



Certificate of Analysis

Product: Brinzolamide micronized sterile

CAS number: 138890-62-7

Batch number:

COPY QA APPROVED

ICROM code: PF-0072

Batch size: 4.55 Kg

28 GIU. 2021

Manufacturing date: May 2021

Analysis number:

Expiry date: May 2024

Quality standard: USP Current Edition

PARAMETERS	RESULTS	SPECIFICATIONS
<i>Characters:</i>		
Appearance	Complies	White to almost white crystalline powder
<i>Identification:</i>		
IR	Positive	Positive
HPLC	Positive	Positive
<i>Tests:</i>		
Loss on drying	0.2%	≤ 0.5%
Sulphated Ashes	< 0.1%	≤ 0.1%
Impurity A (HPLC)	< LOD (0.03%)	≤ 0.5%
<i>Related substances (HPLC):</i>		
impurity B	< 0.05%	≤ 0.3%
impurity C	< 0.05%	≤ 0.3%
impurity D	< 0.05%	≤ 0.3%
impurity E	< 0.05%	≤ 0.3%
any other unidentified impurity	0.05%	≤ 0.10%
total impurity	0.1%	≤ 1.0%
<i>Assay:</i>		
HPLC (dried substance)	101.2%	98.0% to 102.0%
<i>Microbiological quality:</i>		
Sterility	Sterile	Sterile
<i>Physical characteristics:</i>		
<i>Particle Size Distribution:</i>		
PSD d ₅₀	2 µm	1 µm to 5 µm
PSD d ₉₀	4 µm	≤ 10 µm

Date: June 25, 2021

Chiara Ghinami
Quality Control Manager

Quality Assurance Revision: *Alma Santa 25/6/21*

I declare that the product is manufactured in accordance with the guidelines on Good Manufacturing Practice for Active Substances

Qualified Person Release:

G. Ungari 28/06/2021

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