



TYPICAL CERTIFICATE OF ANALYSIS

Product : Quinine Hydrochloride EP			Page 1 of 1
Reference : European Pharmacopoeia-10			
Manufactured By : Nicotine Vault		Product code : QHCL	
Self Life (Retest Date) : 3 years		Batch Size : 300 Kg	
SR.NO	TESTS	SPECIFICATION	RESULTS
1	Appearance	White or almost white or colorless, Fine, silky needles, often in clusters.	A white Fine, silky needles, often in clusters.
2	Solubility	Soluble in water, Freely soluble in ethanol (96 per cent)	Soluble in water, Freely soluble in ethanol (96 per cent)
3	Identification A,B,C,D & E	A) By TLC B) By Color test C) By fluorescence test D) To give reaction of Chloride E) By PH	Complies Complies Complies Complies Complies
4	Appearance of solution	Solution is clear and not more intensely colored than reference solution Y6.	Complies
5	pH	6.0 to 6.8	6.72
6	Specific Optical Rotation	-245.0° to -258.0°	-248.88°
7	Other cinchona alkaloids By HPLC		
7.1	Impurity C (Dihydroquinine)	Not more than 10.0%	5.17%
7.2	Any impurity eluted before quinine	Not more than 5.0%	0.63%
7.3	Any other impurity	Not more than 2.5%	0.01%
8	Loss on drying	6.0% to 10.0%	7.15%
9	Sulphated ash	Not more than 0.1 %	0.06%
10	Sulphates	Not more than 500 ppm	Complies
11	Barium	To Complies the test as per BP	Complies
12	Assay (on dry basis)	99.0% to 101.0%	99.66%
REMARK : As opinion of under signed product is <u>Complies/ does not Comply</u> ass per prescribe EP-10.			