

LOTE/BATCH: BFJ1056W

METAPHARMACEUTICAL

N DE LOTE:

0100722

gh 12/07/2022



CERTIFICATE OF ANALYSIS

IMI FABI LLC

209 Marshall Street, Benwood, West Virginia 26031

Quality Assurance Contact: Erin Moore: (304) 233-0050
Sales Office: Benwood, West Virginia (304) 233-0050

Date: 3/29/2022

Talc: 3355 USP/EP/JP/ChP Talc BC

Customer: IMI FABI S.p.A.

Lot Nr. BFJ1056W

Date Manufactured: 2/25/2022

Expiration Date: 2/25/2027

Manufacture location: Benwood, WV

Specifications				
Description	Method	Min	Max	Result
Brightness L*	M.I. 93002	94		97.70
Moisture %	M.I. 93005		0.3	0.08
Bulk Density #/cu.ft.	M.I. 98028	25	30	26.62
-325 mesh screen %	M.I. 93004	96		99.90
Black Specks	M.I. 93010		10	0.00
Microbial counts / g	USP		100	PASS
Microbial gram neg.	USP		0	PASS
MoldYeast	USP		50	PASS

Raw Material Identification Number: PLPE7203XFAN001

This product meets or exceeds current regulatory requirements established by: CTFA, USP, JP, EP, ChP.

This product is suitable for oral and topical application.

This product does not contain detectable levels of asbestiform minerals using standard test methods.

This product does not contain Bovine, Ovine or Caprine materials of any type.

This product meets characters for appearance for EP monograph: light, homogeneous, white or almost white powder, greasy to the touch (non abrasive)

This product meets characters for Solubility for EP monograph: practically insoluble in water, in ethanol and in dilute solutions of acids and alkali hydroxides.

Rev. 1/2021

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Analyte	Specification	Result	Interpretation
Identification	To pass test	To Pass test	CTFA 16 ED
Loss on Ignition (825°C)	≤ 6.0%	0.7%	CTFA 16 ED
Water-Soluble Iron	No blue color	Passes test	CTFA 16 ED
Acid Soluble Substances	≤ 6.0%	0.4%	CTFA 16 ED
Water Soluble Substances	≤ 0.1%	0.05%	CTFA 16 ED
Arsenic	≤ 3 ppm	<0.1 ppm	CTFA 16 ED
Lead	≤ 5 ppm	< 2 ppm	CTFA 16 ED

Analysis by independent certified laboratory. Analysis performed on incoming raw material and not on a representative sample from this lot.

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USP Methods, Specifications, Analytical results			
Analyte	Specification	Result	Interpretation
Identification			
A. IR Spectrum	To pass test	Passes test	USP/NF 2021
B.	To pass test	Passes test	USP/NF 2021
C.	To pass test	Passes test	USP/NF 2021
Loss on Ignition <733> (1075°C)	≤ 7.0%	5.2%	USP/NF 2021
Water Soluble Substances	≤ 0.1%	0.05%	USP/NF 2021
Limit of Iron <852>	≤ 0.25%	0.13%	USP/NF 2021
Limit of Lead <852>	≤ 0.001%	< 2ppm	USP/NF 2021
Limit of Calcium <852>	≤ 0.9%	0.11%	USP/NF 2021
Limit of Aluminum <852>	≤ 2.0%	0.24%	USP/NF 2021
Absence of Asbestos			USP/NF 2021
Procedure 2 (X-ray Diffraction)		Passes test	USP/NF 2021
Content of Magnesium <852>	17.0% - 19.5%	18.2%	USP/NF 2021
Acidity and Alkalinity NaOH	≤ 0.3 ml	0.3 ml	USP/NF 2021
Acidity and Alkalinity HCl	≤ 0.4 ml	0.3 ml	USP/NF 2021

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EP Methods, Specifications, Analytical results			
Analyte	Specification	Result	Interpretation
Production / Asbestos	To pass test	Passes test	Meets PH Eur 10 ED
Identification			
A. IR Spectrum	To pass test	Passes test	Meets PH Eur 10 ED
B.	To pass test	Passes test	Meets PH Eur 10 ED
C.	To pass test	Passes test	Meets PH Eur 10 ED
Loss on Ignition (1075°C)	≤ 7.0%	5.2%	Meets PH Eur 10 ED
Water Soluble Substances	≤ 0.2%	0.05%	Meets PH Eur 10 ED
Iron	≤ 0.25%	0.13%	Meets PH Eur 10 ED
Aluminum	≤ 2.0%	0.24%	Meets PH Eur 10 ED
Calcium	≤ 0.9%	0.11%	Meets PH Eur 10 ED
Lead	≤ 10 ppm	< 2 ppm	Meets PH Eur 10 ED
Magnesium	17.0% - 19.5%	18.2%	Meets PH Eur 10 ED
Acidity and Alkalinity HCl	≤ 0.4 ml	0.3 ml	Meets PhEur 10 ED
Acidity and Alkalinity NaOH	≤ 0.3 ml	0.3 ml	Meets PhEur 10 ED

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Analyte	Specification	Result	Interpretation
Identification			
1	To pass test	Passes Test	Meets JP 17 ED
2	To pass test	Passes Test	Meets JP 17 ED
Acid Soluble Substances	≤ 2.0%	0.4%	Meets JP 17 ED
Water Soluble Substances	≤ 4.0 mg	0.5 mg	Meets JP 17 ED
Arsenic	≤ 4 ppm	<0.1 ppm	Meets JP 17 ED
Loss on Ignition (1050° - 1100°C)	≤ 7.0%	5.2%	Meets JP 17 ED
Acid or Alkalinity (Hydrochloric Acid)	≤ 0.4 ml	0.3 ml	Meets JP 17 ED
Acidity or Alkalinity (Sodium Hydroxide)	≤ 0.3 ml	0.3 ml	Meets JP 17 ED
Magnesium	17.0% - 19.5%	18.2%	Meets JP 17 ED
Iron	≤ 0.25%	0.13%	Meets JP 17 ED
Aluminum	≤ 2.0%	0.24%	Meets JP 17 ED
Calcium	≤ 0.9%	0.11%	Meets JP 17 ED
Lead	≤ 10 ppm	< 2 ppm	Meets JP 17 ED

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Analyte	Specification	Result	Interpretation
Acidity or alkalinity	To pass test	Passes test	Meets ChP 20 Ed
Water Soluble Substance	≤ 0.1%	0.05%	Meets ChP 20 Ed
Acid Soluble Substance	≤ 2.0%	0.4%	Meets ChP 20 Ed
Loss of Ignition (600-700°C)	≤ 5.0%	0.7%	Meets ChP 20 Ed
Iron	≤ 0.25%	0.13%	Meets ChP 20 Ed
Lead	≤ 0.001%	< 2 ppm	Meets ChP 20 Ed
Calcium	≤ 0.9%	0.11%	Meets ChP 20 Ed
Aluminum	≤ 2.0%	0.24%	Meets ChP 20 Ed
Arsenic	≤ 0.0002%	< 0.0002%	Meets ChP 20 Ed
Magnesium	17.0% - 19.5%	18.2%	Meets ChP 20 Ed
Absence of Asbestos			
Procedure 2 (X-ray Diffraction)	Passes Test	Passes test	Meets ChP 20 ED
Identification			
ID 1	To pass test	Passes Test	Meets ChP 20 ED
ID 2	To pass test	Passes Test	Meets ChP 20 ED
ID 3	To pass test	Passes Test	Meets ChP 20 ED

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