



安徽万和制药有限公司

ANHUI WAN HE PHARMACEUTICAL CO.,LTD

Yangcun Industry Park, Tianchang City, Anhui Province, China

Tell: 86-21-53081360 Fax: 86-21-53081260

## CERTIFICATE OF ANALYSIS

Product Name	VITAMIN K1	Code Name	C004
Specification	Bulk drug(Injection)	Batch Quantity	101.0KGS
Batch NO.	V191104	Package	Aluminum Tin
MFG. Date	NOV.15,2019	EXP.Date	NOV.14,2021
Items		Standard of EP9.2	Result of Test
Appearance of solution		The solution is clear	Conform
Refractive index		About 1.526	1.526
Identification	A	Examined between 275-340nm, test solution shows an absorption max at 327nm which the specific absorbance is 67-73 and min at 285nm. Between 230-280nm Test solution also shows four absorbance max, at 243, 249, 261 and 270 nm respectively	Conform
	B	The principal peak in the chromatogram obtained with the test solution is similar in retention time and size to principal peak in the chromatogram obtained with reference solution(d)	conform
	C	A green colour is produced which becomes violet-red on heating and then reddish-brown on standing	Conform
Related substances	Eluting before trans-epoxyphytomenadione	Single impurity $\leq 0.15\%$	0.02%
		Total impurities $\leq 0.2\%$	0.15%
	Eluting between cis-phytomenadione and trans-phytomenadione	Single impurity $\leq 0.4\%$	0.18%
		Total impurities $\leq 0.5\%$	0.23%
	Eluting after trans-phytomenadione	Single impurity $\leq 0.25\%$	0.13%
		Total impurities $\leq 0.5\%$	0.39%
	Total	$\leq 1.2\%$	0.77%
Reporting threshold		$\leq 0.05\%$	Conform
Acid value		$\leq 2.0$	1.2
Sulphated ash		$\leq 0.1\%$	0.02%
Impurity A (TLC)		$\leq 0.2\%$	Conform
Total Plate Count		$< 250 \text{ cfu/g}$	Complies
Yeast & Mold		$< 50 \text{ cfu/g}$	Complies
Coliforms		$< 3 \text{ cfu/g}$	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
Methanol	Less than 0.3%	NF
Ether	Less than 0.5%	0.02%
Absolute Alcohol	Less than 0.5%	0.05%
Assay	Trans-epoxyphytomenadione	≤4.0%
	Trans-phytomenadione	≥75.0%
	Total three compound	97.0%---103.0%
Conclusion	The product comply with EP9.2	

Principle: Kai Guo

Re-check:Lili Liu

Analyst:Yunyun Chen

Country of Origin:China

Storage condition: keep away from light, store in cool and dry place.

Packing condition: inner packing:100g/tin;1kg/tin;5kg/tin. Out-packing:carton

