TECHNICAL INFORMATION

The Effect of PVP Viscosity on the Binding Performance in Naproxen Tablets

Aim of the study

This study aimed to compare the performance of **VIVAPHARM® PVP K25**, **VIVAPHARM® PVP K30**, and **VIVAPHARM® PVP K90** respectively as wet-granulation binders in a naproxen immediate-release formulation.
The correlation between viscosity and binding power as well as the effect of the K-value on dissolution rates were analysed.

Povidone

Povidone is a synthetic polymer resulting from a chemical reaction and subsequent polymerization of the building-block monomer N-vinyl-pyrrolidone.

Povidone (polyvinylpyrrolidone, PVP) is available in different grades, described by the K-value – a parameter that is derived from the relative viscosity of an aqueous povidone solution.[1]
Increasing K-values go along with a growing adhesive strength of the polymer. This correlation enables the appropriate grade to be used in each formulation in the proper concentration to achieve optimum performance.

JRS PHARMA offers three grades of povidone for wet granulation: **VIVAPHARM® PVP K25**, **VIVAPHARM® PVP K30** and **VIVAPHARM® PVP K90** (Table 1).

Grade	K-Value	Typical Relative Kinematic Viscosity for 10 g/l Solutions in Water at 25 °C
VIVAPHARM® PVP K25	24.0 – 27.0	1,15
VIVAPHARM® PVP K30	29.0 – 32.0	1.25
VIVAPHARM® PVP K90	85.0 – 95.0	4.30

Tab. 1 **VIVAPHARM® PVP** Grades

Naproxen

Naproxen is a nonsteroidal anti-inflammatory drug (NSAID) advised to treat diseases of joints, such as rheumatoid arthritis, osteoarthritis, and gout but also non-rheumatic conditions, such as period pain, back pain, sprains, and strains. It may be administered orally or rectally using a convenient once or twice daily regimen.[2,3]

Formulation

Naproxen is a poorly compactable drug and is therefore typically wet granulated. In this case study, wet granulation of naproxen was performed with solutions of VIVAPHARM® PVP K25, VIVAPHARM® PVP K30 or VIVAPHARM® PVP K90, respectively, as a binder.

The percentage of each wet binder was adjusted to achieve binder solutions with comparable viscosity, so that the adhesive performance remained constant between the three formulations.

VIVAPHARM® PVPP XL was added as an extragranular superdisintegrant and magnesium stearate as a lubricant.

Products	Formulation with PVP K25 [%]	Formulation with PVP K30 [%]	Formulation with PVP K90 [%]
Naproxen 450 mg	90.47	92.47	95.47
VIVAPHARM® PVP K25	7.00	–	–
VIVAPHARM® PVP K30	–	5.00	–
VIVAPHARM® PVP K90	–	–	2.00
VIVAPHARM® PVPP XL (Crospovidone)	2.02	2.02	2.02
Magnesium Stearate	0.51	0.51	0.51
Total	**100**	**100**	**100**

Tab. 2 Composition of the Tested Tablets

The goal of each formulation was to achieve sufficient tablet hardness with low friability and fast dissolution of the API. The performance of VIVAPHARM® PVP K25, VIVAPHARM® PVP K30 and VIVAPHARM® PVP K90 was compared to demonstrate the difference between the three grades. For each formulation listed above, the tablet hardness, friability, and dissolution profile were measured, to assess the effect of the binders' concentration and K-value on these parameters.

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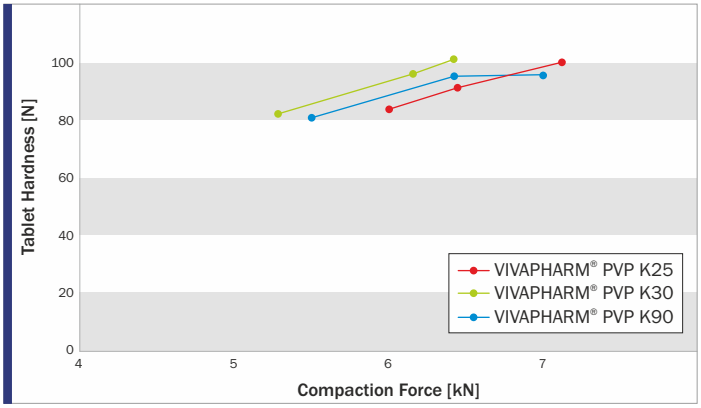
Results

Compaction profile

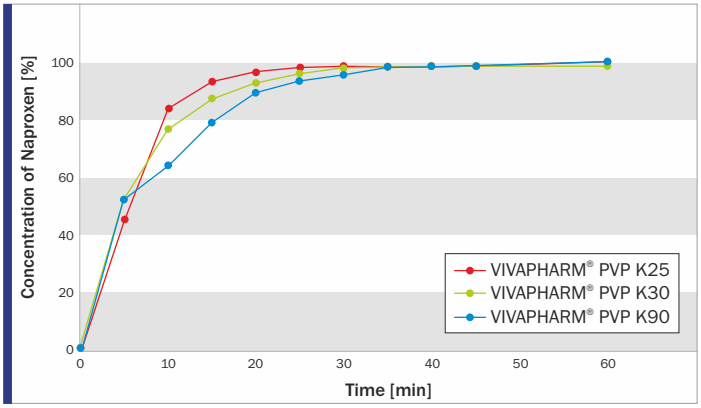
Wet granulation with 2 % VIVAPHARM® PVP K90, 5 % VIVAPHARM® PVP K30 and 7 % VIVAPHARM® PVP K25 respectively resulted in tablets with comparable crushing strength.
Similar crushing strength was achieved with a lower use level of binder upon increasing the K-value of the povidone. So that the 2 % VIVAPHARM® PVP K90 formulation could achieve comparable results as the 7 % VIVAPHARM® PVP K25 formulation.

Dissolution Profile

The dissolution profiles of tablets granulated with VIVAPHARM® PVP K25, VIVAPHARM® PVP K30 and VIVAPHARM® PVP K90 are comparable, facilitating 80 % Naproxen release in 15 minutes.
The slight increase in release rate with decreasing K-value can be attributed to the lower viscosity and slightly higher solubility of the excipient.



Graph 1 Tablet Hardness Profile of Naproxen Core Tablets



Graph 2 Release Profile of Naproxen over Time

Summary

All three formulations, using VIVAPHARM® PVP K25, VIVAPHARM® PVP K30 or VIVAPHARM® PVP K90 as binder, resulted in tablets with sufficient hardness and low friability at low compression forces.
The concentration of binder needed to reach the target hardness decreased in the order K25 (7%) > K30 (5%) > K90 (2%), thus illustrating the superior adhesive power of VIVAPHARM PVP K 90 compared to other povidone grades with lower K-value.
Dissolution testing showed that 80 % of naproxen was released in 15 minutes for each formulation. Furthermore, observations showed that dissolution rates moderately decreased with increasing K-values.
These differences offer opportunities to optimize specific formulations depending on the active ingredient.

References

[1] Povidone Monograph - European Pharmacopoeia 10th Edition
[2] United Kingdom National Health Service – Naproxen (https://www.nhs.uk/medicines/naproxen/)
[3] Todd, P.A., Clissold, S.P. Naproxen. Drugs 40, 91–137 (1990).

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