

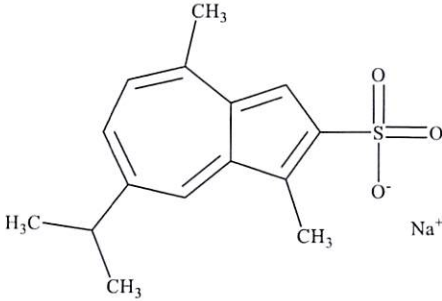
Certificate of Analysis

Certificate No.: 20240222003

Date: February 22, 2024



Retest date: January 22, 2027

Compound Name: Sodium Gualenate Impurity 4 Sodium Salt	
Synonyms:	7-isopropyl-1,4-dimethylazulene-2-sulfonate, sodium salt (1:1)
TLC Catalogue Number:	G-040005
CAS Number:	93914-28-4
Molecular Weight:	277.36 22.99
Molecular Formula:	C ₁₅ H ₁₇ O ₃ S. Na
Source:	TLC Pharmaceutical Standards
Source Lot No.:	5983-056A15
Storage Conditions:	Hygroscopic, store at 2-8 °C
Solubility:	Methanol, DMSO, DMF, Water



The chemical structure shows a azulene ring system (fused 7-membered and 5-membered rings). The 7-membered ring has a methyl group (CH₃) at position 1 and an isopropyl group (CH(CH₃)₂) at position 3. The 5-membered ring has a methyl group (CH₃) at position 4 and a sulfonate group (-SO₃⁻Na⁺) at position 2.

Test Description	Specifications	Results
Visual Description	Blue solid	Conforms
Identification		
IR	Conforms to structure	Conforms
MS	Conforms to structure	Conforms
¹H NMR	Conforms to structure	Conforms
Purity (HPLC)	Not less than 95.0%	99.2%
Impurity (HPLC)	RT 8.19, 0.15%; RT 12.85, 0.59%	
Residual Solvents (NMR)	0.1% acetonitrile	
Assay (qNMR)	Not less than 90.0%	90.6%
Recommendation:	Release. The compound contains 0.2% Sodium Gualenate (Guaiazulene 3-Sulfonate Sodium Salt) (RT 8.19, TLC No. G-040001) according to its HPLC.	

Name	Department	Signature	Date
Reviewed and approved by:	Quality Control		02/23/2024
Approved by:	Quality Assurance		02/23/2024

Attachments: HPLC, IR, MS and NMR spectra.