Certificate of Analysis

Product name: **Betamethasoni valeras micr.**

Batch number / Weight: **23E29-B03-238447 / 10 G**

Analysed according to: **Ph.Eur.11.3**

Number of analysis / Inspection Code **23E29-B03 / INS-23-4414**

Reference Code / No.: **V01236 / BV 004/0722**

Tests	Requirement	Result	Unit	Standard remark
Protocol number		1296/S/0623		
Appearance	Fine, (almost) white crystalline powder	Conform		
Particle size	99% <25 µm / 90% <10 µm	Conform		
Identification A	Conform	Conform		
Identification B	Conform	Conform		
Melting point	About 192 with decomposition	194,41	°C	
Specific optical rotation	+77 - +83	+77,4		
Related substances	Conform	Conform		
Impurity A	<=0,7	<0,05	%	
Impurity C	<=0,15	<0,05	%	
Impurity E	<=0,3	<0,05	%	
Impurity G	<=0,3	<0,05	%	
Impurity H	<=0,15	<0,05	%	
Impurity I	<=0,15	<0,05	%	
Unspecified impurities	<=0,10	<0,05	%	
Total impurities	<=1,5	0,00	%	
Loss on drying	<=0,5	0,10	%	
Assay Betamethasone valerate	97,0 - 103,0	102,23	%m/m	
Correction factor		1,001		

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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

29-03-2024

Expiration: 30-06-2027

Conclusion: APPROVED

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

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