

Certificate of Analysis

Product name: Salbutamol sulfate
Number of analysis: T0009075
Batch number / Weight: 24K15-H06-00988 / 100g
Producer / Producer Batch Number: Supriya Lifescience Ltd/SLL-SS-0424040
Analysed according to: PH.EUR 11.5

Tests	Requirement	Result	Unit	Standard remark
Appearance	White or almost white, crystalline powder	Conform		
Solubility	Freely soluble in water, practically insoluble or very slightly soluble in ethanol (96 per cent) and in methylene chloride	Conform		
Identification A	Conform	Conform		IR
Identification C	Conform	Conform		Reaction (a) of sulfates
Appearance of solution	Clear	Conform		
Appearance of solution	<=BY6	Conform		
Acidity or alkalinity	<= 0,4	0,25	mL	
Related substances	Conform	Conform		
Impurity F	<=0,3	0,05	%	
Impurity C	<=0,15	0,086	%	
Impurity O	<=0,15	0,00	%	
Impurity N	<=0,15	0,00	%	
Unspecified impurities	<=0,10	0,071	%	
Total impurities	<=1,0	0,37	%	
Boron	<=50	<50	ppm	
Loss on drying	<=0,5	0,43	%	
Sulfated ash	<=0,1	0,01	%	
Assay	98,0-101,0	100,04	%	
TSE/BSE-statement	No contamination with TSE/BSE-risk materials	Conform		

Analysis performed by the authorized internal lab and by the authorized lab of Fagron Services Northern Europe Sp.zo.o.

Release:
 Konstantina Tziolia
 Pharmacist - QA Manager / QP

18/11/2024

Expiration: 03-2029

Conclusion: APPROVED



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