

TALC ANALYSIS CERTIFICATE

BR-CQL-F-055

Data: 12/04/2018

Folha: 1/1

CERTIFICATE OF ANALYSIS

PRODUCT **TALMAG PHARMA-S**BATCH: **CPA1066V**QTY. (t): **25,000**

PRODUCTION/DATE (S):

07/03/2021

CONTROLLED PARAMETERS	METHOD	RESULTS	SPECIFICATION
Whiteness FMY (*)	(%) INSTRUMENTAL	91	Min. 90
Soluble in HCl	(%) BIS 1462	0,62	Máx. 2,0
Residue on 200# (75µm)	(%) ABNT	0,6	Máx. 1,5
Loose density	(g/cm ³) SCOTT VOLUMETER	0,36	0,35 / 0,45
Loss on ignition	(%) USP/EP/JP**	4,9	Máx. 7,0
Total aerobic microorganisms	(UFC/g) USP/EP**	<10	Máx. 100
Total of yeasts and molds	(UFC/g) USP/EP**	<10	Máx. 10
Gram negative bacilli	USP/EP**	Ausente	Absent in 10 g
Pseudomonas	USP/EP**	Ausente	Absent in 10 g
Escherichia coli	USP/EP**	Ausente	Absent in 10 g
Salmonella	USP/EP**	Ausente	Absent in 10 g
Staphylococcus Aureus	USP/EP**	Ausente	Absent in 10 g
Candid	USP/EP**	Ausente	Absent in 10 g
Clostridium	USP/EP**	Ausente	Absent in 10 g
ASSURANCE	METHOD		
MgO (%)	28,2 / 32,3	Spectrometry FRX	
SiO ₂ (%) mín.	56,0	Spectrometry FRX	
Al ₂ O ₃ (%) máx.	1,5	Spectrometry FRX	
Fe ₂ O ₃ (%) máx.	0,35	Spectrometry FRX	
CaO (%) máx.	0,1	Spectrometry FRX	
MnO (%) máx.	0,05	Spectrometry FRX	
TiO ₂ (%) máx.	0,05	Spectrometry FRX	
Absorption linseed oil (g/100g)	45,0 / 65,0	INSTRUMENTAL	
Moisture (%) máx.	0,50	ABNT	
Heavy metals (ppm) máx.	40,0	EE PLASMA	
Fe (%) máx.	0,25	USP/EP/JP**	
Pb (%) máx.	0,001	USP/EP/JP**	
Ca (%) máx.	0,9	USP/EP/JP**	
Al (%) máx.	2,0	USP/EP/JP**	
Mg (%)	17,0 / 19,5	USP/EP/JP**	
Arsenic (ppm) máx.	4	JP**	
Fe soluble in H ₂ O	Absent	BIS 1462	
pH	7,0 / 9,0	EP**	
Asbestos	Absent	DRX	
Substances Soluble in H ₂ O (%) máx.	0,08	USP/EP/JP**	
Infrared	3677 ± 2 cm ⁻¹ 1018 ± 2 cm ⁻¹ 669 ± 2 cm ⁻¹	USP/EP**	
Identification B	Pass in test	USP/EP**	
Identification C	Pass in test	USP/EP**	
Substances Soluble in acid (%) máx.	0,1	USP**	
Acidity e Alkalinity	Passa no teste	USP**	

NOTE

1. Representative results for batch (25 tons)
2. Typical values were statistically calculated according to the brand database.
3. (*) Elrepho 3000, standard 100% = MgO P.A.
4. Expiration date: 60 months (provided it is kept on the established conditions and in its original packaging).
5. Invoice:
6. N° DCB: 08264
7. N° of CAS registry: 14807-96-6
8. USP - United States Pharmacopoeia / EP - European Pharmacopoeia / JP - Japanese Pharmacopoeia
9. ** Current version

APPROVAL: