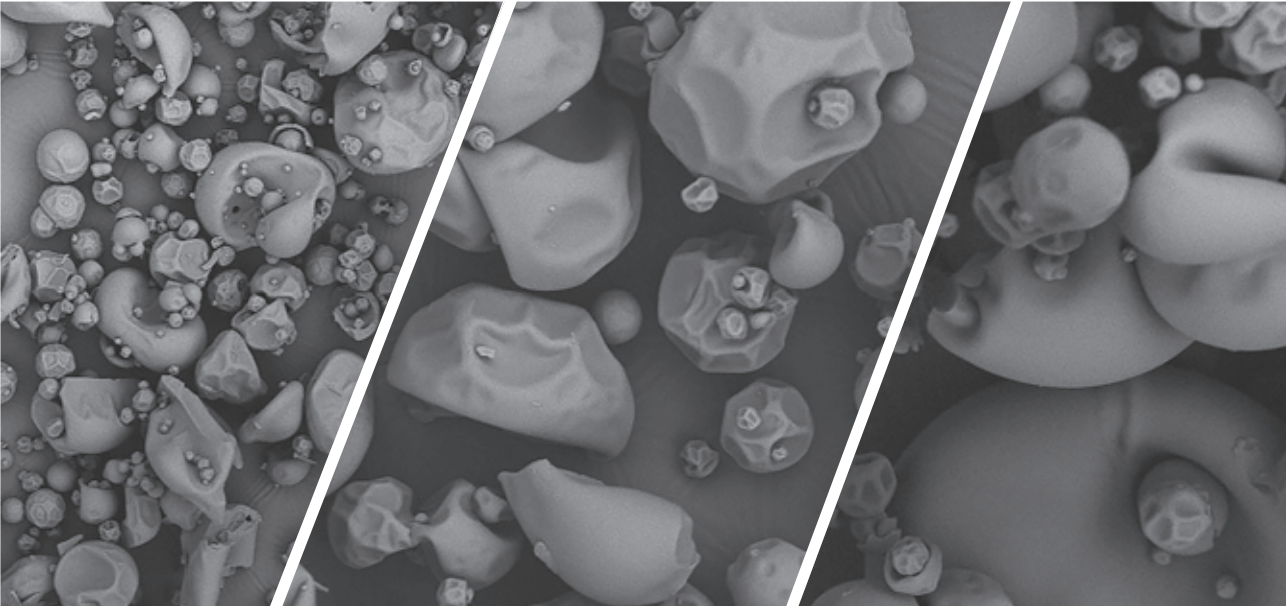


# VIVAPHARM® PVP/VA 64

Copovidone, Ph. Eur., NF, JPE, E 1208, FCC

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Zooming in on Product Quality

Stringent Specification  
High Purity  
Superb Quality



# VIVAPHARM® PVP/VA

Copovidone, Ph. Eur, NF,  
JPE, E 1208, FCC

## VIVAPHARM® PVP/VA 64

Stringent Specification • High Purity • Superb Quality

**VIVAPHARM® PVP/VA 64**, the ultimate tablet binder for all processing technologies (wet and dry granulation, direct compression, HME), is suitable for pharmaceutical and nutraceutical applications.

Full Regulatory Compliance with:

- Ph. Eur.
- NF
- JPE
- E 1208
- FCC

JRS PHARMA has defined very low internal impurity limits for

- Aldehydes
- Vinylpyrrolidone
- 2-Pyrrolidone
- Peroxide

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

JRS PHARMA has, therefore, defined peroxide limits well below the compendial requirements for product release.

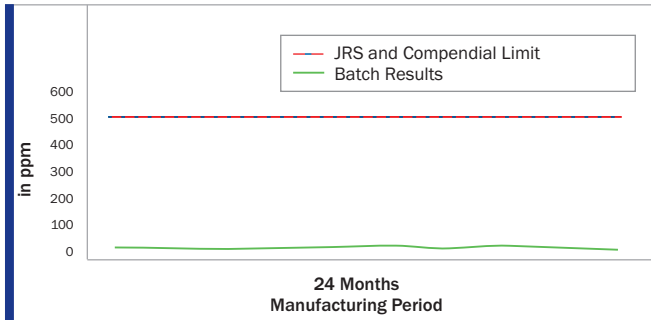
**VIVAPHARM® PVP/VA** is analyzed and released at the Analytical Competence Center in Pirna, Germany.

PVP/VA 64	Tightest Compendial Limit (Pharmaceutical Monographs)	VIVAPHARM® PVP/VA 64	Competitor A	Competitor B
<b>Impurities</b>				
Aldehydes	≤ 500 ppm	≤ 500 ppm	≤ 500 ppm	≤ 500 ppm
1-Vinyl-2-pyrrolidone (Impurity A)	≤ 10 ppm	<b>≤ 5 ppm</b>	<b>≤ 5 ppm</b>	≤ 10 ppm
2-Pyrrolidone (Impurity B)	≤ 0.5 %	≤ 0.5 %	≤ 0.5 %	≤ 0.5 %
Peroxides	≤ 400 ppm	≤ 400 ppm	≤ 400 ppm	≤ 400 ppm
Vinyl Acetate	≤ 10 ppm	<b>≤ 5 ppm</b>	<b>≤ 5 ppm</b>	≤ 10 ppm
Hydrazine	≤ 1 ppm	≤ 1 ppm	≤ 1 ppm	≤ 1 ppm
Heavy metals	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm	≤ 10 ppm
Lead	≤ 10 ppm	<b>≤ 2 ppm</b>	-	-
<b>Microbiology</b>				
TAMC	-	<b>≤ 100 cfu / g</b>	<b>≤ 100 cfu / g</b>	≤ 200 cfu / g
TYMC	-	<b>≤ 20 cfu / g</b>	≤ 100 cfu / g	<b>≤ 20 cfu / g</b>
E. coli	-	<b>Negative in 1 g</b>	<b>Pass equals negative</b>	-
Ps. aeruginosa	-	<b>Negative in 1 g</b>	<b>Pass equals negative</b>	-
Salmonella	-	<b>Negative in 10 g</b>	<b>Pass equals negative</b>	-
Staph. aureus	-	<b>Negative in 1 g</b>	<b>Pass equals negative</b>	-

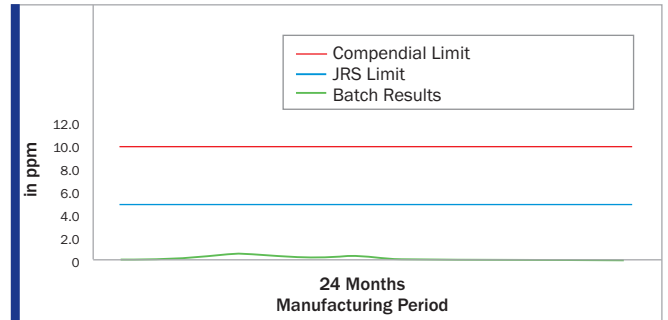
Tab 1 VIVAPHARM® PVP/VA 64 Impurities Overview Competitors

## 24 Months Production Impurity Data

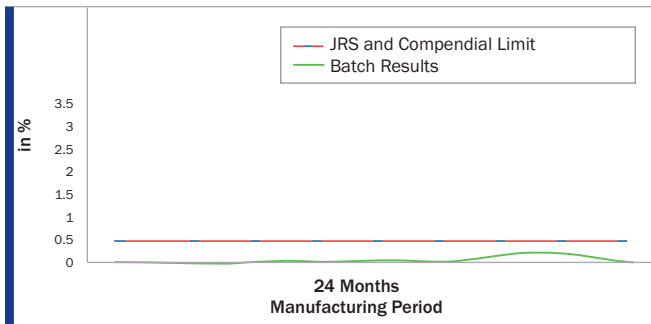
### Aldehydes



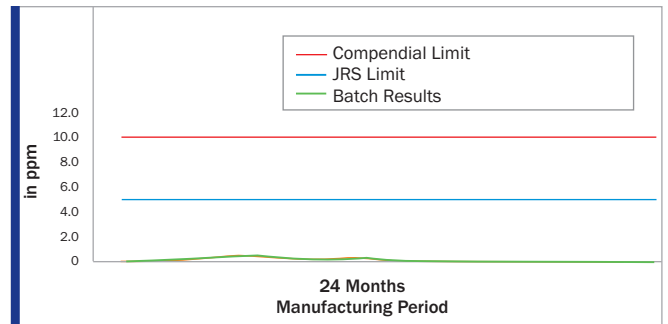
### Vinylpyrrolidone



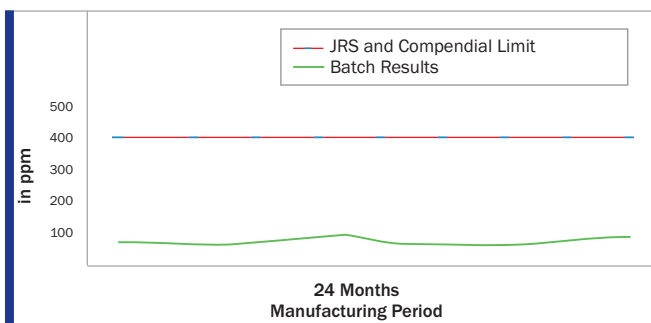
### 2-Pyrrolidone



### Vinyl Acetate



### Peroxide



## 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, JPE 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

