



安徽万和制药有限公司

ANHUI WAN HE PHARMACEUTICAL CO.,LTD

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N DE LOTE:

0190523

CERTIFICATE OF ANALYSIS

Product Name	VITAMIN K1 (PHYTOMENADIONE)	Code Name	C004
Specification	Bulk drug(Injection)	Batch	20.0KGS
Batch NO.	V230301	Package	Aluminum Tin
MFG. Date	MAR.27,2023	EXP.Date	MAR.26,2025
Items	Standard of EP11.0		Result of Test
Appearance of solution	The solution is clear		Conform
Refractive index	About 1.526		1.526
Identification	A	Optical rotation (see Tests).- 0.05° to + 0.05°, measured at 25 °C.	Conform
	B	Ultraviolet and visible absorption spectrophotometry(2.2.25) Spectral range:275-340nm for test solution(a);230-280nm for test solution(b) Absorption maxima:327nm for test solution(a);243nm,249nm,261nm and 270nm for test solution(b) Absorption minimum:285nm for test solution(a) Specific absorbance at the absorption maximum at 327nm;67to 73 for the test solution(a)	conform
	C	Examine the chromatograms obtained in the assay	Conform
Related substances	Impurity B	≤0.2%	0.06%
	Unspecified impurities for each impurity	≤0.15%	0.14%
	Total	≤1.0%	0.70%
	Reporting threshold	≤0.05%	Conform
Acid value		≤2.0	1.2
Sulphated ash		≤0.1%	0.03%
Impurity A (TLC)		≤0.2%	Conform
Total Plate Count		<250cfu/g	Complies
Yeast & Mold		<50cfu/g	Complies
Coliforms		<3cfu/g	Absent



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E.Coli		<10cfu/g	Absent
Staphylococcus aureus		< 10 cfu/g	Complies
Lead		<3ppm	<3ppm
Cadmium		<1ppm	<1ppm
Mercury		<0.1ppm	<0.1ppm
Arsenic		<1ppm	<1ppm
Assay	Trans-phytomenadione	≥85.0%	85.66%
	Sum of trans-phytomenadione and cis-phytomenadione isomers	97.0%---103.0%	98.20%
Conclusion		The product comply with EP11.0	

Principle: Kai Guo

Re-check:Lili Liu

Analyst:Yunyun Chen

