

CHININI SULFAS 100 g

Lot No.: 24B20-APR24041

Autorisation :	1890R05555	Date Of Analysis :	06/11/2023
Analytical Reference :	Ph. Eur. 10.6 [01/2016 :0019]	Production Number :	280224-GS23111
CNK :	3490-836	Expiry Date :	08/2028

ANALYTICAL TESTS

CHARACTERS	SPECIFICATION	RESULT
Appearance	White or almost white, crystalline powder or fine, colourless needles	Complies
IDENTIFICATION	SPECIFICATION	RESULT
Identification A	Chromatogram complies	Complies
Identification B	A green colour develops	Complies
Identification C	Intense blue fluorescence appears under UV light (366 nm), disappears almost completely on addition of HCl	Complies
Identification D	Reaction (a) of sulfates	Complies
Identification E	5.7 to 6.6	Complies
TESTS	SPECIFICATION	RESULT
Appearance of solution	Clear and not more intensely coloured than reference solution GY ₆	Complies
pH	5.7 to 6.6	6.2
Specific optical rotation	- 237 to - 245 (dried substance)	- 241
Other cinchona alkaloids		
Impurity C	≤ 10%	5%
Any impurity eluted before quinine	≤ 5%	2%
Any other impurity	≤ 2.5%	< 0.2%
Loss on drying	3.0% to 5.0%	4.3%
Sulfated ash	≤ 0.1%	0.02%
ASSAY	SPECIFICATION	RESULT
Potentiometric titration	99.0% to 101.0% (dried substance)	100.1%
Manufacturer identification code: S/GS/160		

CONCLUSION: COMPLIES

RESPONSIBLE PHARMACIST: