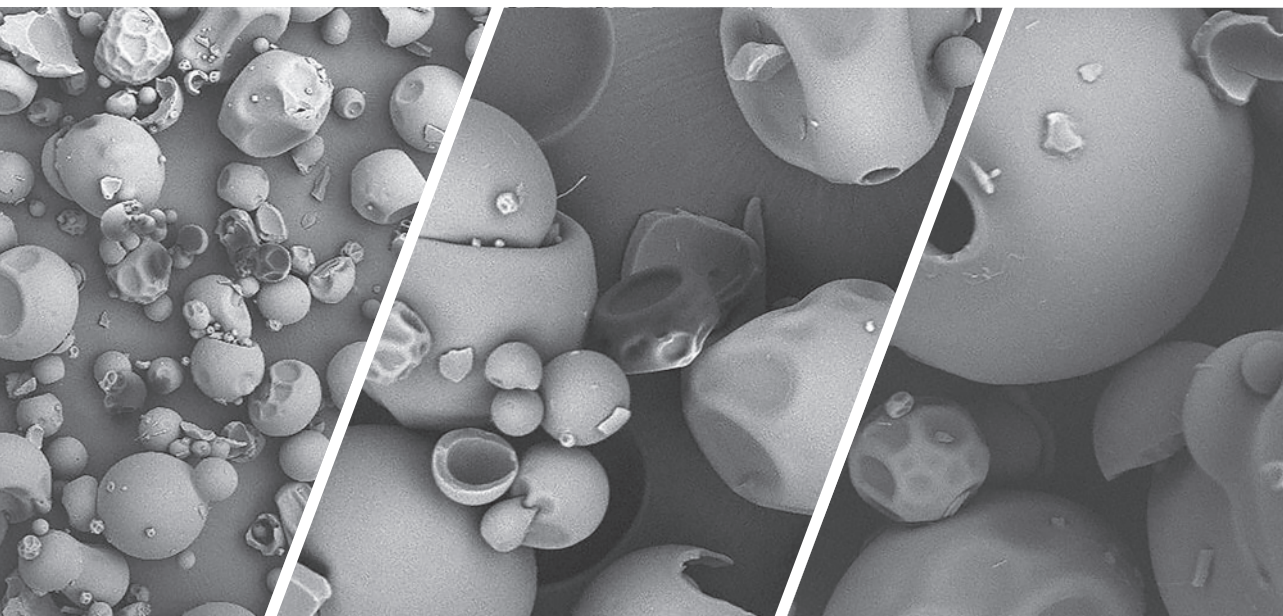


VIVAPHARM® PVP

Povidone, Ph. Eur, USP, JP, E 1201, FCC



Zooming in on Product Quality

Stringent Specification
High Purity
Superb Quality

VIVAPHARM® PVP

VIVAPHARM® PVP is a tablet binder designed for wet granulation, suitable for pharmaceutical as well as nutraceutical applications, and fully compliant with

- Ph. Eur.
- USP
- E 1201
- FCC*

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

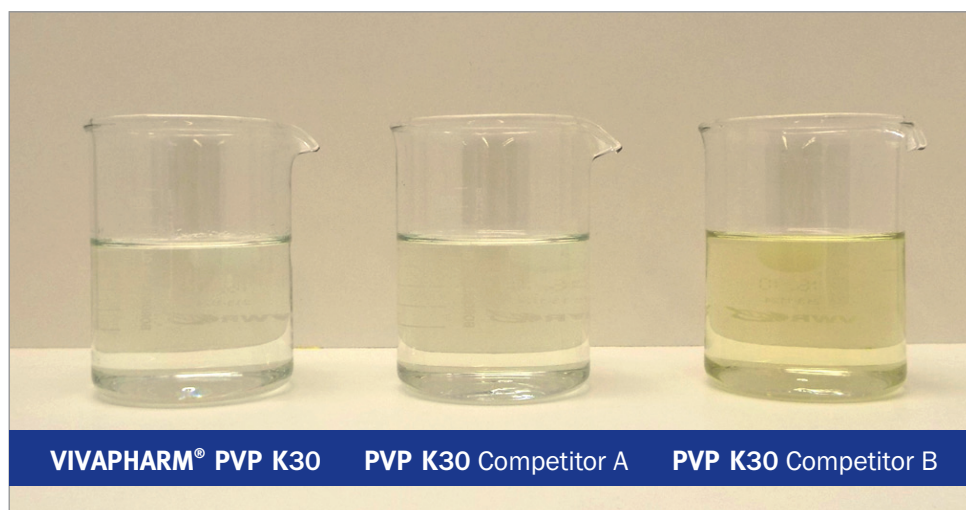
JRS PHARMA has defined very low internal impurity limits for

- 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 of the active ingredient.

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

* Molecular weight of the K25 grades is not covered in the FCC.



Pic. 1 Clarity of 10 % PVP K30 in Solution

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Fig. 1: **VIVAPHARM® PVP K25** Specification

Fig. 2: **VIVAPHARM® PVP K30** Specification

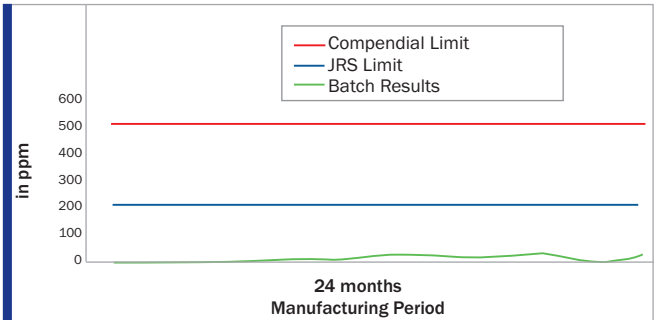
VIVAPHARM® PVP K25

PVP K25	Tightest Compendial Limit (Pharmaceutical Monographs)	VIVAPHARM® PVP K25	Competitor A	Competitor B
Impurities				
Aldehydes	≤ 500 ppm	≤ 200 ppm	≤ 500 ppm	≤ 500 ppm
1-Vinyl-2-pyrrolidone (Impurity A)	≤ 10 ppm	≤ 5 ppm	≤ 10 ppm	≤ 5 ppm
2-Pyrrolidone (Impurity B)	≤ 3 %	≤ 3 %	≤ 3 %	≤ 3 %
Peroxides	≤ 400 ppm	≤ 400 ppm	≤ 400 ppm	≤ 400 ppm
Hydrazine	≤ 1 ppm	≤ 1 ppm	≤ 1 ppm	≤ 1 ppm
Heavy metals	≤ 10 ppm	≤ 10 ppm	as Lead:	≤ 10 ppm
Lead	≤ 10 ppm	≤ 2 ppm	≤ 2 ppm	≤ 5 ppm
Micorbiology				
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	-

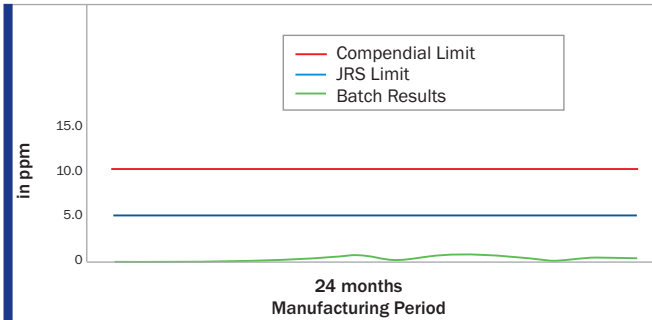
Tab 1 VIVAPHARM® PVP K25 Impurities Overview Competitors

24 Months Production Impurity Data

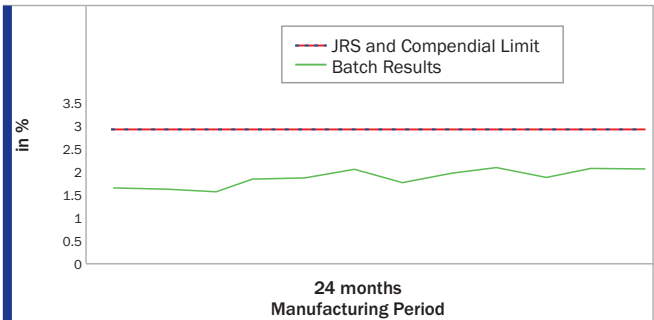
Aldehydes



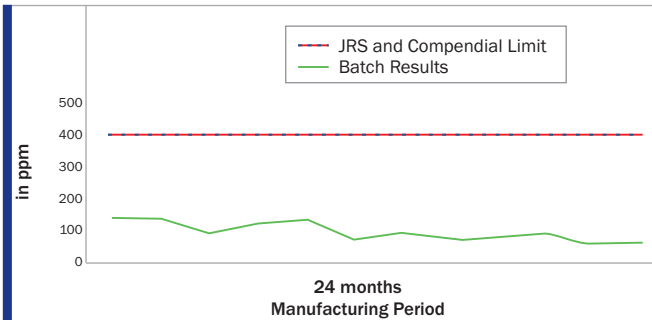
Vinylpyrrolidone



2-Pyrrolidone



Peroxide



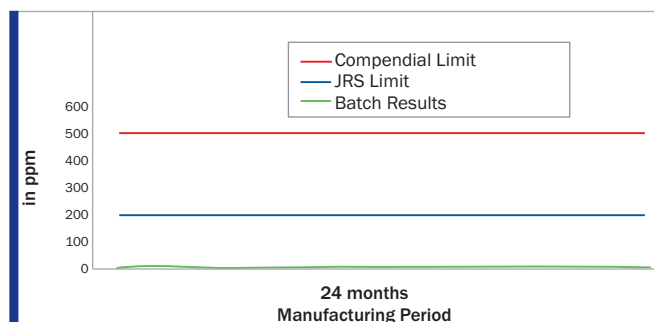
VIVAPHARM® PVP K30

PVP K30	Tightest Compendial Limit (Pharmaceutical Monographs)	VIVAPHARM® PVP K30	Competitor A	Competitor B
Impurities				
Aldehydes	≤ 500 ppm	≤ 200 ppm	≤ 200 ppm	≤ 500 ppm
1-Vinyl-2-pyrrolidone (Impurity A)	≤ 10 ppm	≤ 5 ppm	≤ 5 ppm	≤ 10 ppm
2-Pyrrolidone (Impurity B)	≤ 3 %	≤ 2 %	≤ 2 %	≤ 3 %
Peroxides	≤ 400 ppm	≤ 400 ppm	≤ 400 ppm	≤ 400 ppm
Hydrazines	≤ 1 ppm	≤ 1 ppm	≤ 1 ppm	≤ 1 ppm
Heavy metals	≤ 10 ppm	≤ 10 ppm	as Lead:	≤ 10 ppm
Lead	≤ 10 ppm	≤ 2 ppm	≤ 5 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	–
Pseu. aer.	–	Negative in 1 g	Pass equals negative	–
Salmonella	–	Negative in 10 g	Pass equals negative	–
Staph. aure.	–	Negative in 1 g	Pass equals negative	–

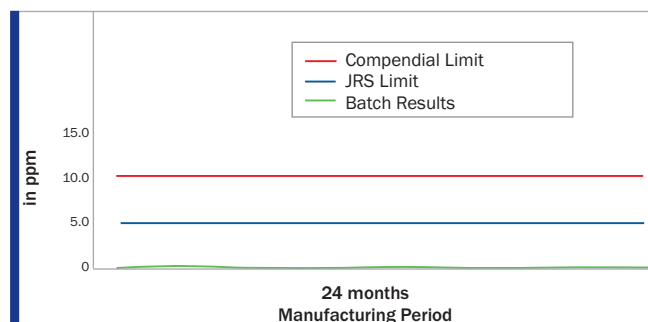
Tab 2 VIVAPHARM® PVP K30 Impurities Overview Competitors

24 Months Production Impurity Data

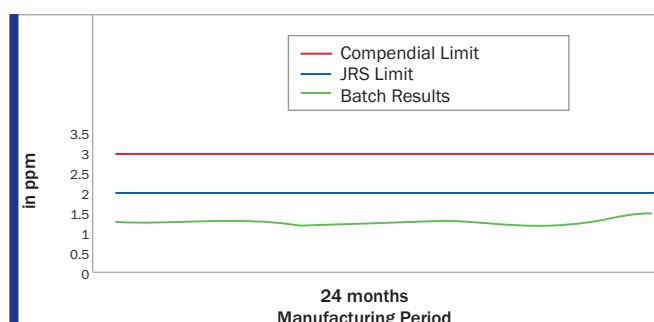
Aldehydes



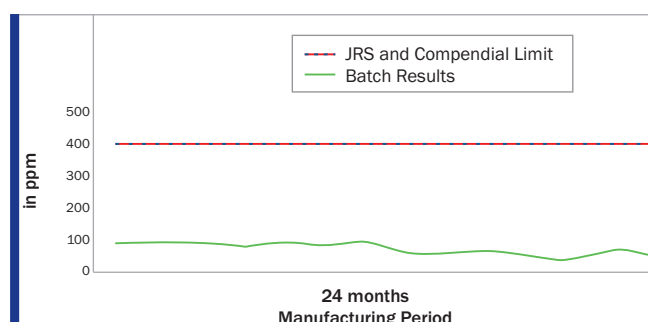
Vinylpyrrolidone



2-Pyrrolidone



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., USP, 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

