



Characterization methods are accredited according to **ISO 17034:2016**

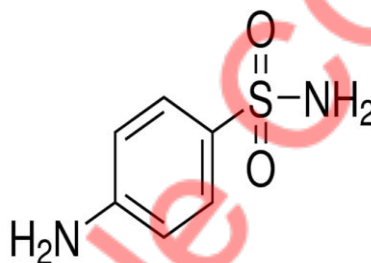
PRODUCT INFORMATION SHEET

SULFANILAMIDE

IUPAC Name: 4-Aminophenylsulfonamide

CAS No: 63-74-1

Structure:



Identification:

Version No.: 02	Certificate No: DRA/RM/S-02/25/003
Lot No : 003	Catalogue Number: S-02
Unit Quantity: 2 gm	Chemical Formula: C ₆ H ₈ N ₂ O ₂ S
Molecular Weight: 172.2 g/mol	Assay: 99.14 per cent
Date of Issue : 30/08/2025	u _{CRM} = ±0.20
Manufacturing: August 2025	Valid up to: July 2028
Storage: Keep container tightly closed, protected from light and store between 2°C to 8°C.	

Uncertainty

The assigned Uncertainty covers uncertainty contribution from Characterization, In homogeneity, Storage & transport stability etc (wherever applicable) , is the combined standard Uncertainty ,calculated using a coverage factor (K= 2) which gives a level of confidence of approx.95%. As per ISO 17034:2016 & ISO Guide 35, ISO 33405:2024, for this pharmaceutical standard assigned uncertainty value is considered to be negligible w.r.t. defined limits of method specific assays for which the DRA/CRM is used.



Metrological Traceability and Measurement methods

Assigned value is traceable to SI units through use of Primary Standard mass balance methods (Physical & Chemical) with Inter Laboratory Collaborative studies using Indian Pharmacopeia standards specifications. Characterization done by combination of Primary Reference Methods viz. NMR, LCMS, with use of pure substance/traceable RM/CRM in compliances with ISO Guide 35, ISO 33405:2024 & ISO/IEC-17025.

Commutability

Not Applicable

Intended Use

This reference material intended for R& D and analytical use only. Not for drug, house hold or other uses.

Instruction for handling and use

Allow the sealed container to equilibrate at ambient/room temperature before opening for use. Do not dry, use "As on basis".

Validity

Stated Validity is applied, when material stored under recommended conditions with proper handling.

Associated uncertainty:

The associated uncertainty U_{CRM} reported with the certified values is calculated as combined expanded uncertainty $U_{CRM}=k.U_{CRM}$ in accordance with EA 4/02 with $k=2$ as the coverage factor for a 95 % coverage probability.

The combined uncertainty U_{CRM} is derived for combination of the squared uncertainty contribution:

$$U_{CRM} = \sqrt{U^2_{\text{Characterisation}} + U^2_{\text{Homogeneity}} + U^2_{\text{Stability}}}$$

$U_{\text{Characterisation}}$: Is the uncertainty in accordance with ISO/IEC 17025 which includes the contribution of the primary reference material and the measuring system.

$U_{\text{Homogeneity}}$: Is the between bottle variance in accordance with ISO 17034. The assessment of homogeneity is performed by analysis of a representative number of systematically chosen samples units.

$U_{\text{Stability}}$: Is the uncertainty obtained from short term and long term stability in accordance with ISO 17034. The Stability studies are the basis for the quantification of the expiry date of this volumetric standard for the unopened bottle.



***Dove Research & Analytics, Unit-II
(RMP Division) Panchkula (Haryana)***



RC-1021

NMR & MASS:

The material confirms to ^1H -NMR and Mass.

Accreditation:

The laboratory of Dove Research & Analytics Unit-II (RMP Division), is Accredited as per ISO 17034:2016; General requirements for the competence of reference material producers and ISO/IEC 17025 General requirement for the competence of testing and Calibration Laboratories.

Safety Information

Refer to the material safety data sheet

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Approving Officer

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