Certificate of Analysis

Product name: **Salbutamoli sulfas**

Batch number / Weight: **23H24-B03-232863 / 100 G**

Producer / Producer Batch Number: Supriya Lifescience LTD. / SLL/SS/0723059

Analysed according to: **Ph.Eur.11.2**

Number of analysis / Inspection Code **23H24-B03 / INS-23-8694**

Reference Code / No.: **V01853 / SLL/SS/0723059**

Tests	Requirement	Result	Unit	Standard remark
Appearance	(Almost) white, crystalline powder	Conform		
Identification B	Conform	Conform		
Identification E	White	Conform		
Appearance of solution	Clear <=BY6	Conform		
Optical rotation	-0,10 - +0,10	+0,005	°	
Acidity or alkalinity	Conform	0,25	ml	
Related substances	Conform	Conform		
Impurity D	<=0,3	0,00	%	
Impurity F	<=0,3	0,00	%	
Impurity C	<=0,2	0,00	%	
Impurity N	<=0,2	0,07	%	
Impurity O	<=0,2	0,00	%	
Unspecified impurities	<=0,10	0,000	%	
Total impurities	<=0,9	0,07	%	
Boron	<=50	Conform	ppm	
Loss on drying	<=0,5	0,14	%	
Sulphated ash	<=0,1	0,02	%	
Metallic residues	CHMP/ICH/353369/2013	Conform		Data producer
Residual solvents	CPMP/ICH/82 260/06	Conform		Data producer
Assay Salbutamol sulphate	98,0 - 101,0	99,80	%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 Fagron PL lab

Release:
Dominika Sołtysik
Qualified Person

05-01-2024

Expiration: 30-06-2028

Conclusion: APPROVED

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