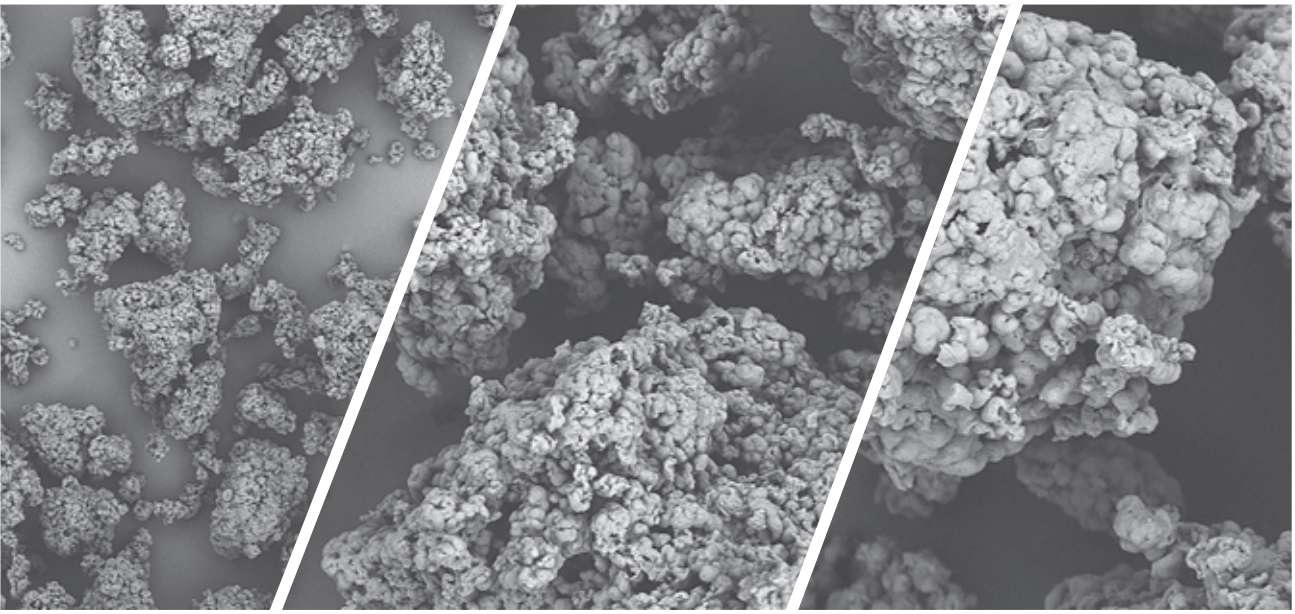
VIVAPHARM® PVPP

Crospovidone, Ph. Eur, NF, JP, E 1202, FCC



Zooming in on Product Quality

Stringent Specification
High Purity
Superb Quality

JRS PHARMA
The Global Excipient Maker

JRS FAMILY
A Member of the JRS Group

VIVAPHARM® PVPP

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 of potentially toxic degradants of the active ingredient.

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

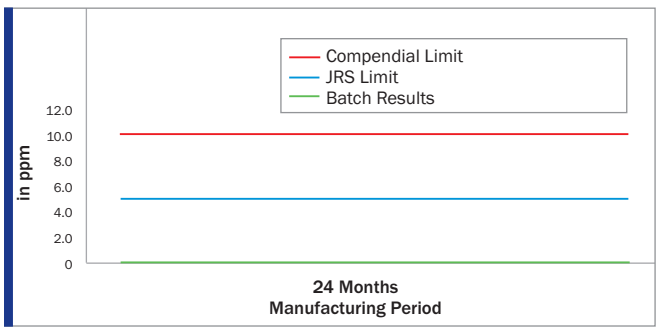
VIVAPHARM® PVPP XL

PVPP XL	Tightest Compendial Limit (Pharmaceutical Monographs)	VIVAPHARM® PVPP XL	Competitor A	Competitor B
Impurities				
1-Vinyl-2-pyrrolidone (Impurity A)	≤ 10 ppm	**≤ 5 ppm**	**≤ 5 ppm**	≤ 10 ppm
Peroxides	≤ 400 ppm	≤ 400 ppm	≤ 400 ppm	≤ 400 ppm
Heavy metals	≤ 10 ppm	≤ 10 ppm	as Lead:	≤ 10 ppm
Lead	–	**≤ 2 ppm**	≤ 5 ppm	–
Microbiology				
TAMC	–	**≤ 100 cfu / g**	**≤ 100 cfu / g**	≤ 200 cfu / g
TYMC	–	**≤ 20 cfu / g**	≤ 100 cfu / g	**≤ 20 cfu / g**
E. coli	–	**Negative in 1 g**	**Pass equals negative**	–
Ps. aeruginosa	–	**Negative in 1 g**	**Pass equals negative**	–
Salmonella	–	**Negative in 10 g**	**Pass equals negative**	–
Staph. aureus	–	**Negative in 1 g**	**Pass equals negative**	–

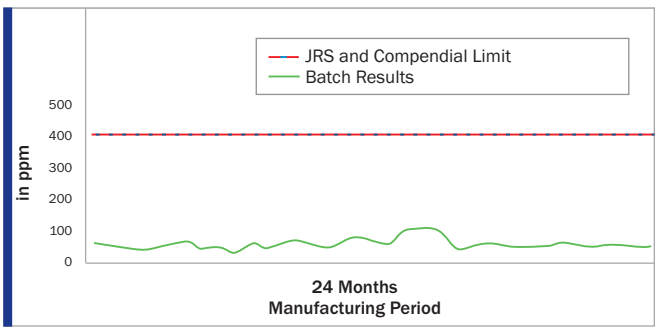
Tab 1 **VIVAPHARM® PVPP XL** Impurities Overview Competitors

24 Months Production Impurity Data

Vinylpyrrolidone



Peroxide



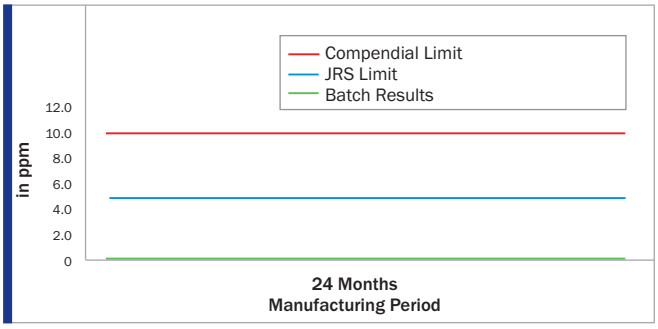
VIVAPHARM® PVPP XL 10

PVPP XL 10	Tightest Compendial Limit (Pharmaceutical Monographs)	VIVAPHARM® PVPP XL 10	Competitor A	Competitor B
Impurities				
1-Vinyl-2-pyrrolidone (Impurity A)	≤ 10 ppm	**≤ 5 ppm**	**≤ 5 ppm**	≤ 10 ppm
Peroxides	≤ 1000 ppm	**≤ 400 ppm**	**≤ 400 ppm**	≤ 1000 ppm
Heavy metals	≤ 10 ppm	≤ 10 ppm	as Lead:	≤ 10 ppm
Lead	–	**≤ 2 ppm**	≤ 5 ppm	–
Microbiology				
TAMC	–	**≤ 100 cfu / g**	**≤ 100 cfu / g**	≤ 200 cfu / g
TYMC	–	**≤ 20 cfu / g**	≤ 100 cfu / g	**≤ 20 cfu / g**
E. coli	–	**Negative in 1 g**	**Pass equals negative**	–
Ps. aeruginosa	–	**Negative in 1 g**	**Pass equals negative**	–
Salmonella	–	**Negative in 10 g**	**Pass equals negative**	–
Staph. aureus	–	**Negative in 1 g**	**Pass equals negative**	–

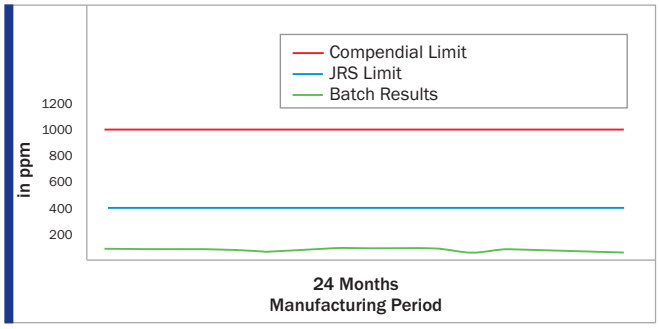
Tab 2 **VIVAPHARM® PVPP XL 10** Impurities Overview Competitors

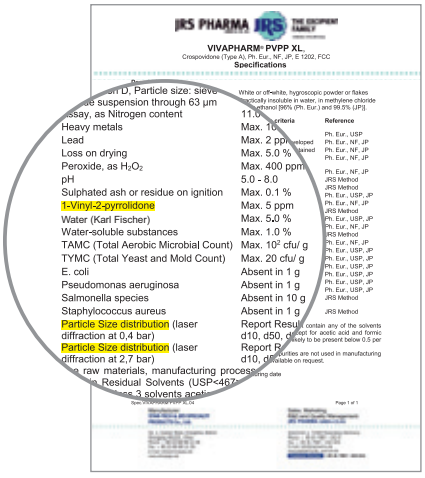
24 Months Production Impurity Data

Vinylpyrrolidone



Peroxide

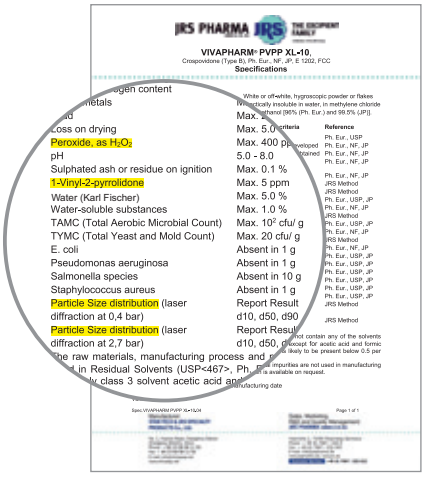




VIVAPHARM® PVPP XL
Crospovidone (Type A), Ph. Eur., NF, JP, E 1202, FCC
Specifications

	White or off-white, hygroscopic powder or flakes	
	Practically insoluble in water, in methylene chloride and in ethanol (96% (Ph. Eur.) and 99.5% (JP)).	
Assay, as Nitrogen content	11.0 - 12.8 %	
	Criteria	Reference
Heavy metals	Max. 10 ppm	Ph. Eur., USP
Lead	Max. 2 ppm	Ph. Eur., NF, JP
Loss on drying	Max. 5.0 %	Ph. Eur., NF, JP
Peroxide, as H_2O_2	Max. 400 ppm	Ph. Eur., NF, JP
pH	5.0 - 8.0	JRS Method
Sulphated ash or residue on ignition	Max. 0.1 %	JRS Method
1-Vinyl-2-pyrrolidone	Max. 5 ppm	Ph. Eur., USP, JP
Water (Karl Fischer)	Max. 5.0 %	Ph. Eur., NF, JP
Water-soluble substances	Max. 1.0 %	JRS Method
TAMC (Total Aerobic Microbial Count)	Max. 10^2 cfu/ g	Ph. Eur., NF, JP
TYMC (Total Yeast and Mold Count)	Max. 20 cfu/ g	Ph. Eur., USP, JP
E. coli	Absent in 1 g	Ph. Eur., USP, JP
Pseudomonas aeruginosa	Absent in 1 g	Ph. Eur., USP, JP
Salmonella species	Absent in 10 g	Ph. Eur., USP, JP
Staphylococcus aureus	Absent in 1 g	JRS Method
Particle Size distribution (laser diffraction at 0,4 bar)	Report Result	
Particle Size distribution (laser diffraction at 2,7 bar)	d10, d50, d90	

Fig. 1
VIVAPHARM® PVPP XL
Specification



VIVAPHARM® PVPP XL-10,
Crospovidone (Type B), Ph. Eur., NF, JP, E 1202, FCC
Specifications

	White or off-white, hygroscopic powder or flakes	
	Practically insoluble in water, in methylene chloride and in ethanol (96% (Ph. Eur.) and 99.5% (JP)).	
Assay, as Nitrogen content	Max. 12.8 %	
	Criteria	Reference
Loss on drying	Max. 5.0 %	Ph. Eur., USP
Peroxide, as H_2O_2	Max. 400 ppm	Ph. Eur., NF, JP
pH	5.0 - 8.0	Ph. Eur., NF, JP
Sulphated ash or residue on ignition	Max. 0.1 %	Ph. Eur., NF, JP
1-Vinyl-2-pyrrolidone	Max. 5 ppm	JRS Method
Water (Karl Fischer)	Max. 5.0 %	JRS Method
Water-soluble substances	Max. 1.0 %	Ph. Eur., USP, JP
TAMC (Total Aerobic Microbial Count)	Max. 10^2 cfu/ g	Ph. Eur., NF, JP
TYMC (Total Yeast and Mold Count)	Max. 20 cfu/ g	JRS Method
E. coli	Absent in 1 g	Ph. Eur., NF, JP
Pseudomonas aeruginosa	Absent in 1 g	Ph. Eur., USP, JP
Salmonella species	Absent in 10 g	Ph. Eur., USP, JP
Staphylococcus aureus	Absent in 1 g	Ph. Eur., USP, JP
Particle Size distribution (laser diffraction at 0,4 bar)	Report Result	JRS Method
Particle Size distribution (laser diffraction at 2,7 bar)	d10, d50, d90	

Fig. 2
VIVAPHARM® PVPP XL 10
Specification

JRS PHARMA

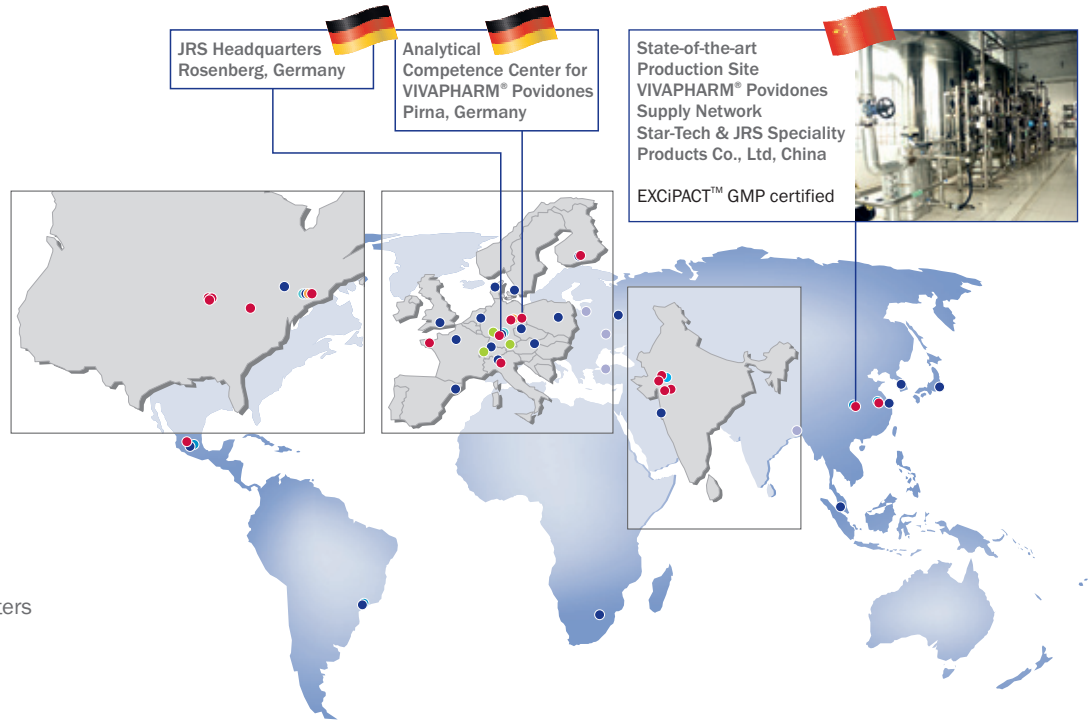
The Global Excipient Maker

Regulatory and Quality Assurance

- EXCiPACT™ GMP certified
- ISO 9001 and ISO 14001 certified
- Audit information questionnaire in accordance with IPEC GMP Audit guideline for bulk pharmaceutical excipients (BPE)
- Conforms to Ph. Eur., NF, JP monograph requirements
- CEP, US and Chinese Drug Master Files (DMFs) available
- Halal certified
- Kosher certified
- Full documentation package and regulatory support available
- BSE / TSE free
- Genetically Modified Organisms (GMO) free
- Pesticide & Herbicide free
- Allergen free
- Elemental Impurity Information according to ICH Q3D Guideline
- Tableting functionality regularly tested to ensure consistent quality and performance

Global Network

GMP Manufacturing and Service Sites



- Excipients
- Coatings
- Biopharma Services
- JRS Sales Companies (Additionally, dedicated representatives in almost every country.)
- Technical Competence Centers
- Application Labs

JRS PHARMA The Global Excipient Maker
JRS FAMILY A Member of the JRS Group

www.jrspharma.com

JRS PHARMA GMBH & CO. KG
Business Unit Excipients
73494 Rosenberg (Germany)
Phone: +49 7967 152-312
ExcipientsService@JRSPharma.de

5298_GB_V2_0.02104PDF