

Certificate of Analysis

Product name: **Tripelennamini hydrochloridum**

Batch number / Weight: **23H21-B04-233338 / 10 G**

Analysed according to: **USP**

Number of analysis / Inspection Code **23H21-B04 / INS-23-6336**

Reference Code / No.: **V01856 / 131452**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White, crystalline powder Its solutions are practically neutral to litmus	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Identification C	Conform	Conform		
Loss on drying	$\leq 1,0$	0,02	%	
Residue on ignition	$\leq 0,1$	0,00	%	
Organic impurities	Conform	Conform		
Any impurity	$\leq 0,1$	0,03	%	
Total impurities	$\leq 1,0$	0,06	%	
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Tripelennamine hydrochloride	98,0 - 102,0	100,14	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

All the manufacturing stages of this batch have been carried out in full compliance with the GMP requirements of the EU and with the national legal requirements.

Analysis performed by the authorized lab Fagron PL lab

Release:
Ewelina Gadzinowska
Qualified Person

22-09-2023

Expiration: 30-06-2024

Conclusion: APPROVED

This document has been produced electronically from our quality system and is valid without signature.

fagron.pl Fagron Services Northern Europe Sp. z o.o.
ul. Armii Krajowej 3
32-540 Trzebinia, Poland
e-mail: fsne@fagron.pl