

**QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS OF FINISH PRODUCT**

Name of the product :		QUNICAN-600			
Generic name:		QUININE DIHYDROCHLORIDE INJECTION IP 300MG/ML			
Batch No.:		245701		Batch Size:	25500 AMPOULES
Mfg. Date:		APR-2024	Exp. Date:	MAR-2027	Sample Size:
Date of receipt:		10/04/2024		Date of Analysis:	25/04/2024
Date of release:		25/04/2024		Q.C Reference No.:	QDI-24399

Sr. No.	TESTS	SPECIFICATIONS	RESULT
1.	Description	A clear, almost colourless to light yellow solution.	A clear, almost colourless to light yellow solution.
2.	Identification	A. By TLC: The principle spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution. B. A strong blue fluorescence is produced. C. Reaction of chloride: A curdy white precipitate is formed which is insoluble in nitric acid but soluble, after well washed with water, in dilute ammonia solution from which it is reprecipitated by the addition of dilute nitric acid.	Complies Complies Complies
3.	Fill Volume	NLT 2.0 ml	2.1 ml
4.	pH	Between 1.5 to 3.0	1.6
5.	Bacterial Endotoxins Test	To comply	Complies
6.	Particulate matter	NMT 6000 particles/Ampoule $\geq 10 \mu\text{m}$ NMT 600 particles/ Ampoule $\geq 25 \mu\text{m}$	55 particles/Ampoule 10 particles/Ampoule
7.	Related substances	1. Dihydroquinine: NMT 10.0 % 2. Quinine: NMT 5.0% 3. Any other related substance: NMT 2.5%	Not detected Not detected Not detected
8.	Assay: Each ml contains:		
	Content of Quinine Dihydrochloride IP 300.0 mg	95.0% to 105.%	99.12%
9.	Sterility	Product must be sterile.	Sterile

Remark: The sample complies/ does not comply with the prescribed standards of quality as per above tests as per IP Specification.

	ANALYSIS BY	CHECKED BY	APPROVED BY
SIGNATURE			
DESIGNATION	QC CHEMIST	QC OFFICER	MANAGER QA & QC