

Certificate of Analysis

Product name: Diphenhydramini hydrochloridum
Batch number / Weight: 24E16-B02-002657 / 25 g
Producer / Producer Batch Number: Supriya Lifescience LTD. / SLL/DPH/0324029
Analyzed according to: Ph. Eur. 11
Number of Analysis / Certificate no.: 24E16-B02 / QO0004960

	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification C	IR spectrum	Conform		
Identification D	It gives reaction (a) of chlorides	Conform		
Appearance of solution	Clear / colour <=BY6	Conform		
Acidity or alkalinity	<= 0,5 ml NaOH (0,01M)	0,40	ml	
Related substances	Conform	Conform		
Impurity A	<= 0,5	<0,05	%	
Any other impurity	<= 0,3	0,05	%	
Total impurities	<= 1,0	0,05	%	
Loss on drying	<= 0,5	0,15	%	
Sulfated ash	<= 0,1	0,04	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		DP
Residual solvents	CPMP/ICH/82 260/06	Conform		DP
Assay	99,0 - 101,0	100,67	% m/m	
TSE/BSE-statement:	No contamination with TSE/BSE-risk materials	Conform		DP

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 FSNE lab

Release:

7-10-2024
 Agnieszka Pszczółka
 Qualified Person

Expiration: 28-2-2029

Conclusion: APPROVED

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