

Certificate of Analysis

Product: Sulpiride

Batch number: 21043

Batch size: 575,0 Kg

Analysis number: PF203/21

Quality standard: Eur. Ph. Current Edition

COPY QA APPROVED

04 FEB. 2022

CAS number: 15676-16-1

ICROM code: PF-0001

Manufacturing date: September 2021

Retest date: September 2026

PARAMETERS	RESULTS	SPECIFICATIONS
<i>Characters:</i>		
Appearance	Complies	White or almost white crystalline powder
<i>Identification:</i>		
IR	Positive	Positive
Melting point	180°C	177°C to 181°C
<i>Tests:</i>		
Solution (10% in 12% acetic acid)	Clear, < Ref. Sol. Y ₆	Clear, ≤ Ref. Sol. Y ₆
Sulphated ash	< 0.1%	≤ 0.1%
Loss on drying	< 0.1%	≤ 0.5%
Chlorides	< 100 ppm	≤ 100 ppm
Iron	< 10 ppm	≤ 10 ppm
Impurity A (TLC)	< 0.1%	≤ 0.1%
Related substances (HPLC):		
any impurity	< 0.05%	≤ 0.10%
total	< 0.05%	≤ 0.3%
Methanol (GC)	< 500 ppm	≤ 500 ppm
<i>Assay:</i>		
Potentiometric (dried substance)	100.1%	98.5% to 101.0%

Date: November 06, 2021

Chiara Ghinami

Quality Control Manager

Quality Assurance Revision: *Clara Scrovia* 14.12.21

I declare that the product is manufactured in accordance with the guidelines on Good Manufacturing Practice for Active Substances

Qualified Person Release:

[Signature] 14/12/2021