



TYPICAL CERTIFICATE OF ANALYSIS

Product : Quinine Sulphate EP			Page 1 of 1
Reference : European Pharmacopoeia-10			
Manufactured By : Nicotine Vault		Product code : QS	
Self Life (Retest Date) : 3 years		Batch Size : 300 Kg	
SR.NO	TESTS	SPECIFICATION	RESULTS
1	Appearance	White or almost white, crystalline powder or fine, colorless needles.	A white powder.
2	Solubility	Slightly soluble in water, sparingly soluble in boiling water and in ethanol (96%)	Slightly soluble in water, sparingly soluble in boiling water and in ethanol (96%)
3	Identification A,B,C,D & E	Test A) By TLC B) By fluorescence test C) By fluorescence test D) To give reaction of sulphates E) By PH	Complies Complies Complies Complies Complies
4	Appearance of solution	Solution is clear and not more intensely colored than reference solution GY6	Complies
5	pH	5.7 to 6.6	6.36
6	Specific Optical Rotation	-237.0° to -245.0°	-237.39°
7	Other cinchona alkaloids by HPLC Impurity C	Not more than 10.0 %	5.59%
	Any related substance Eluted before quinine	Not more than 5.0 %	1.35%
	Any other related substance	Not more than 2.5%	0.06%
8	Loss on drying	3.0% to 5.0%	4.0%
9	Sulphated ash	Not more than 0.1%	0.04%
10	Assay (on dry basis)	99.0% to 101.0%	99.90%
REMARK : As opinion of under signed product is <u>Complies/ does not Comply</u> ass per prescribe EP-10.			