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Star-Tech & JRS Specialty Products Co., Ltd.

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Company Brief



Star-Tech & JRS Specialty Products Co., Ltd is the first Chinese foreign joint venture pharmaceutical excipient enterprise in China. The investment of 1st stage is CNY160 million with capacity of 5000 mt of PVP products. We pay attention to R&D in order to Give a system solution for our high quality customer. The main applications of our Products are pharmaceutical, nutritional, and medical instruments.



Our partner **JRS group** is a family enterprise with 140 years of history. It is a leading pharmaceutical excipient company in the world. It has 7 R & D centers, 17 pharmaceutical excipients production bases and 25 sales companies around the world .

Complete Regulatory Qualifications

Enterprise Qualification		Food Production Licence				
		EXCiPACT GMP Certification				
		Halal & Kosher Certification				
		ISO9001, ISO15001, ISO22000, ISO45001				
Registration Information	ITEMS	Stardone® K25	Stardone® K30	Stardone® K90	Polystardone®	Stardone® VA64
	CHINA CDE	F20180000231	F20209990252	F20180000233	F20180000229	F20180000230
	EDMQ CEP	CEP2014-314	CEP2014-314	CEP2016-046	CEP2014-337	CEP2014-365
	US DMF	28892	28892	28892	28972	29000



Stardone® K Series

- The low molecular Stardone® K25, K30 are used as binder, disperser, thickening agent in oral solid dosage forms. They also can be used as carrier of solid dispersion to improve dissolution of poorly insoluble water drug.
- The high molecular Stardone® K90 is used as binder, thickening agent in oral solid dosage forms. They also can be used as sustained-release material to slow the release of the drug.



Polystardone®

- Polystardone ® is used as super disintegrants in oral solid dosage forms. The advantage is over 10% additive amount didn't create gel.
- They can be used as suspension stabilizer in solution preparation.
- They also can be used as carrier of solid dispersion to improve the dissolution or to slow the release of the drug.



Stardone® VA64

- Stardone® VA64 is an excellent direct binder with outstanding compressibility and elastic deformation, to be used in oral solid dosage forms.
- They also can be used as coating film forming agent to make the film softer.
- The low Tg (105 °C) make them as a very good carrier in hot melt extrusion process.

Stardone® K25, K30, K90

Stardone® K30 is the classic wet binder with optimal balance between adhesive strength and ease of handling.

Characteristic	Benefits
Solubility in a Wide Range of Organic Solvents	Fast dispersibility in solvents(including water). Aqueous solutions are preferred to solvent-based systems but may not be suitable for drugs which are degraded by hydrolysis. Hence solubility in a range of organic solvents is favorable
Low Viscosity Solution	Ease of handling→ high viscosity binder solution may cause clogging of spray nozzle.
High Binding Efficiency	Lower use levels required to produce tablets with higher breaking force and lower friability at potentially lower compaction force.
High Water Solubility	No impact on drug dissolution at high use levels.

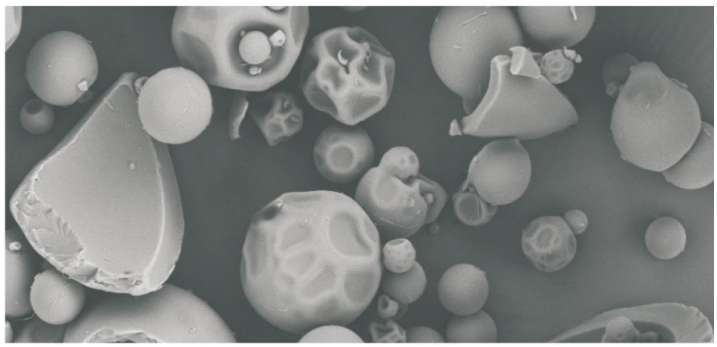
Application

Stardone® K30 is the ideal binder in all wet granulation processes by any of the methods below:

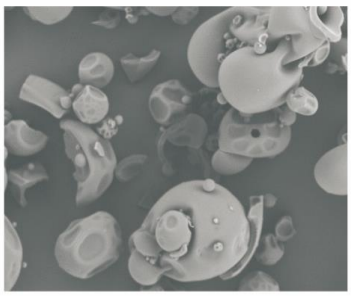
- ✓ Wet addition: As granulation solution
- ✓ (binder + solvent)
- ✓ Dry addition: Dry mixture of API and binder;
- ✓ Solvent is added to the dry mix
- ✓ Combination: Some binder is mixed with the API, and the rest is dissolved in the granulation solution → the preferred choice if the amount of solvent is restricted.

Reference Drugs:

- Metformin Hydrochloride Tablet
- Paracetamol Tablet
- Telmisartan Tablet
- Metronidazole Tablet
- Glimepiride Tablet
- Orlistat Capsules
- Domperidone Tablet



SEM of Stardone® K30



SEM of Stardone® K25



SEM of Stardone® K90

Case Study: Naproxen

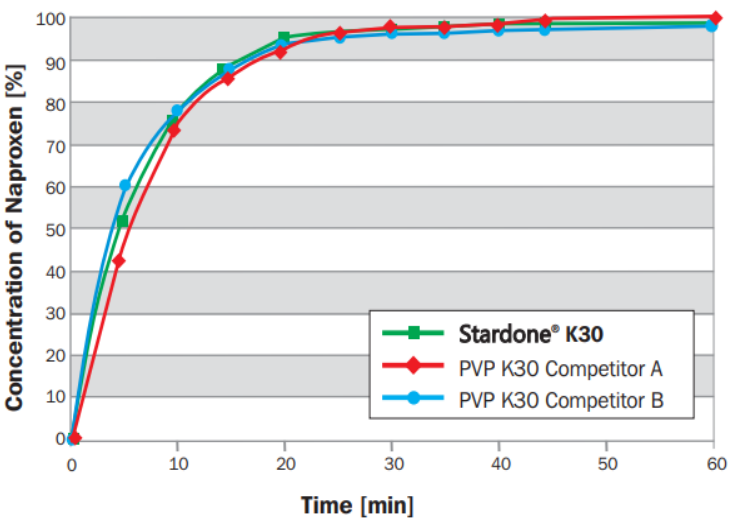
Naproxen, a BCS* class II drug whose bioavailability is rate-limited due to its poor solubility, was chosen as a model API.
It is typically wet granulated because of its poor compactibility. In many cases, the addition of other binder-fillers before tableting is necessary in order to achieve suitable tablet hardness with low friability. In this case study, wet granulation of Naproxen was performed with 5 % of Povidone K30 as a binder solution.

Formulation	
Products	Amount(%)
Naproxen 450mg	92.47
Stardone® K30	5
Polystardone® XL	2.02
Magnesium Stearate	0.51
Total	100

Formulation Results

Stardone®K30 and other povidone products achieved the target tablet crushing strength of 100 N at similar compaction forces. All products performed within the same range in terms of friability and disintegration time, facilitating 75 % Naproxen release in 10 minutes.

Parameter	**Stardone®K30**	PVP K30 Competitor A	PVP K30 Competitor B
Total Weight	500 mg	500 mg	500 mg
Tablet Hardness	100 N	100 N	100 N
Compression Force	6.4 kN	6.5 kN	7.7 kN
Tensile Strength	0.45 Mpa	0.43 Mpa	0.43 Mpa
Friability	0.00%	0.00%	0.00%
Disintegration Time	2 min 52 s	3 min 5 s	3 min 34 s

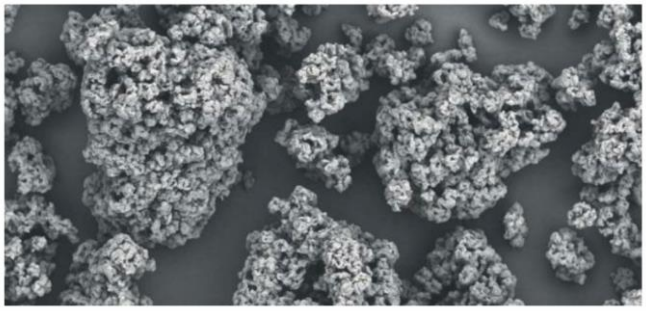


Summary

At low compression force (6.4kN), good tablet hardness with 0 % friability and a short disintegration time of 3 minutes was achieved. In addition, more than 75 % of Naproxen was released in less than 10 minutes. This demonstrates the effectiveness of **Stardone® K30** not only as wet binder but also as a dissolution enhancer for an immediate release oral tablet. The formulation eliminates the need for other binder-fillers, leading to a reduction in tablet size, better patient compliance, and marketing benefits.

Polystardone® XL, XL-10, M

Tablet disintegration involves the fast breakage of a solid dosage structure via contact with water or gastric fluids. It enables dissolution of the bio-active components as a prerequisite for achieving the desired and required bioavailability**.** **Polystardone®** is unsurpassed in its performance and versatility as a super disintegrant in formulations.



SEM of Polystardone®

Benefits

Rapid disintegration at low concentrations (1 - 5 %)
Functions via a combination of disintegration mecha-nisms: wicking, shape recovery, and swelling, thus imparting its unsurpassed versatility as a super disintegrant in formulations
Suitable for direct compression, wet granulation, anddry granulation
Increased tablet tensile strength and reduced friability due to high compressibility. Especially suitable for poorly compressible APIs
No gel formation even at higher concentrations (10 %),ideal for ODTs
Non-ionic polymer– no ionic interaction with cationic APIs to retard drug release, unlike anionic disintegrants, which may slow dissolution due to interaction with cationic APIs (i.e. Ranitidine, Cetirizine)

Application

Polystardone combines different mechanisms to achieve rapid tablet disintegration at low concentrations. Due to its viscoelasticity, Polystardone is highly compactable, resulting in robust tablets with increased tensile strength and reduced friability. The SEM of Polystardone® show a granular and porous structure with a large surface area. We can use like below methods:

- ✓ Wet Granulation: intra and extra granular super disintegrant due to high wetting capacity without gel formation during the granulation process.
- ✓ Dry Granulation: Ideal intra and extra granular super disintegrant due to excellent compressibility and hight surface area to volume ratio.
- ✓ Direct Compression: Free-flowing property translates to easy handing. Unique, viscoelastic characteristic results in high compressibility which increases tablet tensile strength and reduces friability. Especially suitable for poorly compressible APIs.

Reference Drugs:

- ➢ Valsartan and Amlodipine Tablet
- ➢ Olandipine Tablets
- ➢ Entecavir Tablet
- ➢ Isoniazid Tablets
- ➢ Rosuvastatin Calcium Tablet
- ➢ Levofloxacin Tablet
- ➢ Lrbesartan Capsules

Product Name	Particle Size (D50)
Polystardone XL	90~130um
Polystardone XL-10	25~35um
Polystardone M	8~15um

***We can make different particle accordingly to contract**.

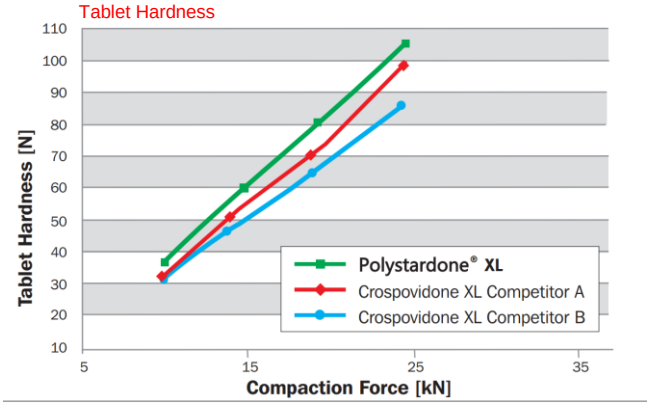
Case Study

A combination of water-insoluble and water-soluble, medium-compactable matrix was chosen to compare the functionality of **Polystardone®** XL and XL-10 against competitor products.

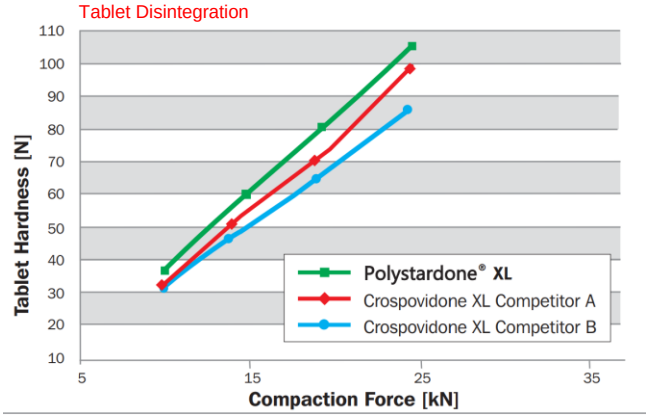
Formulation	
Products	Amount(%)
Calcium Hydrogen Phosphate	72.75
Spray-dried Lactose	24.25
Crospovidone	2
Sodium Stearyl Fumarate	1
Total	100

- The performance of **Polystardone®** XL is comparable to marketed products A and B in terms of disintegration time and tablet tensile strength.
- **Polystardone®** XL-10 provided the additional benefit of increasing tablet hardness of the medium-
- compactable matrix of DCP and lactose of up to 25 %.The disintegration time was also dramatically reduced from 13 minutes to less than 20 seconds. The performance of **Polystardone®** XL-10 is comparable to other established Crospovidone XL-10 products in terms of disintegration time and tablet crushing strength.
- The case study demonstrates the effectiveness of **Polystardone®** as a super disintegrant for a tablet matrix containing both water-soluble (lactose)and insoluble (calcium hydrogen phosphate) medium-compactable fillers. The performance of **Polystardone®** was compared to competitors materials.
- As illustrated above, both **Polystardone®** X. and **Polystardone®** XL-10 have similar performance to equivalent products in terms of compactibility and disintegration capabilities. The choice of tablet matrix in the case study illustrates the disintegration mechanism of **Polystardone®** XL and **Polystardone®** XL-10, ensures rapid disintegration regardless of compaction force. Furthermore, **Polystardone®** XL-10 offers additional benefits in increasing tablet tensile strength without a compromise in its disintegration efficiency.

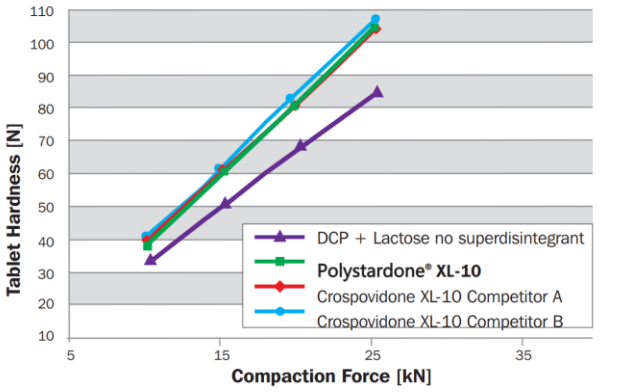
Tablet Hardness



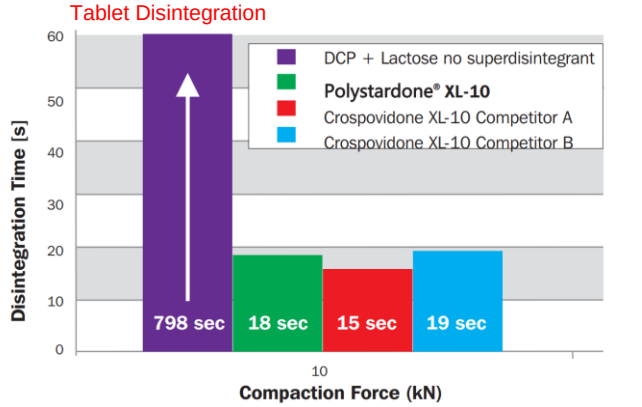
Tablet Disintegration



Tablet Hardness

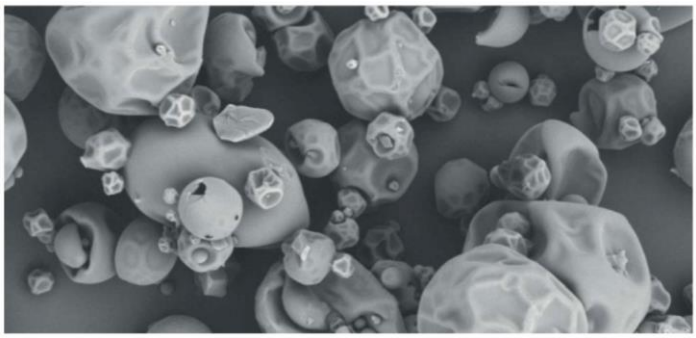


Tablet Disintegration



Stardone® VA64

The objective of drug formulation is to develop a product that delivers therapeutic effectiveness in terms of the correct dosage and required bioavailability, while also ensuring that the final product is robust and disintegrates according to its drug release requirement. **Stardone® VA64** is the ultimate tablet binder that extends its excellent adhesive property in wet granulation, as well as in dry granulation and direct compression.



SEM of Stardone® VA64

Characteristic	Benefits
Non-ionic copolymer	There is no interaction with ionic APIs.
Less hygroscopic than povidone homopolymers of similar molecular weight	Ideally suited as co-film-former.
Free-flowing powder Plastic deformation	Hollow particle morphology an increased surface area that enhances particle bonding and good compressibility
Large surface area due to hollow, spherical particle morphology	Excellent binder at 2 - 10% use level. Performs synergistically with other direct
Ideal glass transition temperature (Tg) for hot meltextrusion	The lower Tg (105°C) makes **Stardone® VA 64** an ideal polymer matrix for solid dispersions/solutions via hot melt extrusion, which enhances the dissolution of poorly soluble drug actives.

Application

- ✓ Direct Compression: Excellent binder at 2 - 10 % use level. Performs synergistically with other direct
- ✓ Dry Granulation: Can be used as a binder in dry granulation (roller compaction)
- ✓ Wet Granulation: Enables wet granulation of moisture sensitive APIs due to low hygroscopicity.
- ✓ Hot Melt Extrusion: Acts as a polymer matrix for solid dispersions/solutions via hot melt extrusion due to
- ✓ ideal glass transition temperature at 105 °C
- ✓ Film Coating: Ideally suited as co-film-former

Reference Drugs:

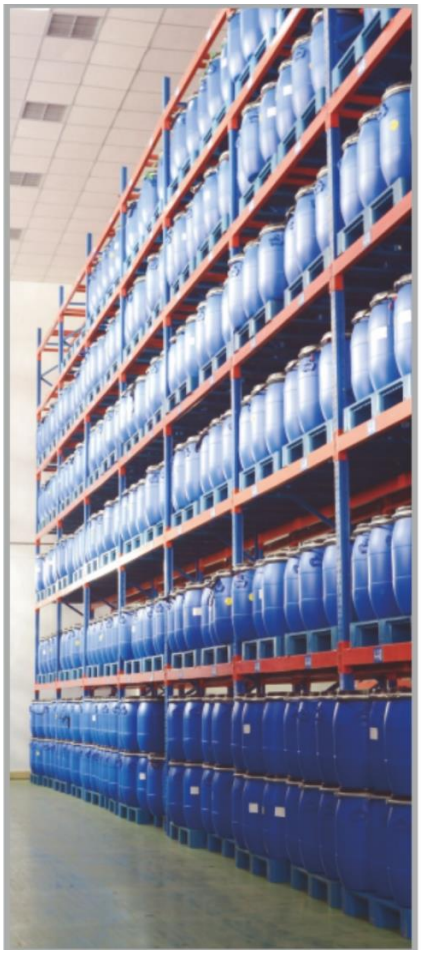
- ➢ Citalopram Hydrobromide Tablet
- ➢ Lopinavir-ritonavir Tablet
- ➢ Ritonavir Tablet
- ➢ Rigagliptin metformin Tablet
- ➢ Tofacatib Citrate sustained-release Tablet
- ➢ Nifedipine Controlled release Tablet
- ➢ Suvoresan Tablet
- ➢ Fenofibrate Tablet
- ➢ Olapalil Tablet
- ➢ Rametylamine Tablet
- ➢ Ledipevisophobuvir Tablet
- ➢ Sofovevo Tablet

Package and Storage

Products	Specification	Inner Package	Outside Package	Storage Condition
Stardone® K25	25kg/Drum	Two PE Bags	HDPE drum	Sealed Storage
Stardone® K30	25kg/Drum	Two PE Bags	HDPE drum	Sealed Storage
Stardone® K90	25kg/Drum	Two PE Bags	HDPE drum	Sealed Storage
Stardone®VA64	20kg/Drum	Two PE Bags	HDPE drum	Sealed Storage
Polystardone® XL	20kg/Drum	Two PE Bags	Fiber drum	Sealed Storage
Polystardone® XL-10	20kg/Drum	Two PE Bags	Fiber drum	Sealed Storage
Polystardone® M	20kg/Drum	Two PE Bags	Fiber drum	Sealed Storage











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