

# Hangzhou Huarong Pharm Co., Limited

No. 5 Yongfuqiao Road, Gongshu District, Hangzhou, Zhejiang Province, China.

TEL: 0086-571-86758373

FAX: 0086-571-81131109

## CERTIFICATE OF ANALYSIS

Product Name	Vinorelbine Tartrate	Batch Number	C1503230
Quantity	4185.83g	Manufacture Date	2023.03.14
Report Date	2023.03.27	Retest Date	2026.03.13

Items	Specification	Result
<b>Characters</b>		
Appearance	White or almost white powder	White powder
<b>Identification</b>		
Identification A	IR Spectrum of the sample corresponds to that of the Vinorelbine Tartrate RS	Conforms
Identification B	The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay	Conforms
Identification C	Tartrates reaction: Positive for Tartrate	Positive reaction
<b>Related Substances</b>		
3,6-Epoxy vinorelbine	Not more than 0.3%	0.05%
Related compound A	Not more than 0.2%	0.01%
Impurity I	Not more than 0.15%	0.02%
Any Other Impurity	Not more than 0.10%	0.03%
Sum of impurities other than 3,6-Epoxy vinorelbine	Not more than 0.7%	0.16%
<b>Clarity of Solution</b>	The solution(10mg/ml water) is clear	Solution is clear
<b>Color of Solution</b>	The absorbance of the solution(10mg/ml water) at 420 nm is not greater than 0.03	0.003
<b>pH</b>	3.3~3.8	3.5
<b>Water</b>	Not more than 4.0%	2.2%
<b>Residual Solvents</b>		
Chloroform	Not more than 60ppm	<2ppm(LOQ)
Methylene Chloride	Not more than 600ppm	Not detected
Methanol	Not more than 3000ppm	<148ppm(LOQ)
Acetone	Not more than 5000ppm	602ppm
Ethyl ether	Not more than 5000ppm	1249ppm
n-Hexane	Not more than 290ppm	<37ppm(LOQ)
Tetrahydrofuran	Not more than 720ppm	Not detected
<b>Residue on Ignition</b>	NMT 0.1%	0.02%
<b>Microbial Limit</b>		
Total Aerobic Bacteria	NMT 100CFU/g	<10cfu/g
Total Combined Yeasts and Molds	NMT 50CFU/g	<10cfu/g
Escherichia Coli	Absent/g	Absent
<b>Bacterial Endotoxins</b>	Less than 2 EU/mg	Conforms
<b>Assay</b>	98.0%~102.0% (anhydrous substance)	99.5%

Conclusion: The product complies with the enterprise standard. The standard reference USP.

