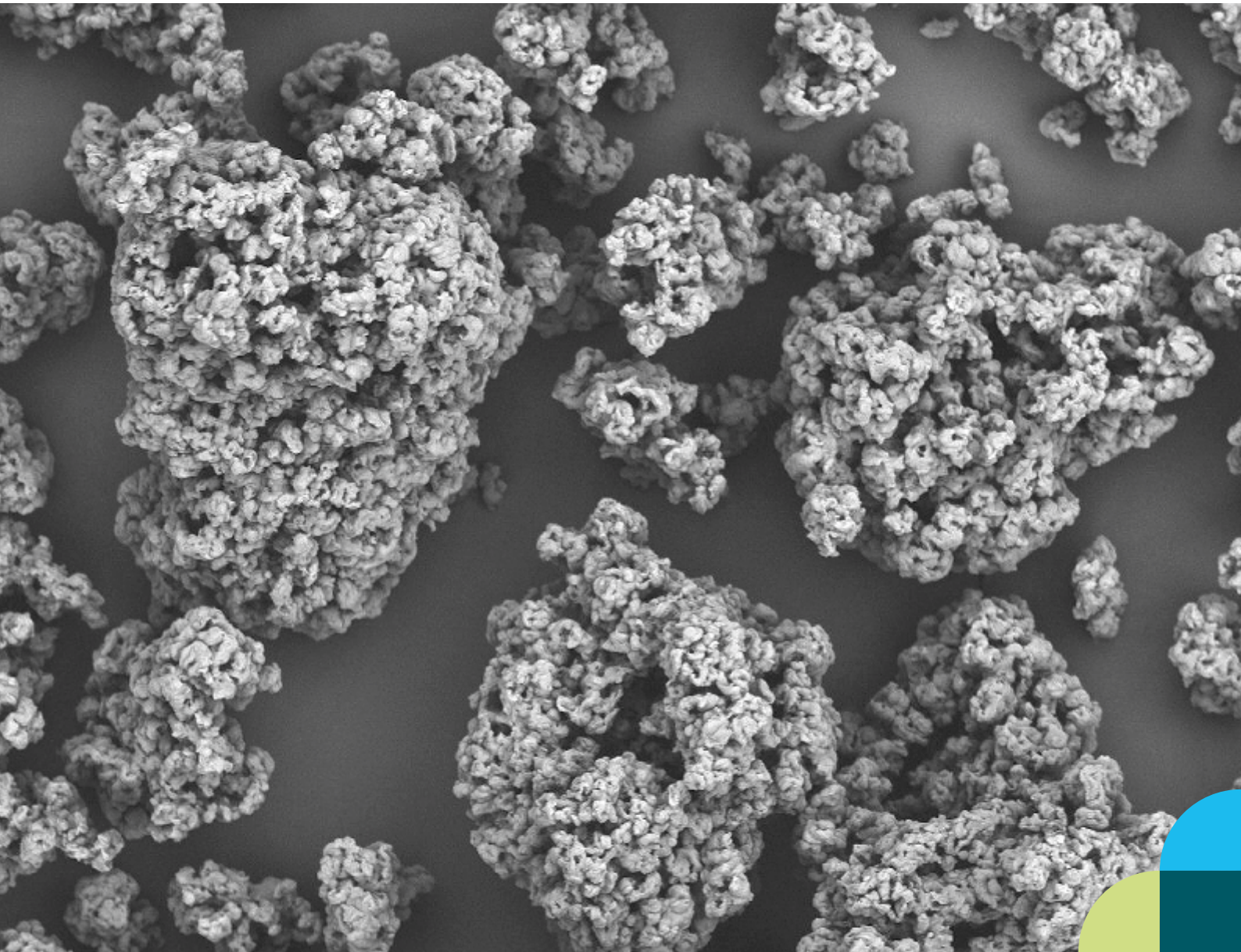
Fibers for Life.

JRS PHARMA

Exceptional Disintegration Performance Unsurpassed Versatility

Crospovidone, Ph. Eur. USP/NF, ChP, JP, E 1202, FCC

VIVAPHARM® PVPP



VIVAPHARM® PVPP

Introduction

VIVAPHARM® PVPP is made up of water-insoluble synthetic crosslinked homopolymers of Pyrrolidone (Figure 1).

VIVAPHARM® PVPP combines different mechanisms to achieve rapid tablet disintegration at low concentrations (1 - 5 %). Due to its viscoelasticity, is VIVAPHARM® PVPP highly compactable, resulting in robust tablets with increased tensile strength and reduced friability. Scanning electron microscope images of VIVAPHARM® PVPP show a granular and porous structure with a large surface area (Figure 2). VIVAPHARM® PVPP enhances the dissolution of poorly soluble drug actives. Due to its nonionic property, it does not bear any risk of interaction with ionic APIs.

VIVAPHARM® PVPP is available in two particle sizes to serve different application requirements. VIVAPHARM® PVPP XL-10 with its small average particle size is well suited for use in ODT or chewable formulations offering a smooth mouthfeel.

Products	Compendial Type	Typical Average Particle Size [µm]
VIVAPHARM® PVPP XL	Type A	125
VIVAPHARM® PVPP XL-10	Type B	30

Tab. 1

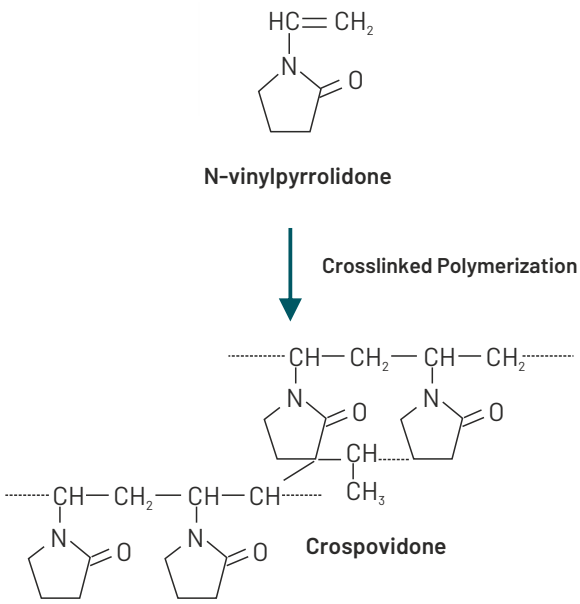


Fig. 1 Chemical Structure of VIVAPHARM® PVPP Crospovidone from the Crosslinked Polymerization of N-vinylpyrrolidone

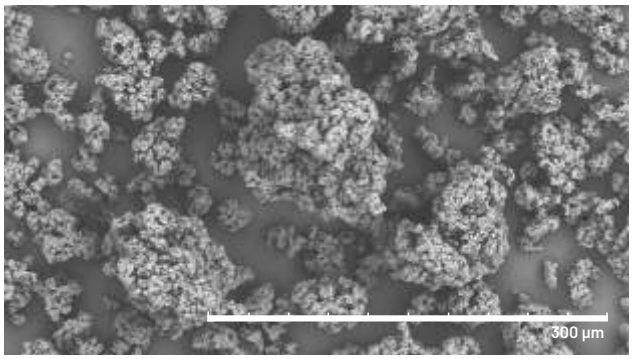


Fig. 2 Typical Scanning Electron Micrograph of VIVAPHARM® PVPP

Mechanisms of Disintegration

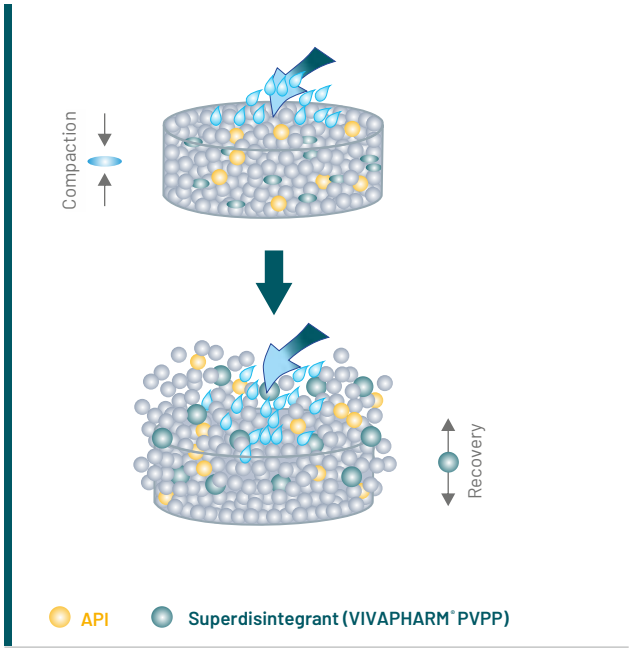


Fig. 3

Shape Recovery

Elastic energy store during the compression of the table is rapidly released upon contact with water.

Physical Properties

- Water-insoluble
- Granular and highly porous
- Viscoelastic deformation
- High cross-link density
- Free-flowing powder
- High surface area to volume ratio
- Non-ionic polymer

Benefits

- Rapid disintegration at low concentrations (1 - 5 %)
- Suitable for direct compression, wet granulation, and dry 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
- Unlike anionic disintegrants, PVPP does not with cationic APIs (i.e. Ranitidine, Cetirizine)

VIVAPHARM® PVPP – Grades

Grades

VIVAPHARM® PVPP XL

The standard superdisintegrant for all immediate release tablet formulations.

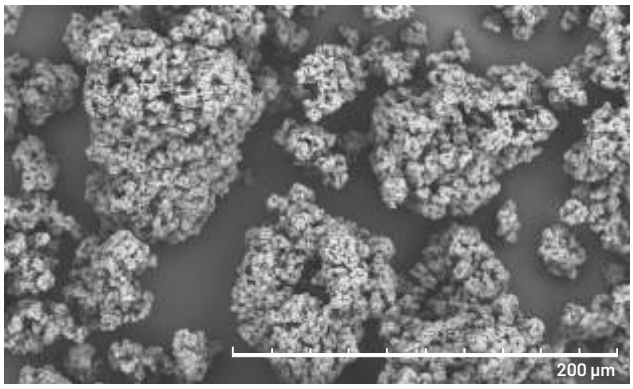


Fig. 4a Typical Scanning Electron Micrograph of VIVAPHARM® PVPP XL (Magnification x500)

A larger particle size and increased porosity leads to rapid wicking and swelling and thus to rapid disintegration.

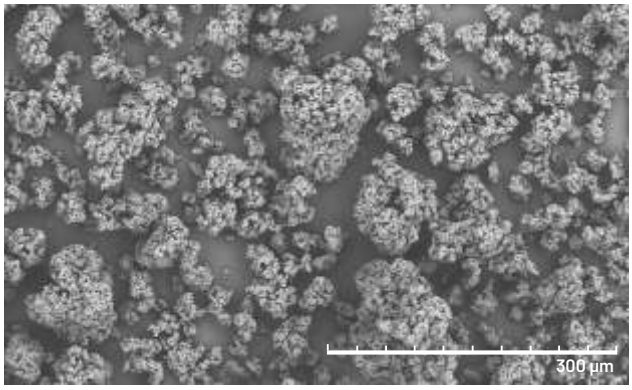


Fig. 4b Typical Scanning Electron Micrograph of VIVAPHARM® PVPP XL (Magnification x250)

VIVAPHARM® PVPP XL-10

A finer particle size makes this grade suitable for ODTs and chewable tablet formulations that require smooth mouthfeel and rapid disintegration.

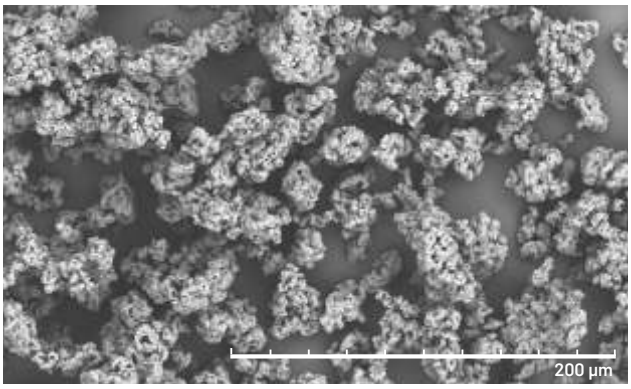


Fig. 5a Typical Scanning Electron Micrograph of VIVAPHARM® PVPP XL-10 (Magnification x500)

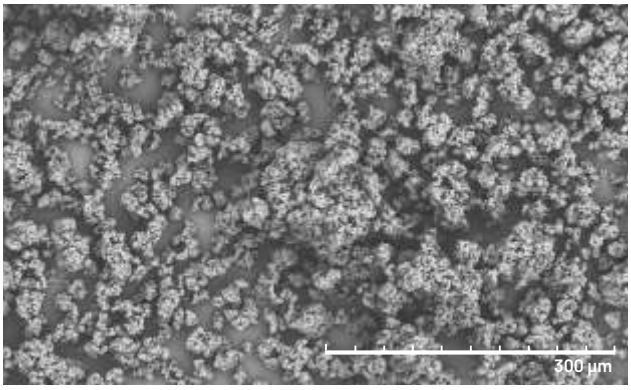


Fig. 5b Typical Scanning Electron Micrograph of VIVAPHARM® PVPP XL-10 (Magnification x250)

Applications

Wet Granulation

Ideal intra and extragranular superdisintegrant due to high wetting capacity without gel formation during the granulation process.

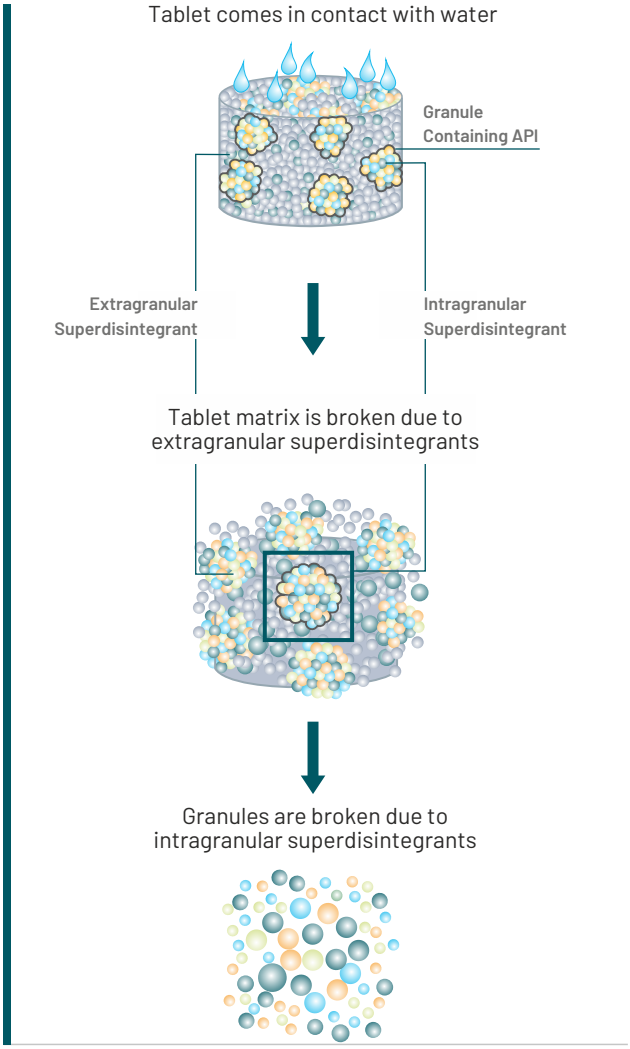


Fig. 6 Wet granulation

Dry Granulation

Ideal intra- and extragranular superdisintegrant due to excellent compressibility and high surface area to volume ratio.

Direct Compression

Free-flowing property translates to easy handling. Unique, viscoelastic characteristic results in high compressibility which increases tablet tensile strength and reduces friability. Especially suitable for poorly compressible APIs.

Special Applications

VIVAPHARM® PVPP does enhance the dissolution and bioavailability poorly water-soluble BCS Class II APIs, e.g. Mefanamic acid [1] or BCS Class IV, e.g. Furosemide [2]. Solubility and dissolution efficiency can be even more enhanced in combination with PVP K30 [1].

References
[1] Nagabhushanam et al. Int J Pharm Pharm Sci 2010, Vol 3(1), 1619.

VIVAPHARM® PVPP Stringent Specification, High Purity, Superb Quality

VIVAPHARM® PVPP superdisintegrants are suitable for pharmaceutical as well as nutraceutical applications and fully compliant with Ph. Eur., NF, JP, E 1202, FCC.

While the above mentioned regulations meet world-wide standards, JRS PHARMA specifies more stringent limits (highlighted in the specification extracts).

Reactive impurities, such as peroxides can cause drug instability, leading to loss in potency and formation ofpotentially toxic degradants of the active ingredient.

JRS PHARMA has therefore defined very low internal impurity limits for the release of VIVAPHARM® PVPP, which is analyzed at our Analytical Competence Center in Pirna, Germany.

To address the issue of increasing peroxide levels due to oxygen exposure during storage, special protective packaging material has been carefully selected.

VIVAPHARM® PVPP XL

	Tightest Compendial Limit (Pharmaceutical Monographs)	VIVAPHARM® PVPP XL
Impurities		
1-Vinyl-2-pyrrolidone (Impurity A)	≤ 10 ppm	≤ 5 ppm ≤ 400 ppm
Peroxides	≤ 400 ppm	≤ 10 ppm
Heavy metals	≤ 10 ppm	≤ 2 ppm
Lead	–	
Microbiology		
TAMC	–	≤ 100 cfu / g
TYMC	–	≤ 20 cfu / g
E. coli	–	Negative in 1 g
Ps. aeruginosa	–	Negative in 1 g
Salmonella	–	Negative in 10 g
Staph. aureus	–	Negative in 1 g

Tab. 2 VIVAPHARM® PVPP XL Impurities Overview Competitors

24 Months Production Impurity Data

The observed impurity data for each manufactured batch within a period of 24 months for VIVAPHARM® PVPP XL is consistently well below the JRS and compendial limits.

Vinylpyrrolidone

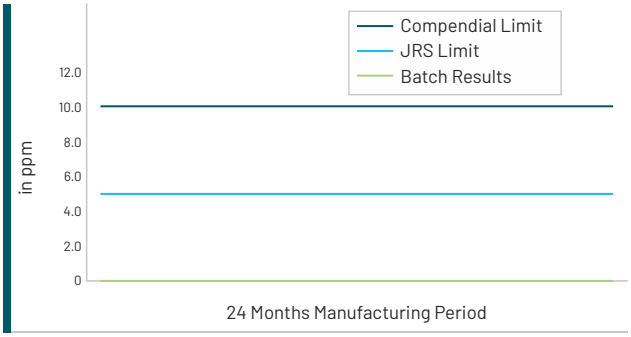


Fig. 7

Peroxide

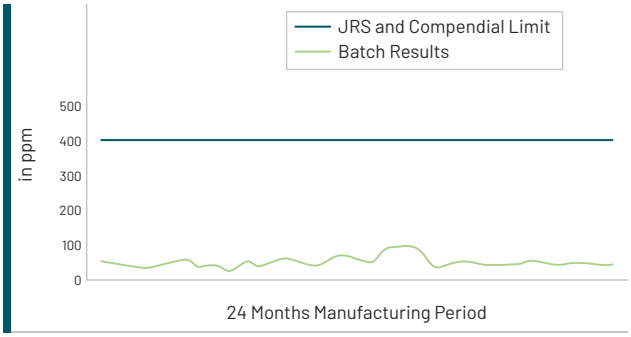


Fig. 8

VIVAPHARM® PVPP XL-10

	Tightest Compendial Limit (Pharmaceutical Monographs)	VIVAPHARM® PVPP XL-10
Impurities		
1-Vinyl-2-pyrrolidone (Impurity A)	≤ 10 ppm	≤ 5 ppm
Peroxides	≤ 1000 ppm	≤ 400 ppm
Heavy metals	≤ 10 ppm	≤ 10 ppm
Lead	–	≤ 2 ppm
Microbiology		
TAMC	–	≤ 100 cfu / g
TYMC	–	≤ 20 cfu / g
E. coli	–	Negative in 1 g
Ps. aeruginosa	–	Negative in 1 g
Salmonella	–	Negative in 10 g
Staph. aureus	–	Negative in 1 g

Tab. 3 VIVAPHARM® PVPP XL-10 Impurities Overview Competitors

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Vinylpyrrolidone

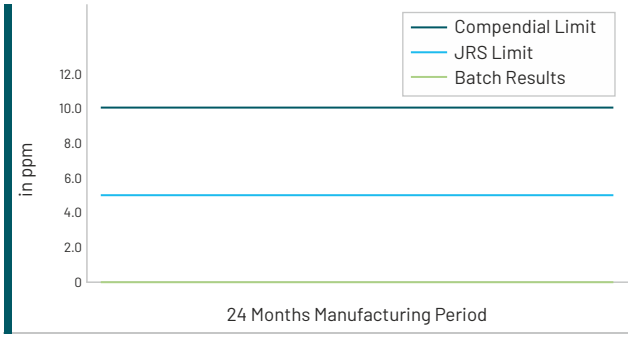

Fig. 9

Peroxide

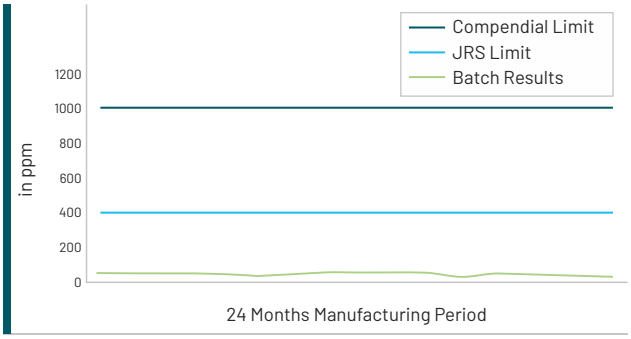

Fig. 10

Disclaimer:
The information provided in this brochure is based on thorough research and is believed to be completely reliable. Application suggestions are given to assist our customers, but are for guidance only. Circumstances in which our material is used vary and are beyond our control. Therefore, we cannot assume any responsibility for risks or liabilities, which may result from the use of this technical advice.

Fibers for Life.

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