



REFERENCE MATERIAL ANALYSIS REPORT

Report ID: D624.2015.01 (Ampouled 091006)

This batch of ampoules was prepared from the bulk material on 6th October 2009.

Compound Name: **7 β , 17 α -Dimethyl-5 β -androstane-3 α ,17 β -diol**

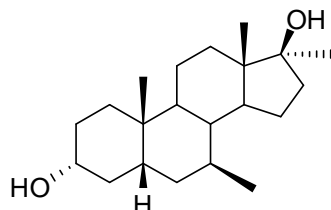
Description: White crystalline solid

Collection Number: D624

Chemical Formula: C₂₁H₃₆O₂

CAS Number: 153546-23-7

Structure:



Batch Number: 99-S-31

Molecular Weight: 320.5

Release date: January 2001

Metabolite of calusterone

Synonym: 3 α ,17 β -Dihydroxy-7 β ,17 α -dimethyl-5 β -androstane

The compound is supplied as a dried aliquot in a sealed ampoule and is intended for a single use to prepare a standard solution containing D624. Open the ampoule and carefully rinse the interior at least three times with a suitable organic solvent (e.g. chloroform). This will transfer 0.987 ± 0.010 mg of anhydrous 7 β , 17 α -dimethyl-5 β -androstane-3 α ,17 β -diol.

GC-FID: Instrument: Agilent 6890N
Column: HP-1 Capillary, 30 m × 0.32 mm I.D. × 0.25 μ m
Program: 180 °C (1 min), 5 °C/min to 250 °C, 20 °C/min to 300 °C (3 min)
Injector: 250 °C Detector Temp: 320 °C
Carrier: Helium Split ratio: 20/1
Relative peak area percentage of main component:
Initial analysis: Mean = 98.9%, s = 0.01% (7 ampoules in duplicate, October 2009)
Re-analysis: Mean = 99.0%, s = 0.01% (5 ampoules in duplicate, September 2012)
Re-analysis: Mean = 99.1%, s = 0.01% (5 ampoules in duplicate, July 2015)

Expiration of certification

The property values are valid till 30th July 2020, i.e. five years from the date of re-certification provided the **unopened** material is handled and stored in accordance with the recommendations below. The material as issued in the unopened container and stored as recommended below should be suitable for use beyond this date, subject to confirmation of batch stability from the issuing body.

The expiry date/shelf life does not apply to ampoules that have been opened. In such cases it is recommended that the end-user conduct their own in-house stability trials.

The long-term stability of the compound in solution has not been examined.

This material has been given a shelf life of five years from the date of re-certification.

This material has demonstrated stability over a minimum period of five years. The measurement uncertainty at the 95% confidence interval includes a stability component which has been estimated from annual stability trials.

Homogeneity assessment

The homogeneity of the material was assessed using purity assay by GC-FID on 7 randomly selected ampoules of the material. The material was judged to be homogeneous at this level of sampling as the variation in analysis results between samples was not significantly different at a 95% confidence level from that observed on repeat analysis of the same sample.

Recommended storage

When not in use, this material should be stored at or below 4 °C in a closed container in a dry, dark area.

Intended Use

For *in vitro* laboratory analysis only.

Caution

Treat as hazardous substance. Use appropriate work practices when handling to avoid skin or eye contact, ingestion or inhalation of dust.

Legal notice

Neither NMI nor any person acting on NMI's behalf assumes any liability with respect to the use of, or for damages resulting from the use of, this reference material or the information contained in this certificate.

Authorised by:

S. R. Davies

Dr Stephen R. Davies,
Team Leader,
Chemical Reference Materials, NMI.
Dated: 11 August, 2015.

Characterisation data and property values specified in this report supersede those in all reports issued prior to 11 August, 2015.