

RADIANT PARENTERALS LTD.

242/5&6 G.I.D.C. ESTATE, WAGHODIA, MOB-9904807801 & 02668262448, WAGHODIA-391760
REG.OFF.: 242/5&6 G.I.D.C. ESTATE, WAGHODIA, C.I.No. : U24230GJ1989PLC011784

QUALITY CONTROL DEPARTMENT

Page 1 of 1

THE DRUG & COSMETIC ACT. 1940 & THE RULES THERE UNDER FORM-39(RULE 150-E(F))

FINISHED PRODUCT CERTIFICATE OF ANALYSIS

Product Name : QUININE DIHYDROCHLORIDE INJECTION IP300MG/ML 2ML	A.R. No. : RPI/F24/079
Packing : 2 ML	Rel. Dt. : 01-05-2024
Generic Name : QUININE DIHYDROCHLORIDE INJECTION IP300MG/ML 2ML	T.R. Slip No. : RPAP24018
Product Code : QUIN15	T.R. Slip Dt. : 19-04-2024
Batch No. : 9Q24001	Analysis Date : 19-04-2024
Actual Batch Size : 26LTR	
Mfg. Dt. : 04/2024	
Exp. Dt. : 03/2027	
Test Packing : 2 ML	
Mfg. Lic No. : G/721	
Sample Size : 197.800 ML	
Released Qty : 26.000 (12093 AMP)	
Test As Per : IP	
Remarks :	
	Location : WAGHODIA.
	Make : RADIANT

Sr.	Test	Result	Specification
1	DESCRIPTION	A clear, almost colourless to light yellow solution.	A clear, almost colourless to light yellow solution.
2	EXTRACTABLE VOLUME	2.1 ml	NLT : 2.0 ml
3	pH	1.93	Between 1.5 to 3.0
4	BET	Complies	To be comply
5	STERILITY TEST	Under Sterility	No growth observed
6	PARTICULATE MATTER	59.20 Particles/Container 0.27 Particles/Container	NMT 6000 partides \geq 10 μ per container NMT 600 partides \geq 25 μ per container
7	ASSAY	294.12 mg [98.04 %]	Each ml Contain Quinine Dihydrochloride IP : 300mg [Limit : 95.0% to 105 %]

Conclusion : The above sample complies as per IP
In the Opinion of the undersigned the sample referred to above is of Standard quality as defined in the Act and the Rules made thereunder for the result given above. "This computer generated certificate of analysis is valid without signature"

ANALYSIS BY

SURESH RATHVA
QC CHEMIST



APPROVED BY

LAKESH V PATEL
QC MANAGER

FGANLCERTQA