TECHNICAL INFORMATION

Utilising **VIVAPHARM® PVP K30** and **VIVAPHARM® PVP K25** as Wet Binders to Optimise Naproxen Immediate Release Tablets

Introduction

The objective of this Technical Information is to demonstrate the effect of viscosity of the selected wet binder on the tableting performance and dissolution of naproxen immediate release tablets.

Povidones are available in different molecular weights. The higher the molecular weight, the greater the viscosity and consequently the adhesive strength. The K-value denotes the intrinsic viscosity of the polymer related to the molecular weight, and is derived from the relative viscosity of the aqueous solution measured at 25 °C. The direct correlation between the molecular weight and properties enables the appropriate grade to be used in each formulation in the appropriate concentration in order to achieve the optimum effect.

In order to provide formulators with flexibility in the choice of wet granulation binders with good adhesive strength and ease of handing, JRS PHARMA offers 2 grades of wet binders: **VIVAPHARM® PVP K30** and **VIVAPHARM® PVP K25** (Table 1).

Grade	K-Value	Typical Dynamic Viscosity for 10 % (g/ml) solutions in water at 20 °C
VIVAPHARM® PVP K25	24.0 – 27.0	3.5 – 5.5
VIVAPHARM® PVP K30	29.0 – 32.0	5.5 – 8.5

Tab. 1 **VIVAPHARM® PVP** Grades

Case Study: Naproxen

Formulation Characteristics

Naproxen is typically wet granulated because of its poor compactability. In this case study, wet granulation of naproxen was performed with either 5 % of **VIVAPHARM® PVP K30** or 7 % of **VIVAPHARM® PVP K25** as a binder solution. **VIVAPHARM® PVPP XL** and magnesium stearate were added as extragranular superdisintegrant and lubricant respectively. The goal of this formulation was to achieve sufficient tablet hardness with low friability and fast dissolution of the API. The performance of **VIVAPHARM® PVP K30** and **VIVAPHARM® PVP K25** were compared to demonstrate the differences between the two grades.

Formulation

Products	Formulation with PVP K30 [%]	Formulation with PVP K25 [%]
Naproxen 450 mg	92.47	90.47
VIVAPHARM® PVP K30	5.00	–
VIVAPHARM® PVP K25	–	7.00
VIVAPHARM® PVPP XL (Crospovidone)	2.02	2.02
Magnesium Stearate	0.51	0.51
Total	**100**	**100**

Tab. 2 Composition of Tested Tablets

Formulation Results of Naproxen

Parameter	5 % VIVAPHARM® PVP K30	7 % VIVAPHARM® PVP K25
Tablet weight	500 mg	500 mg
Tablet hardness	100 N	100 N
Compression force	6.4 kN	7.1 kN
Friability	0.0 %	0.15 %

Tab. 3 Physical Properties of Tested Formulations

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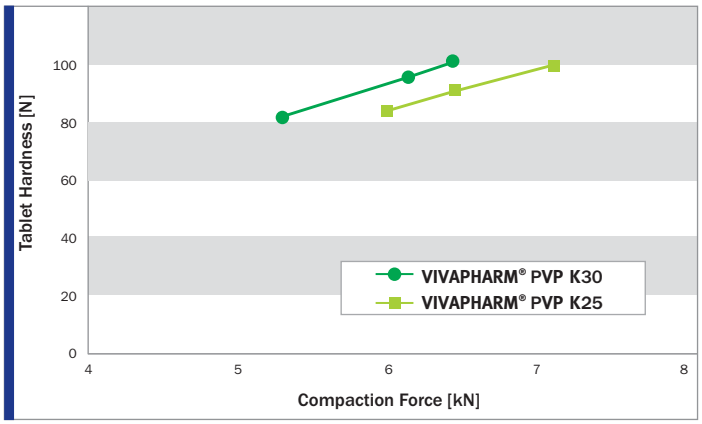
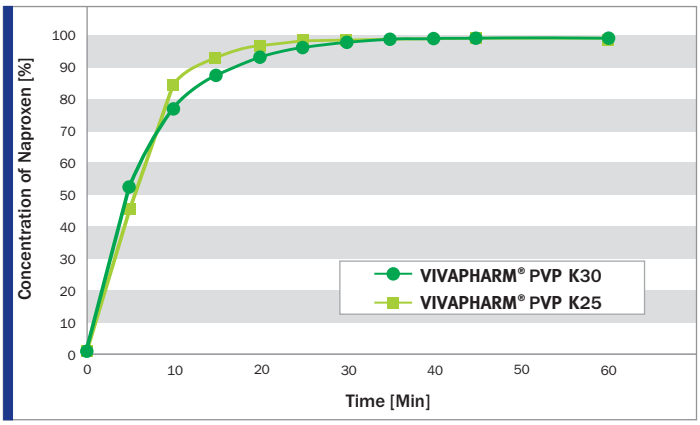
Compaction Profile

Wet granulation with 5 % **VIVAPHARM® PVP K30** resulted in tablets with similar crushing strength at lower compaction forces at a lower use level compared to 7 % **VIVAPHARM® PVP K25**. The friability of the tablets was also lower, respectively.



Dissolution Profile

The dissolution profiles of tablets granulated with **VIVAPHARM® PVP K30** and **VIVAPHARM® PVP K25** are comparable, facilitating 75 % Naproxen release in 10 minutes. The slightly faster release rate of naproxen with **VIVAPHARM® PVP K25** can be attributed to its lower viscosity and slightly higher solubility.



Summary

Both **VIVAPHARM® PVP K30** and **VIVAPHARM® PVP K25** resulted in tablets with sufficient hardness and low friability at low compression forces. In addition, more than 75 % of Naproxen was released in less than 10 minutes.

The case study demonstrates subtle differences between the two grades which can be utilized to optimize specific formulations depending on the properties of the active ingredient.

Due to its higher viscosity and greater adhesive strength, **VIVAPHARM® PVP K30** tend to produce stronger tablets at lower compaction forces at a lower concentration.
On the other hand,**VIVAPHARM® PVP K25** may lead to a slight improvement of the dissolution profile due to its lower viscosity and higher solubility.

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