Stardone[®] K25、K30、K90

Povidone, Ph.CP, EP, USP/NF, JP

Stardone[®] K25、K30、K90 is a classic wet binder with optimal balance between adhesive strength and ease of handing.

Product Properties	Performance Impact
Excellent solubility in water and a range of organic solvents	Fast dispersibility in solvents (including water). Aqueous solution 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 handing→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
Forming complex with APIs	No effect on drug dissolution, can improve the drug dispersion and water solubility
Non-ionic polymer	no contraindication risk of compatibility with ionic pharmaceutical ingredients

Stardone® K25、K30、K90 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 \rightarrow the preferred choice if the amount of solvent is restricted



Typical SEM of Stardone® K30



Typical SEM of Stardone® K25



Typical SEM of Stardone® K90



Case Study: Stardone® K30

Naproxen, 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.

Stardone®K30 against other similar products on the market was compared.

Formulation Results of Naproxen

Formulation

Products	Amount(%)
Naproxen	92.47
Povidone K30	5.00
PolyStardone® XL	2.02
Magnesium Stearate	0.51
Total	100

Parameter	Stardone® K30	Import competitor A	Import competitor B	Domestic competitor C	Domestic competitor D
Tablet Weight	500 mg	500 mg	500 mg	500 mg	500 mg
Tablet Hardness	100 N	100 N	100 N	100 N	100 N
Compression Force	6.4 kN	6.5 kN	6.3 kN	7.6 kN	7.4 kN
Tensile Strength	0.45 Mpa	0.43 Mpa	0.43 Mpa	0.40 Mpa	0.40 Mpa
Friability	0.0 %	0.0 %	0.0 %	0.5 %	0.6%
Disintegration Time	2 min 59 s	3 mim 5 s	2 min 52 s	3 min 54 s	3 min 47 s



Average(n=6)% Naproxen Dissolved

Summary

In this case, Stardone® K30 has similar performance to that of import competitor A and B, and is better than domestic competitor C and D in terms of tablet compressibility, tensile strength, friability, and disintegration time.