



PT PILAROS INDONESIA

LAPORAN PEMERIKSAAN BAHAN BAKU

No: LBB.01.018590.01

ZINC SULFAS H₂O

CONTROL

Tgl berlaku :

21 FEB 2023

Mengganti : LBB.01.018590.00

Tgl berlaku : 22 Oktober 2020

Hal 1 dari 2

CONF
m.k.
12/22

Nama Etiket : Zinc Sulfate Monohydrate Jumlah Diterima : 1 x 25 kg

Manufacturer : Merck

Supplier : Setia Jaya Era Unggul

No. Batch/Lot : A1710982

Kondisi kemasan : Mb. cokelat

Reassay Date : 05 - Agustus - 2025

Exp. Date : 28 - Feb - 2026 (MSL)

Jumlah wadah

yang disampling : 1

Jumlah Sampling : 38 g

No. LPB : B3901835

Tgl LPB : 11-07-2024

No. Analisa : 56

No. LSA : 04404386

Tgl LSA : 05-08-2024

Storage : Below 30 °C

No.	JENIS PEMERIKSAAN	HASIL	SYARAT
1.	Pemerian ¹	Sampel berupa serbuk hablur berwarna putih tidak berbau dan larutan memberi reaksi asam terhadap lakmus. ✓	Sampel harus berupa hablur transparan atau jarum-jarum kecil, serbuk hablur atau butir, tidak berwarna atau berwarna putih, tidak berbau dan larutan memberi reaksi asam terhadap lakmus.
2.	Identifikasi a. Metode Raman Spectroscopy ² b. Identifikasi Zink ¹ c. Identifikasi Sulfat ¹	Identifikasi a. MS ✓ b. MS ✓ c. MS ✓	Identifikasi a. Positive match (p-value ≥ 0,05) b. (1) Terbentuk endapan putih (2) Endapan tidak larut c. - Identifikasi A (1) Terbentuk endapan putih (2) Endapan tidak larut (3) Endapan tidak larut - Identifikasi B (1) Terbentuk endapan putih (2) Endapan larut - Identifikasi C Terbentuk endapan
3.	Kelarutan a. Purified water ¹ b. Gliserol ¹ c. Etanol ¹	Kelarutan a. Mudah larut ✓ b. Mudah larut ✓ c. Tidak larut ✓	Kelarutan a. Sampel mudah larut dalam purified water b. Sampel mudah larut dalam gliserol c. Sampel tidak larut dalam etanol.
4.	Keasaman ¹	MS ✓	Tidak terbentuk warna merah muda
5.	Alkali dan Alkali Tanah ¹	0,1 ✓	Bobot residu tidak lebih dari 5 mg
6.	Arsen ¹	NA ppm	≤ 14 ppm
7.	Timbal ¹	220 ✓ ppm	≤ 20 ppm

 PT PHAROS INDONESIA	LAPORAN PEMERIKSAAN BAHAN BAKU		No: LBB.01.018590.01
	ZINC SULFAS 1 H ₂ O		Tgl berlaku : 21 FEB 2023
			Mengganti : LBB.01.018590.00
			Tgl berlaku : 22 Oktober 2020
		Hal 2 dari 2	
No.	JENIS PEMERIKSAAN	HASIL	SYARAT
8.	Kadar	99,6 ✓	99,0 - 100,5%, dihitung sebagai ZnSO ₄ .H ₂ O
Catatan :			
Referensi :			
1. F1 V1, Hal 1804 - 1805, 2020, Direktorat Jenderal Bina Kefarmasian dan Alat Kesehatan, Kementerian Kesehatan RI 2. Internal Specifications			
SAMPLER		ANALIS	DITERIMA / DITOLAK
Nama : Angi		Nama : Bella	Nama : Rakh
Paraf : [Signature]		Paraf : [Signature]	Paraf : [Signature]
Tgl : 11-7-24		Tgl : 20-07-24	Tgl : 05-08-24





Certificate of Analysis

1.08882.9025 Zinc sulfate monohydrate EMPROVE® ESSENTIAL Ph Eur,USP
Batch A1710982 ✓

	Spec. Values		Batch Values	
Assay (complexometric)	99.0 - 100.5	%	99.7	%
Identity	passes test		passes test	
Appearance of solution	passes test		passes test	
Free acid	passes test		passes test	
pH-value (5 %; water)	4.0 - 5.6		4.3	
Chloride (Cl)	≤ 0.005	%	≤ 0.005	%
As (Arsenic)	≤ 0.0003	%	≤ 0.0003	%
Cd (Cadmium) (*)	≤ 0.0002 %	%	0.00004	%
Cr (Chromium)	≤ 0.0005	%	≤ 0.0005	%
Fe (Iron)	≤ 0.003	%	≤ 0.003	%
Hg (Mercury)	≤ 0.0005	%	≤ 0.0005	%
Ni (Nickel) (*)	≤ 0.0005 %	%	0.00006	%
Pb (Lead) (*)	≤ 0.001 %	%	0.00019	%
Se (Selenium)	≤ 0.003	%	≤ 0.003	%
Tl (Thallium) (*)	≤ 0.0010	%	0.0002	%
Alkali- and alkaline earth metals (as sulfate)	≤ 0.5	%	≤ 0.5	%
Residual solvents (ICH Q3C)	excluded by manufacturing process		excluded by manufacturing process	
Loss on Drying (105 °C)	≤ 1.0	%	≤ 1.0	%

Elemental impurity specifications have been set considering ICH Q3D (Guideline for Elemental Impurities). Class 1-3 elements are not likely to be present above the ICH Q3D option 1 limit, unless specified and indicated (*).
Corresponds to Ph.Eur., USP

Date of manufacture (DD.MM.YYYY) 13.02.2021
Date of examination (DD.MM.YYYY) 12.05.2021
Minimum shelf life (DD.MM.YYYY) 28.02.2026 ✓

Claudia Wiegand
Responsible laboratory manager quality control

This document has been produced electronically and is valid without a signature.

THE UNITED STATES OF AMERICA

Department of the Interior
Bureau of Land Management

Washington, D.C. 20250

For the purpose of this document, the following definitions apply:

1. "Land" means any area of land, whether or not it is currently being used for any purpose.

2. "Use" means any activity, whether or not it is currently being used for any purpose.

3. "Management" means any activity, whether or not it is currently being used for any purpose.

4. "Conservation" means any activity, whether or not it is currently being used for any purpose.

5. "Development" means any activity, whether or not it is currently being used for any purpose.

6. "Recreation" means any activity, whether or not it is currently being used for any purpose.

7. "Education" means any activity, whether or not it is currently being used for any purpose.

8. "Research" means any activity, whether or not it is currently being used for any purpose.

9. "Monitoring" means any activity, whether or not it is currently being used for any purpose.

10. "Evaluation" means any activity, whether or not it is currently being used for any purpose.

11. "Reporting" means any activity, whether or not it is currently being used for any purpose.

12. "Communication" means any activity, whether or not it is currently being used for any purpose.

13. "Coordination" means any activity, whether or not it is currently being used for any purpose.

14. "Integration" means any activity, whether or not it is currently being used for any purpose.

15. "Implementation" means any activity, whether or not it is currently being used for any purpose.

16. "Maintenance" means any activity, whether or not it is currently being used for any purpose.

17. "Improvement" means any activity, whether or not it is currently being used for any purpose.

18. "Protection" means any activity, whether or not it is currently being used for any purpose.

19. "Preservation" means any activity, whether or not it is currently being used for any purpose.

20. "Restoration" means any activity, whether or not it is currently being used for any purpose.

21. "Rehabilitation" means any activity, whether or not it is currently being used for any purpose.

22. "Reconstruction" means any activity, whether or not it is currently being used for any purpose.

23. "Renovation" means any activity, whether or not it is currently being used for any purpose.

24. "Repair" means any activity, whether or not it is currently being used for any purpose.

25. "Replacement" means any activity, whether or not it is currently being used for any purpose.

26. "Removal" means any activity, whether or not it is currently being used for any purpose.

27. "Relocation" means any activity, whether or not it is currently being used for any purpose.

28. "Reinstatement" means any activity, whether or not it is currently being used for any purpose.

29. "Reversion" means any activity, whether or not it is currently being used for any purpose.

30. "Resumption" means any activity, whether or not it is currently being used for any purpose.

31. "Revival" means any activity, whether or not it is currently being used for any purpose.

32. "Rejuvenation" means any activity, whether or not it is currently being used for any purpose.

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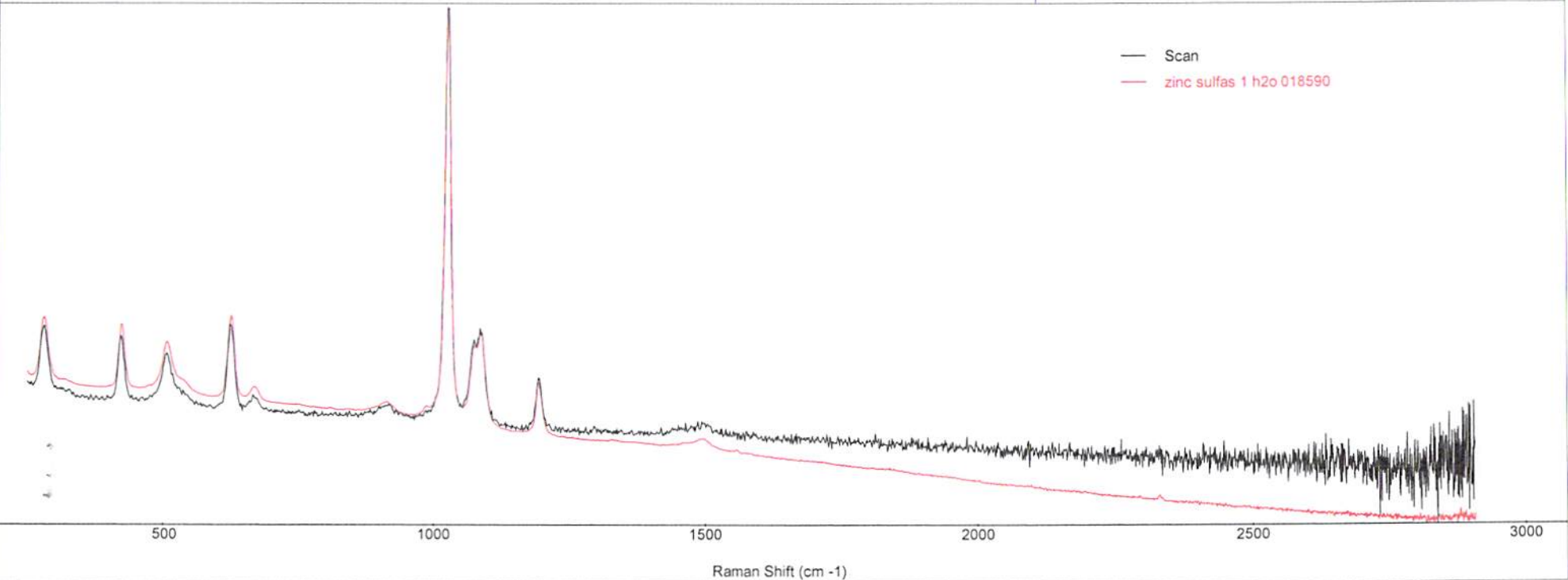
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Positive Match		The measured data is fully consistent with the library item for zinc sulfas 1 h2o 018590. Searched libraries: User only. All results should be verified using other methods or techniques	TruScan GP ID Report		
zinc sulfas 1 h2o 018590	Pval 0.6027		TG2446		
			User Name: awal		
		Software Version: 1.2.3 (19428)			
		Last Tested: 11-Jul-2024 16:55			
		Last Test Result: Pass			
		Calibration Check: Pass			
		CCD Check: Pass			
		Laser Power: Pass			
		Warnings: None			
Method:	Identification				
Scan Label:	Scan-20240711-171519				
Scan time:	11-Jul-2024 17:15				
Batch ID:	ZINC SULFAS H2O B3401835				
Sample ID:	ZINC SULFAS H2O B3401835-001				
Note:					



LABORATORY WORKSHEET

Nama Bahan Baku/ Produk : Zinc Sulfas H₂O
 No LSA/ Batch : 83401835
 Tanggal Mulai : 12-07-24
 Tanggal Selesai :

Pemeriksaan Kadar Pengawet

Instrument :
 No ID : No Kolom : Analyst :
 No Lot WS : Kadar : Zat Aktif :
 ID Timbangan :

Penimbangan	1	2	3	4	5	6
Standar						
Sampel 1-6						

Instrument :
 No ID : No Kolom : Analyst :
 No Lot WS : Kadar : Zat Aktif :
 ID Timbangan :

Penimbangan	1	2	3	4	5	6
Standar						
Sampel 1-6						

Instrument :
 No ID : No Kolom : Analyst :
 No Lot WS : Kadar : Zat Aktif :
 ID Timbangan :

Penimbangan	1	2	3	4	5	6
Standar						
Sampel 1-6						

Instrument :
 No ID : No Kolom : Analyst :
 No Lot WS : Kadar : Zat Aktif :
 ID Timbangan :

Penimbangan	1	2	3	4	5	6
Standar						
Sampel 1-6						

Titras

No Lot Titran : NaEDTA Normalitas : 0.0502N Analyst : Tgl : 15/07/24
 ID Timbangan : Sartorius

Penimbangan	1	2	3	4	5	6
Standar						
Sampel 1-6	<u>0.1700 g</u>	<u>0.1700 g</u>				

No Lot Titran : Normalitas : Analyst : Tgl :
 ID Timbangan :

Penimbangan	1	2	3	4	5	6
Standar						
Sampel 1-6						

No Lot Titran : Normalitas : Analyst : Tgl :
 ID Timbangan :

Penimbangan	1	2	3	4	5	6
Standar						
Sampel 1-6						

LABORATORY WORKSHEET

Nama Bahan Baku/ Produk : *Zinc Sulfas H₂O*
 No LSA/ Batch : *B3401835*
 Tanggal Mulai : *11-07-24*
 Tanggal Selesai :

Pemeriksaan Timbal

Preparasi Sp : 250 mg Sp + 5 ml Purified Water + 10 ML KCl 10% di tabung A + 0.1 ml natrium sulfat,
 5 ml Purified Water + 0.5 ml larutan baku timbal + 10 ml KCl 10% + 0.1 ml natrium sulfat di tabung B
 kocok dan biarkan selama 5 menit, amati

Hasil : Warna larutan tabung A tidak lebih gelap dari tabung B

Kadar

Preparasi Sp : 170 mg sampel + 100 Purified Water + 5 ml buffer ammonia-amonium klorida + EBT.

N : 0.0502

No.		V.Sp	Kadar	Kadar H ₂ O
1	170.0	18.8	89.6%	99.6%
2	170.0	18.8	89.6%	99.6%
Rata-rata			89.6%	99.6%
Rsd			0.00%	0.00%

Paraf Analis :

Verifikasi :

LABORATORY WORKSHEET

Nama Bahan Baku/ Produk : Zinc Sulfas
 No LSA/ Batch : B3401835
 Tanggal Mulai : 11-07-24
 Tanggal Selesai : 29-07-24

Kelarutan

Preparasi Sp : Sp + Purified Water Preparasi Sp : Sp + Etanol
 Hasil : Mudah Larut ✓ Hasil : Tidak Larut ✓
 Preparasi Sp : Sp + Gliserol
 Hasil : Mudah Larut ✓

Identifikasi**Identifikasi Zinc**

Preparasi : Sp + 2ml Purified Water + Kalium heksasianof/erat (II), amati (1). + 1 ml HCl 3N (2)
 Hasil : (1) Terbentuk endapan putih
 : (2) Endapan tidak larut ✓

Identifikasi Sulfat**Identifikasi Sulfat A**

Preparasi : Sp + Purified Water hingga 10 ml, bagi larutan menjadi 2. + BaCl tiap tabung (I)
 : + HCl pada tabung I, amati (2), + asam nitrat pada tabung II, amati (3)
 Hasil : (1) Terbentuk endapan putih
 : (2) Endapan tidak larut ✓
 : (3) Endapan tidak larut

Identifikasi Sulfat B

Preparasi : Sp + 5 ml Purified Water + timbal asetat, amati (1) + amonia asetat, amati (2)
 Hasil : (1) Terbentuk endapan putih
 : (2) Endapan larut ✓

Identifikasi Sulfat C

Preparasi : Sp + 5 ml Purified Water + HCl, amati
 Hasil : Tidak terbentuk endapan ✓

Keasaman

Preparasi Sp : sampel + 10 ml Purified Water + methyl red
 Hasil : Tidak terbentuk warna merah muda ✓

Alkali & Alkali Tanah

Preparasi Sp : 1.12 gr Sp + 150 ml Purified Water + 10 ammonium sulfat 40% encerkan dgn Purified Water, saring
 100 ml filtrat tambahkan 3 tts H₂SO₄ P, uapkan

B1	58.006
B2	58.1240
Hasil	0.1 ✓

Paraf Analis : B35
 Verifikasi : Rujut

LABORATORY WORKSHEET

Nama Bahan Baku/ Produk : Zinc Sulfas
No LSA/ Batch : B3401835
Tanggal Mulai : 11-07-24
Tanggal Selesai : 29-07-24

Pemeriksaan Timbal

Preparasi Sp : 250 mg Sp + 5 ml Purified Water + 10 ML KCl 10% di tabung A + 0.1 ml natrium sulfat,
5 ml Purified Water + 0.5 ml Irutan baku timbal + 10 ml KCl 10% + 0.1 ml natrium sulfat di tabung B
kocok dan biarkan selama 5 menit, amati

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Kadar

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N : 0.0502

No.		V.Sp	Kadar	Kadar H ₂ O
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2	170.0	18.8	89.6%	99.6%
Rata-rata			89.6%	99.6% ✓
Rsd			0.00%	0.00%

Paraf Analisis : Bess
Verifikasi : Ryznuc

-----* PRINTER TIMBANGAN *-----

Tgl:- Jam:-

i	1.1200 g
n	1
x	1.1200 g
s	0.0000 g
srel	0.0000 %
min.	1.1200 g
max.	1.1200 g
dif.	0.0000 g

Sartorius BCE224

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2n 50g
Cawan

-----* PRINTER TIMBANGAN *-----

Tgl:- Jam:-

1	58.0060 g
n	1
x	58.0060 g
s	0.0000 g
srel	0.0000 %
min.	58.0060 g
max.	58.0060 g
dif.	0.0000 g

Sartorius BCE224

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-----* PRINTER TIMBANGAN *-----

Tgl:- Jam:-

1	58.1240 g
n	1
x	58.1240 g
s	0.0000 g
srel	0.0000 %
min.	58.1240 g
max.	58.1240 g
dif.	0.0000 g

Sartorius BCE224

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-----* PRINTER TIMBANGAN *-----

Tgl:- Jam:-

1	0.1700 g
2	0.1700 g
n	2
x	0.1700 g
s .	0.0000 g
srel	0.0000 %
min.	0.1700 g
max.	0.1700 g
dif.	0.0000 g

15/24
07

Sartorius BCE224

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-----* PRINTER TIMBANGAN *-----

Tgl:- Jam:-

1	1.1200 g
n	1
x	1.1200 g
s	0.0000 g
srel	0.0000 %
min.	1.1200 g
max.	1.1200 g
dif.	0.0000 g

12/24
107

Sartorius BCE224

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