



AGENȚIA MEDICAMENTULUI
ȘI DISPOZITIVELOR MEDICALE



GUVERNUL
REPUBLICII MOLDOVA

Guvernul Republicii Moldova
AGENȚIA MEDICAMENTULUI ȘI DISPOZITIVELOR MEDICALE
Laboratorul pentru Controlul Calității Medicamentelor

MD-2028 Chișinău, str. Korolenko 2/1, Chișinău, tel. 022-884-301

Certificat de calitate nr. 35942 din 24.01.2023

Seria: **SP15000562**

Denumirea **Albastru de metilen en gros**

Producător: **Simpsons Ltd., Marea Britanie**

Prezentat la 20.12.2022 de **DepoTrifarm S.R.L.**

Primit 0,05 kilograme prelevate din 25 kilograme depozitate. Consumat - 0,05, restituit - 0

Analiza efectuată conform DAN: Ph. Eur. 07/2019:1132

nr.	Denumire indice	Prevederi DAN	Rezultate analiză
1	Descriere	Pulbere cristalină de culoare albastră-închisă sau verde-închisă cu luciu metalic, higroscopică.	Pulbere cristalină de culoare verde-închisă cu luciu metalic, higroscopică.
2	Identificare	IR; Reacția la cloruri	Corespunde
3	Solubilitate	Foarte puțin solubil în apa și etanol (96%);	Corespunde
4	Pierdere prin uscare	8,0-24,0 %	11,8 %
5	Termen valabilitate	60 luni	03.2026

Concluzie: Eșantionul "Albastru de metilen en gros" seria SP15000562" corespunde DAN Ph. Eur. 07/2019:1132

Raportul de analiza se refera numai la probele analizate și atesta conformitatea indicilor de calitate specificați în prezentul raport.

Șef Laborator pentru Controlul Calității
Medicamentelor

Garuța A.



Agencia Medicamentului și Dispozitivelor Medicale
Medicines and Medical Devices Agency

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CERTIFICATE OF ANALYSIS

Material - Information

Insp. Lot No. 10000572132
 Product Des. SIMBASE METHYLENE BLUE (BB9)
 CAS No. 61-73-4
 C.I. No. 52015

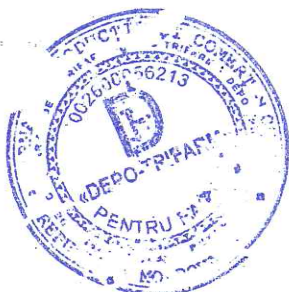
Batch No. SP15000562
 EINECS No. 200-515-2
 C.I. Name Basic Blue 9

Characteristics	Method	Specification	UOM	Result
Appearance		Dark Greenish to Dark Brownish Powder		Complies
Identification (A, B, C, D)				Pass
Solubility at 0.1% (Distilled Water)		Similar to Standard		Pass
Arsenic (as As)		(Max.) 8.00	mg/kg	1.50
Iron		Passes Test		Pass
Lead (as Pb)		(Max.) 20.00	mg/kg	1.10
Zinc		Pass Turbidity Test		Pass
Loss on Drying (105°C)		8.00-15.00	%	14.00
Total colour/Assay		96.00-101.00	%	98.85
Wavelength of Maximum Absorption (λ max) in 1:1 IMS:DI Water		658.0-664.0	nm	661.2
Specific Absorption (E 1%/1cm) at λ max		(Min.) 2300.0		3227.0
				Complies

REACH REGISTRATION DECLARATION:
 We confirm that above product is Not REACH Registered. No obligation of REACH registration due to less than 1 ton/calendar year quantity and/or low volume sales meaning not viable for registration.

Shelf Life

Storage



1825 days from the date of delivery in packed conditions

Ambient temperature. Please keep away from light and moisture.

The compliance to the above mentioned specification can be verified using respective methods of analysis.

Disclaimer : Above information is correct at the time of issue but may be subject to alteration. The information on the specification remains the property of ROHA Group (JJT Group companies). Information is correct to the best of our knowledge and it should not be construed as warranty. Users should conduct their own tests to determine the suitability of this product/data for this purpose. Users must satisfy themselves suitability of product, ingredients in accordance with regulations applicable and suitability of product in end application. Roha Group (JJT Group Companies) shall not be liable for any claims or losses of any nature arising directly or indirectly from use of the information, data or other material on this document.

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