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安徽万和制药有限公司

ANHUI WAN HE PHARMACEUTICAL CO.,LTD

### CERTIFICATE OF ANALYSIS

Product Name	VITAMIN K1	Code Name	C004
Specification	Bulk drug(Injection)	Batch Quantity	110.0KGS
Batch No.	V180901	Package	Aluminum Tin
MFG. Date	SEP.9,2018	EXP.Date	SEP.8,2020
Items	Standard of EP9.2		Result of Test
Appearance of solution	The solution is clear		Conform
Refractive index	About 1.526		1.526
indentification	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 cheomatogram 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-epoxyphytomena dione	Single impurity $\leq 0.15\%$	0.03%
		Total impurities $\leq 0.2\%$	0.02%
	Eluting between cis-phytomenadione and trans-phytomenadione	Single impurity $\leq 0.4\%$	0.20%
		Total impurities $\leq 0.5\%$	0.34%
	Eluting after trans-phytomenadione	Single impurity $\leq 0.25\%$	0.13%
		Total impurities $\leq 0.5\%$	0.22%
	Total	$\leq 1.2\%$	0.70%
	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
Assay	Trans-epoxyphytomenadione	$\leq 4.0\%$	0.6%
	Trans-phytomenadione	$\geq 75.0\%$	81.86%
	Total three compound	97.0%---103.0%	98.56%
Conclusion		The product comply with EP9.2	

Principle: Kai Guo

Re-check:Lili Liu

Analyst:Yunyun Chen