

BUCHLER

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Ihr Auftrag / Your order

16020817/06 dated 02.08.2017

Unser Auftrag / Our order

4893

Datum / Date

03.08.17

Analysenzertifikat / Certificate of Analysis

Product : Quinine Hydrochloride

Lot No. 9068

Formula : $C_{20}H_{24}N_2O_2 \cdot HCl \cdot 2 H_2O$

CAS - No. 6119-47-7

Manufact. date : 06.03.2017

Expiry date : 05.03.2022

Date of release : 15.03.2017

Tests	Specifications	Results
Identification A, B, C, D, E	to pass tests	conform
Appearance of solution	clear and colour $\leq Y 6$	conform
pH	pH 6,0 - 6,8	pH 6,2
Loss on drying	6,0 - 10,0 %	6,5 %
Specific optical rotation	-245° to -258°	-251°
Dihydroquinine Hydrochloride	$\leq 10,0$ %	6,9 %
Any impurity eluted before quinine	$\leq 5,0$ %	2,9 %
Any other impurity	$\leq 2,5$ %	0,0 %
Assay	99,0 - 101,0 %	99,6 %
Sulphated ash	$\leq 0,1$ %	< 0,1 %
Barium	no turbidity produced	conform
Sulphate	≤ 500 ppm	< 500 ppm
Heavy metals	≤ 10 ppm	< 10 ppm
Residual Solvents	meets the pharmacopoeial requirements	conform

Result: the merchandise corresponds to Ph. Eur., 9th Edt., BP 2017

The active ingredients have been manufactured, packaged and analysed according to GMP.

Head of Quality Assurance : Dr. C. von Riesen

Buchler GmbH

FAGRON IBÉRICA, S.A.U.
Corresponde al lote de Fagron:

L18040063

Director Técnico

This certificate is a computer printout and bears therefore no handwritten signature.

