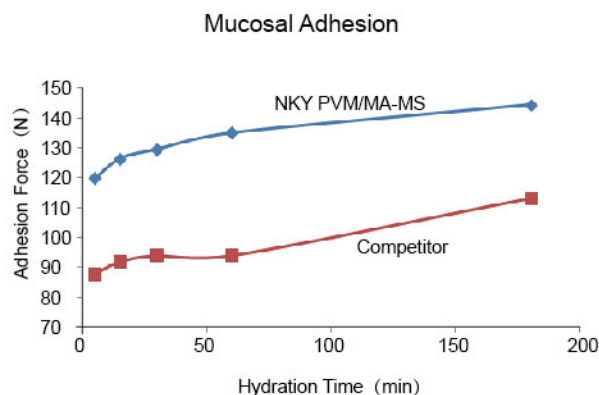
Applications

OraRez[®] MS is an excellent bioadhesive/mucoadhesive. The salt bridges improve the cohesive nature within the polymer, which makes them more able to sustain their adhesive properties over time.

Applications include:

- Bioadhesives and mucoadhesives
- Denture adhesives
- Wound coatings
- Skin protecting films
- Drug delivery

NKY OraRez[®] MS shows excellent initial and long-term mucosal adhesion.

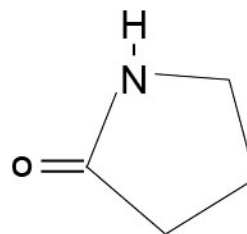




POLYMERS FOR PHARMACEUTICAL

NKY®- 2P

Product name	2-pyrrolidone
CAS NO.	616-45-5
Appearance	Colorless crystal
Properties	Completely miscible with most solvents including water, alcohol, diethyl ether, chloroform, benzene acetate and carbon disulfide; Exist as liquid above 25°C; Easily to recover; Good chemical stability; Incombustible;



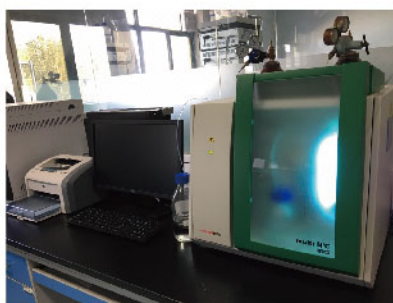
Applications

- Used as an intermediate in the manufacture of polymers such as polyvinylpyrrolidone and polypyrrolidone, and the raw material of acetamide pyrrolidone (piracetam) and amino-butyric acid.
- Acted as an organic compound consisting of a five-membered lactam, which is used in industrial settings as a high-boiling non-corrosive polar solvent for a variety of applications, such as medicines and resins.
- Used as solubilizer for drug active in injectable liquid products;
- Used as high concentration antibiotic solutions for veterinary parenteral formulations.

- NKY has and will always strive to deliver the highest quality products to our customers. NKY is continuously updating and implementing the best technology to manufacture our products, improving and updating our quality management systems and investing in our R&D capabilities.
- NKY has been a supplier of PVP-based excipients to the pharmaceutical industry. Presently, NKY offers the complete range of PVP excipient products to the global pharmaceutical market. All our products are of the highest quality and meet all regulatory specification. In addition, our comprehensive technical support group, our continuing updated quality management system and meticulous after-sales service allows our customers the peace of mind that they have chosen the right partner for their material needs.
- NKY is committed to the development of new pharmaceutical excipients and new innovative preparation techniques to provide new solutions and extra value for our customers. We will continue to work diligently to build our presence in the pharmaceutical industry. It is our mission to not only stay a dependable supplier of high quality pharmaceutical products, but to become a trusted partner that global pharmaceutical companies will want to work with in developing new opportunities and growth.



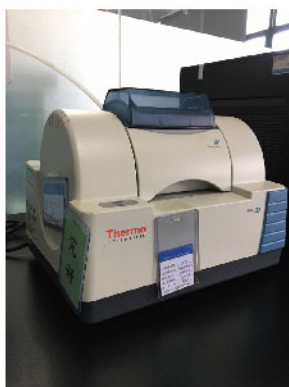
GC 7890B



TOC multi NC UV HS



GC 7697A



FTIR iS5

UV-Vis
EVOLUTION201

Potentiometric Titrator 862

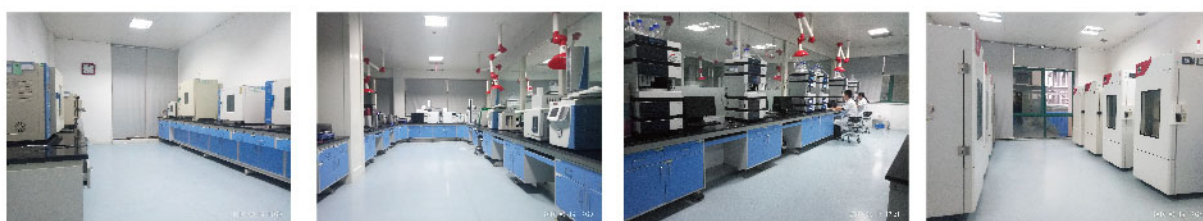


Moisture Meter 870KF

Our factory



Quality Department



R&D Center





NKY PHARMA



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