

Certificate of Analysis

Product name: **Propranolol hydrochloride**
Number of analysis: T0006438
Batch number / Weight: **22E11-H14-00462 / 500mg**
Producer / Producer Batch Number: Changzhou Yabang Pharmaceutical Co., Ltd./M200409
Analysed according to: **PH.EUR 10.2**

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or almost white powder	Conform		
Identification B	Conform	Conform		IR-spectrum
Identification D	Conform	Conform		Chlorides
Melting point	163 - 166	163,8	°C	
Appearance of solution	Clear	Conform		10% <i>m/V</i> MeOH
Appearance of solution	Conform	Conform		10% <i>m/V</i> MeOH
Acidity or alkalinity	Conform	Conform		
Related substances	Conform	Conform		HPLC
Any impurity	<= 0,10	< 0,10	%	
Total	<= 0,2	< 0,2	%	
Loss on drying	<= 0,5	0,1	%	105°C oven
Sulfated ash	<= 0,1	0,01	%	
Assay	99,0 - 101,0	100,3	% <i>m/m</i>	Dried
Metallic residues	Conform	Conform		
Residual solvents	CPMP/ICH/82 260/2006	Conform		
TSE/BSE-statement	No contamination with TSE/BSE-risk materials	Conform		

Analysis performed by the authorized internal lab and by Fagron Czech.

Release:
 Konstantina Tziolia
 Pharmacist - QA Manager / QP

17/05/2022

Expiration: 09-04-2023

Conclusion: APPROVED

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