

Product: Sulpiride

Batch number: 23027

Batch size: 565.0 Kg

Analysis number: PF226/23

Quality standard: Eur. Ph. Current Edition

CAS number: 15676-16-1

ICROM code: PF-0001

Manufacturing date: November 2023

Retest date: November 2028



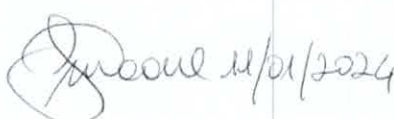
PARAMETERS	RESULTS	SPECIFICATIONS
<i>Characters:</i>		
Appearance	Complies	White or almost white crystalline powder
<i>Identification:</i>		
IR	Positive	Positive
Melting point	180°C	177°C to 181°C
<i>Tests:</i>		
Solution (10% in 12% acetic acid)	Clear, < Ref. Sol. Y ₆	Clear, ≤ Ref. Sol. Y ₆
Sulphated 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)	< LOQ (94 ppm)	≤ 500 ppm
<i>Assay:</i>		
Potentiometric (dried substance)	99.9%	98.5% to 101.0%

Date: January 11, 2024

Chiara Ghinami
Quality Control Manager

Quality Assurance Revision: Francesca Ambrosio 11.01.24

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

Qualified Person Release:  11/01/2024