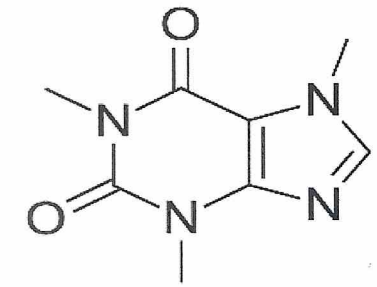
Characterization methods are accredited according to ISO 17034:2016

PRODUCT INFORMATION SHEET

Caffeine

IUPAC Name: 1,3,7-Trimethylpurine-2,6-dione
CAS No: 58-08-2

Structure:



Identification:

Version No.: 02	**Certificate No:** DRA/RM/C-01/26/005
Lot No.: 005	**Catalogue Number**: C-01
Unit Quantity: 2gm	**Chemical Formula**: $C_8H_{10}N_4O_2$
Molecular Weight: 194.19 g/mol	**Purity**: 0.999 mg per mg
Date of Issue : 31/03/2026	u_{CRM}= ±0.18
Manufacturing : March 2026	**Valid up to:** Feb 2029
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/RM is used.

Metrological Traceability and Measurement methods

Assigned value is traceable to SI units through use of Primary Standard mass balance methods (Physical & Chemical) and to higher level of traceability (USP) 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 CRM is intended for calibration of the HPLC equipment.

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 UCRM=k.U_{CRM} in accordance with EA 4/02 with k=2 as the coverage factor for a 95 % coverage probability.

The combined uncertainty Ucrm is derived for combination of the squared uncertainty contribution:

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

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

$U_{Homogeneity}$: 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.

$U_{Stability}$: 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.

NMR & MASS:

The Material confirms to ^{1}H-NMR&MASS.

Traceability Assay:

Comparative Assay demonstrates direct traceability to Pharmacopeial Standards

Assay vs. USP reference standards R160N0-200mg (as is basis)

ASSAY vs. USP REFERENCE STANDARD (as is basis)

ASSAY VALUE	**vs. USP LOT R160N0**
100.1 %	Labeled Content = 0.999 mg/mg

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

Special Note

DRA reference materials are designed and intended to be used in the forms in which they are sold. All values (Certified, non-certified, reference or information) are nullified if the RM is stored or used improperly, damaged, contaminated or otherwise modified in any manner.

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(Approving officer)

Address: *Dove Research & Analytics Unit-II, RMP DIVISION Panchkula Haryana, Plot 290 Industrial Area Phase II FF.* ***Contact detail:*** *9876471976;* ***Email:*** *dove 17034 @ gmail.com,* ***web:*** *www.doveresearchlab.com*