

## 焦作中维特品药业股份有限公司

## JIAOZUO ZHONGWEI SPECIAL PRODUCTS PHARMACEUTICAL CO.,LTD.

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## **CERTIFICATE OF ANALYSIS**

PRODUCT NAME: **Povidone K90** GRADE: **USP 44** 

BATCH NO.: 2305002 QUANTITY: 1500KGS

MANF. DATE: <u>MAY.02,2023</u> EXP.DATE: <u>MAY.01,2026</u>

DETECH ITEM	STANDARD	RESULT
Appearance	White or yellowish-white,hygroscopic powder or flakes	White powder
Solubility	Freely soluble in water in ethanol(96%) and in methanol, very slightly soluble in acetone	Conform
Appearance of Solution	Clearly and not more intensely coloured than reference solution B6,BY6 or R6	Conform
Identification	A. IR spectrum obtained is consistent with that abtained with Povidone CRS.	Conform
	B.An orange-yellow precipitate is formed	Conform
	C.A pink colour is produced	Conform
	D.A red colour is produced	Conform
	E.The substance dissolves	Conform
pH(5% aqueous solution)	4.0-7.0	5.50
Viscosity(Expressed as K Value)	81.0-97.2	91.20
Aldehydes(Expressed as Acetaldehyde)	≤500 ppm	<500ppm
Peroxides(Expressed as H2O2)	≤400 ppm	<400ppm
Formic Acid	≤0.5%	<0.5%
Hydrazine	≤1 ppm	<1.0ppm
Impurity A	≤10 ppm	4.8ppm
Impurity B	≤3.0%	<3.0%
Heavy Metals(As Pb)	≤10 ppm	<10 ppm
Water	≤5.0%	3.10%
Sulphated Ash	≤0.1%	0.05%
Nitrogen Content	11.5-12.8%	12.0%
Total Aerobic plate count ,CFU/g	≤100	<100

Mold/Yeast,CFU/g	≤100	<100
Staphylococcus aureus,CFU/g	Negative	Negative
Salmonella,CFU/g	Negative	Negative
Pseudomonas aeruginosa,CFU/g	Negative	Negative
E.coli CFU/g	Negative	Negative

**Conclusion:** 

生作中维 The above Specifications comply with the requirements of current USP 44.

ANALYSER: