

## Certificate of Analysis

**Product name:** **Chlorpromazini hydrochloridum**

**Batch number / Weight:** **22J25-B02-225102 / 25 G**

**Analysed according to:** **Ph. Eur. 10.8**

**Number of analysis / Inspection Code** **22J25-B02 / INS-22-9281**

**Reference Code / No.:** **V01761 / 71154C1221**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder, it decomposes on exposure to air and light	Conform		
Identification A	acc to Ph.Eur.	Conform		
Identification C	acc to Ph.Eur.	Conform		
pH	3,5 - 4,5	4,02		
Impurity F	<=0,15	<0,15	%	
Related substances	Conform	Conform		
Impurity B	<=0,3	<0,05	%	
Impurity C	<=0,3	<0,05	%	
Impurity D	<=0,3	<0,05	%	
Impurity A	<=0,15	<0,05	%	
Impurity E	<=0,15	0,000	%	
Any other impurity	<=0,10	<0,05	%	
Total impurities	<=1,0	<0,05	%	
Loss on drying	<= 0,5	0,21	%	
Sulphated ash	<= 0,1	0,01	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Chlorpromazine hydrochloride	99,0 - 101,0	100,81	%m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		Data producer

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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 Own lab

Release:

Ewelina Gadzinowska

Qualified Person

20-12-2022

Expiration: 31-12-2026

Conclusion: APPROVED

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