



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 K30

GRADE: USP 44

BATCH NO.: 2306035

QUANTITY: 4,000 KGS

MANF. DATE JUN.28,2023

EXP.DATE: JUN.27,2026

TEST ITEM	STANDARD	RESULT
Appearance	White or off-white powder	Conform
Solubility	Freely soluble in water, in ethanol(96 percent) and in methanol very slightly soluble in acetone	Conform
Appearance of solution	colorless or yellowish-white solution	Conform
Identification	A. IR spectrum obtained is consistent with that obtained with Povidone CRS.	Conform
	B.An orange-yellow precipitate is formed.	Conform
	C.A pale blue precipitate is formed.	Conform
	D.A deep red color is produced.	Conform
	E.The substance dissolves	Conform
pH(5% in water solution)	3.0-5.0	3.52
Water	≤5.0%	3.30%
Residue on Ignition	≤0.1%	0.05%
Heavy metals (as Pb)	≤10ppm	<10ppm
Limit of Aldehydes	≤500ppm	<500ppm
Limit of Hydrazine	≤1ppm	<1ppm
Vinylpyrrolidone (HPLC)	≤10 ppm	6.0ppm
2-Pyrrolidone	≤3.0%	1.80%
Peroxides(H ₂ O ₂)	≤400ppm	210 ppm
Formic Acid	≤0.5%	0.04%
K Value(1.0% in water solution)	27.0-32.4	30.30
Nitrogen Content(On anhydrous basis)	11.5%-12.8%	11.90%
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:

The above Specifications comply with the requirements of Pharma Grade USP44.

ANALYSER:

梁小真

