



焦作中维特品药业有限公司

JIAOZUO ZHONGWEI SPECIAL PRODUCTS PHARMACEUTICAL CO.,LTD.

Add:No.115,Xinyuan-Dong Road,Wen County,Jiaozuo City,Henan Province,454800,China

Tel:+86-391-6109928

Fax:+86-391-6109918

E-mail: export01@zw-pvp.com

Website: www.zw-pvp.com

CERTIFICATE OF ANALYSIS

PRODUCT NAME: PVP K15

GRADE: Ph.Eur

BATCH NO.: 20220910

QUANTITY: 1000G

MANF. DATE: SEP.10,2022

EXP.DATE: SEP.09,2025

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 B ₆ ,BY ₆ or R ₆	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 pink colour is produced	Conform
	D.A red colour is produced	Conform
	E.The substance dissolves	Conform
pH(5% aqueous solution)	3.0-5.0	4.2
Viscosity(Expressed as K Value)	12.75-17.25	16.9
Aldehydes(Expressed as Acetaldehyde)	≤500 ppm	200ppm
Peroxides(Expressed as H ₂ O ₂)	≤400 ppm	140ppm
Formic Acid	≤0.5%	0.04%
Hydrazine	≤1 ppm	<1.0ppm
Impurity A	≤10 ppm	4.1ppm
Impurity B	≤3.0%	2.2%
Heavy Metals(As Pb)	≤10 ppm	<10 ppm
Water	≤5.0%	3.02%
Sulphated Ash	≤0.1%	0.039%
Nitrogen Content	11.5-12.8%	11.9%
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.co.1 CFU/g	Negative	Negative

Conclusion:

The above Specifications comply with the requirements of current Ph.Eur.

ANALYSER:

