TEMAD Co.

ACTIVE PHARMACEUTICAL INGREDIENTS

Quality Control Department

Product: **Hydroxychloroquine Sulfate**	Batch No.: **HYC 0311101**	
Analysis Date: Feb 16 2025	Man. Date: Feb 08 2025	Retest Date: Feb 08 2028
Quantity: 510 Kg	Total drum No.: 17	Customer: .....

Method of Analysis: **Current USP, BP**

Tests	Standards	Results
Description	White or practically white, crystalline powder. Is odorless, and has a bitter taste	Conforms
Solubility	Freely soluble in water; practically insoluble in alcohol, in chloroform, and in ether	Conforms
pII	About 4.5	4.02
Melting rang	Melts at about 240 °C	239 °C
Identification	A: The retention time of the major peak of the Sample solution corresponds to that of the Standard solution, as obtained in the Assay	Conforms
	B: Infrared Spectroscopy: Meets the requirements	Conforms
	C: Chemical Identification Tests, Sulfate: Meets the requirements	Conforms
Loss on drying	Not more than 2.0 %	0.16 %
Appearance of solution	The solution is clear and not more intensely coloured than reference solution Y_7	Conforms
Sulfated ash	N.M.T 0.1 %	0.0346 %
Organic impurities	Desethyl hydroxychloroquine: N.M.T 0.40%	0.2035 %
	Sulfohydroxychloroquine: N.M.T 0.15%	0.0823 %
	Any unspecified impurity: N.M.T 0.10%	Not detected
	Total impurities: N.M.T 0.6%	0.3859 %
Assay (dried basis)	98.0 … 102.0 %,	99.63 %
Residual solvents	Ethanol: Not more than 5000 ppm	504 ppm
	Chloroform: Not more than 60 ppm	Not detected
Packaging and storage	Preserve in well-closed, light-resistant containers.	

Analyst	Q.C. Manager	Authorized Person	Q.C. Stamp
Najdi 05.06.31	Dr.Salmani	M.Sc. Hosein Yousefi Authorized Person License number: 665/51744	TEMAD MASHHAD Q.C. PASSED

Checked by:..

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