

Certificate of Analysis

Product name: Propyphenazonum

Batch number / Weight: 20A15-B04-197109 / 100 G

Analysed according to: Ph. Eur.

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or slightly yellowish, crystalline powder	Conform		
Identification A	102 - 106	103,6	°C	
Identification B	Conform	Conform		IR-spectrum
Appearance of solution	Clear / colourless	Conform		4%m/V in alcohol 50% V/V
Acidity or alkalinity	Conform	Conform		
Related substances	Conform	Conform		TLC
Unspecified impurities	<=0,10	0,06	%	
Total impurities	<=0,2	0,06	%	
Loss on drying	<=0,5	0,04	%	4 h 60 °C, 670 Pa
Sulphated ash	<=0,1	0,03	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Propyphenazone	99,0 - 101,0	100,07	%m/m	Dried
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

Analysis performed by the authorized lab.

Release:

Dorota Sutkowska Qualified Person

17-03-2020

Expiration: 31-07-2024

Conclusion: APPROVED

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