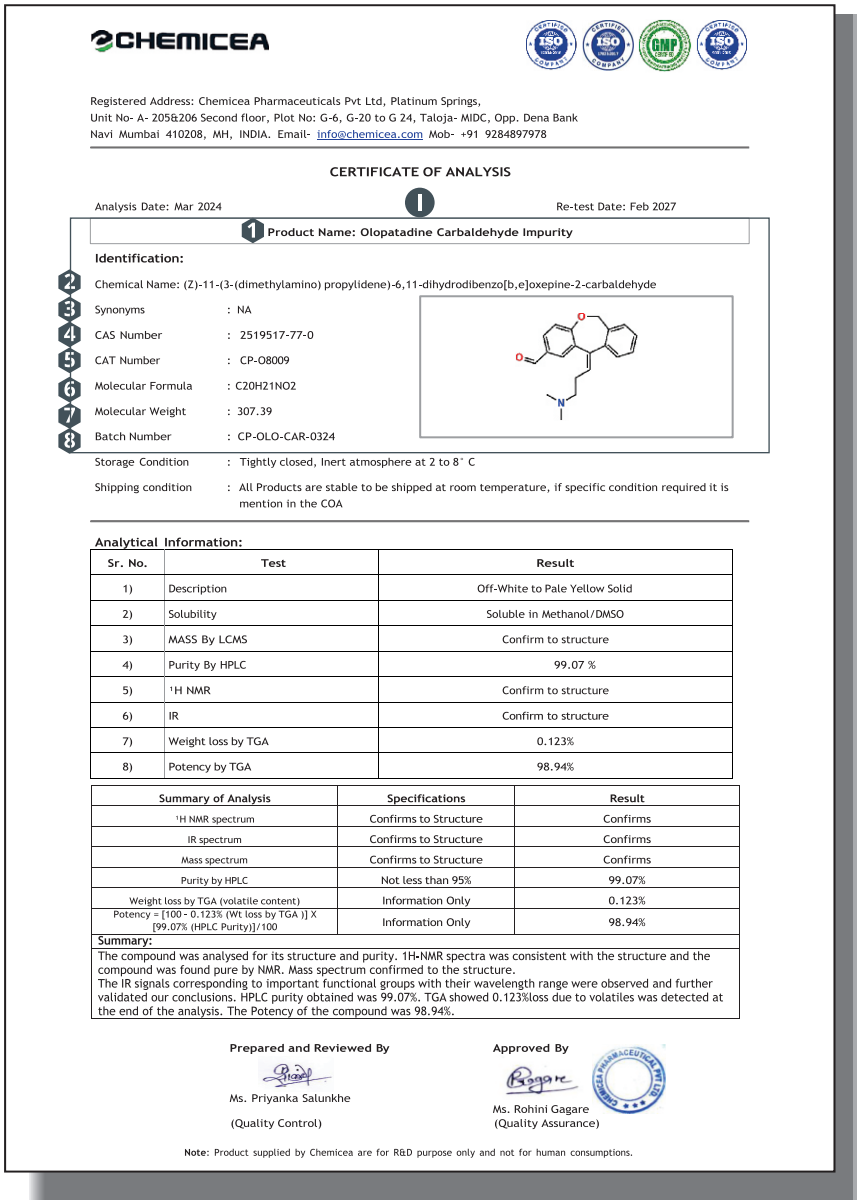
CHEMICEA

Certificate of Analysis (COA) Explained

Complete Guide: How Chemicea Performs Analysis of Pharmaceutical Reference Standards



CHEMICEA

Registered Address: Chemicea Pharmaceuticals Pvt Ltd, Platinum Springs,
Unit No- A- 205&206 Second floor, Plot No: G-6, G-20 to G 24, Taloja- MIDC, Opp. Dena Bank
Navi Mumbai 410208, MH, INDIA. Email- info@chemicea.com Mob- +91 9284897978

CERTIFICATE OF ANALYSIS

Analysis Date: Mar 2024 (I) Re-test Date: Feb 2027

1 Product Name: Olopatadine Carbaldehyde Impurity

Identification:

2 Chemical Name: (Z)-11-(3-(dimethylamino) propylidene)-6,11-dihydrodibenzo[b,e]oxepine-2-carbaldehyde

3 Synonyms : NA

4 CAS Number : 2519517-77-0

5 CAT Number : CP-O8009

6 Molecular Formula : C20H21NO2

7 Molecular Weight : 307.39

8 Batch Number : CP-OLO-CAR-0324

Storage Condition : Tightly closed, Inert atmosphere at 2 to 8° C

Shipping condition : All Products are stable to be shipped at room temperature, if specific condition required it is mention in the COA

Analytical Information:

Sr. No.	Test	Result
1)	Description	Off-White to Pale Yellow Solid
2)	Solubility	Soluble in Methanol/DMSO
3)	MASS By LCMS	Confirm to structure
4)	Purity By HPLC	99.07 %
5)	^{1}H NMR	Confirm to structure
6)	IR	Confirm to structure
7)	Weight loss by TGA	0.123%
8)	Potency by TGA	98.94%

Summary of Analysis	Specifications	Result
^{1}H NMR spectrum	Confirms to Structure	Confirms
IR spectrum	Confirms to Structure	Confirms
Mass spectrum	Confirms to Structure	Confirms
Purity by HPLC	Not less than 95%	99.07%
Weight loss by TGA (volatile content)	Information Only	0.123%
Potency = [100 - 0.123% (Wt loss by TGA)] X [99.07% (HPLC Purity)]/100	Information Only	98.94%

Summary:
The compound was analysed for its structure and purity. 1H-NMR spectra was consistent with the structure and the compound was found pure by NMR. Mass spectrum confirmed to the structure.
The IR signals corresponding to important functional groups with their wavelength range were observed and further validated our conclusions. HPLC purity obtained was 99.07%. TGA showed 0.123%loss due to volatiles was detected at the end of the analysis. The Potency of the compound was 98.94%.

Prepared and Reviewed By
Ms. Priyanka Salunkhe
(Quality Control)

Approved By
Ms. Rohini Gagare
(Quality Assurance)

Note: Product supplied by Chemicea are for R&D purpose only and not for human consumptions.

What the Certificate of Analysis (COA) Tells You?

At Chemicea Pharmaceutical, a **Certificate of Analysis (COA)** is an essential document that confirms the quality and authenticity of each product. It provides critical information that assures customers that the product meets all required standards and specifications.

What is a Certificate of Analysis (COA)?

A COA provides comprehensive information about a product's characteristics, confirming its adherence to specified quality and safety standards. It includes results from rigorous testing conducted using advanced analytical techniques such as High-Performance Liquid Chromatography (HPLC), Nuclear Magnetic Resonance (NMR), and Liquid Chromatography-Mass Spectrometry (LC-MS), IR, Weight Loss by TGA, Potency by TGA. The COA serves as a guarantee of the product's quality and suitability for its intended use.

What Information Does a COA Include?

I. Product Identification:

This section outlines key product identification and tracking details to ensure clarity and accuracy in handling chemical substances. Here's a breakdown of each element:

1. **Product Name:**
   The commercial or common name used to identify the product. The name of reference standard may be as per EP, USP or common name.
2. **Chemical Name:**
   The precise scientific name of the compound, usually adhering to IUPAC (International Union of Pure and Applied Chemistry) rules, ensuring clarity and consistency across scientific fields.
3. **Synonyms:**
   Provides alternative name of the product in different pharmacopeia.
4. **CAS Number:**
   A unique numerical identifier assigned by the Chemical Abstracts Service, which is widely used for chemical substances, ensuring correct identification across databases.
5. **Catalog Number:**
   An internal identifier used by suppliers or manufacturers to manage their products efficiently, aiding in inventory tracking.
6. **Molecular Formula:**
   Represents the chemical composition of the substance, showing the types and numbers of atoms in a molecule.
7. **Molecular Weight:**
   The sum of the atomic weights of all the atoms in a molecule, important for stoichiometric calculations and formulation in research and manufacturing.
8. **Batch Number:**
   Enables traceability back to production.

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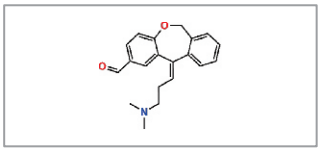

II

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II. Analytical Information

- **Analysis Date:** The specific date when a product was tested, which is crucial for verifying the accuracy and relevance of the data used in a certification process, as technology and standards can change over time, making older test results potentially outdated.

- **Retest Date:** The specified timeframe within which a product, material, or sample must be reanalyzed to verify its potency. Retest is vital step to continue use of reference standard. Without doing retest company cannot use the standard.

These dates ensure traceability and ongoing reliability of the product.

Test	What It Tells You ?
1. Description	Confirms the product's physical appearance, ensuring no contamination. If the product is hygroscopic in nature, the same mentioned in description. The appearance also includes color, texture, and physical state, which are inspected visually or using tools such as colorimeters for accurate evaluation.
2. Solubility	Indicates compatibility with solvents and usability in specific applications. For solid samples, solubility is checked by adding a known quantity of the compound to solvents like methanol, acetonitrile, DMSO, water also MeOH : ACN mixture. The solvent in which product is soluble can be considered as a diluent for performing HPLC.
3. MASS By LC-MS	Verifies molecular weight and structure to confirm the product's identity. This technique is highly accurate and trusted for analyzing complex compounds. It helps to identify the molecular weight of the product.

4. Purity By HPLC	High-Performance Liquid Chromatography (HPLC) is a highly precise method to quantify the purity of a compound. HPLC can measure the exact percentage of the active ingredient and detect impurities at trace levels. Purity is determined by injecting a dissolved sample into the HPLC system and analyzing the peaks to calculate the percentage of the main compound. If we perform HPLC by pharmacopeial method then we can confirm the product consistency with respect to their RT & RRT.
5. ^{1}H NMR	Validates hydrogen atom distribution, confirming molecular structure. This technique provides high accuracy in determining the positions and environments of hydrogen atoms in a molecule. It gives the information of functional groups, support determining the stereochemistry of the product. NMR is one of the best techniques for determining the structure of an unknown compound.
6. IR	Identifies functional groups to confirm the product's chemical composition. Infrared (IR) spectroscopy analyzes the absorption of infrared light by molecular bonds, providing a fingerprint of the compound's functional groups. This technique is essential for verifying the chemical identity and ensuring that the compound matches its intended structure, offering additional confidence in product authenticity and quality.
7. Weight Loss by TGA	Thermogravimetric Analysis (TGA) measures the weight loss of a sample as it is heated under controlled conditions. This test helps determine the moisture content, volatile impurities and residue content in the sample. Weight loss up to 450 °C is considered volatile & moisture content residue left after heating at 850 °C is inorganic content.
8. Potency by TGA	Potency by TGA is calculated by subtracting the volatile, moisture and inorganic content from the HPLC purity. **Potency Formula** Potency = [100 – (Weight Loss by TGA) %] × [(HPLC Purity) %] / 100

Importance:

- **Consistency:** Ensures the precise quantification of the active ingredient.
- **Regulatory Compliance:** Validates product quality for pharmaceutical standards.
- **Product Efficacy:** Confirms the active ingredient meets the required therapeutic effectiveness.

III. Storage and Handling

What Storage and Handling Tell You?

The **Storage and Handling** section provides critical insights into how to maintain the product's quality & stability. It ensures the product is stored and transported in conditions that preserve its intended properties, avoiding risks such as degradation, contamination, or loss of potency. Here's what this section tells you:

1 Short-Term Storage:

- Recommends specific conditions, such as 2 to 8°C, to prevent contamination and degradation.
- Ensures stability during handling and initial usage.

Example: A compound stored outside its recommended temperature range may degrade compromising its potency.

2 Long-Term Storage:

- Recommends specific conditions, such as Tightly Closed, Inert Atmosphere at -20 °C storage.
- Advises optimal storage environments to avoid environmental risks like moisture, light or heat.
- Ensures chemical and physical stability over the product's shelf life.

Example: Avoiding exposure to direct sunlight prevents photodegradation of light-sensitive compounds.

3 Shipping Conditions:

- Specifies proper packaging and transit conditions, including temperature control if required.
- Protects the product from fluctuations during transportation.

Example: Cold-chain logistics for unstable compounds maintain their activity and reliability upon delivery.

4 Why This Matters:

- **Preservation of Quality:** Prevents chemical changes or contamination.
- **Safety:** Reduces the risk of degradation that could render the product unsafe.
- **Strength:** Ensures the product delivers its intended therapeutic or scientific results.

IV. Expiry Date

What the Expiry Date Tells You?

The expiry date mentioned in the COA provides a clear timeline within which the product retains its intended quality, safety, and potency. It is the timeframe during which the product remains stable under the recommended storage conditions.

Key Points:

1. Product Usability: The expiry date ensures that the product maintains its integrity and effectiveness during its shelf life. Using a product post its expiry date could lead to reduced potency, degradation.
2. Regulatory Compliance: It is a vital aspect for meeting pharmaceutical and scientific standards.

Why Is a COA Important?

01 Transparency

- ☑ The COA provides detailed and accurate information about the product's composition, purity, and stability. It ensures that users are fully informed about what they are receiving.
- ☑ Example: A COA lists the HPLC purity percentage and impurity profile, giving a clear picture of the product's quality.

02 Traceability

- ☑ Each COA includes batch-specific data, enabling users to trace the product back to its production source and manufacturing records.
- ☑ Batch and catalog numbers in the COA help link the product to its production history, aiding in quality investigations if needed.

03 Quality Assurance

- ☑ The COA confirms that the product meets global quality standards and specifications, such as purity, potency, and stability.

04 Regulatory Compliance

- ☑ The COA ensures compliance with international pharmacopeial and regulatory guidelines, reducing risks during audits and inspections.

05 Decision-Making Support

- ☑ Provides all necessary information for clients to make informed decisions regarding the suitability of the product for their specific applications.

06 Signature of Authorized Persons

- ☑ A "COA" signature of authorized persons It means the signature of a designated individual with the authority to verify the accuracy of a Certificate of Analysis (COA), essentially confirming that the test results and information presented on the document are accurate and reliable, as signed by someone officially permitted to do so within the company or laboratory that produced the COA.

Conclusion

The COA is an essential document that provides detailed insight into a product's quality, purity and suitability. By understanding what the COA tells you can make informed decisions with confidence in Chemicea's commitment to excellence. If you have questions about your COA or need further clarification our team is here to help.

Chemicea Pharmaceutical Pvt. Ltd.

Global Leader in Pharmaceutical Impurity Standards & Analytical Excellence

Expertise & Specialties

- ☑ 7000+ Impurity & Reference Standards in Stock
- ☑ 300+ Nitrosamine & NDSRI Compounds
- ☑ Metabolites, Glucuronides, Phytochemicals, Extractable & Leachable, Peptides
- ☑ Custom Synthesis for Complex & Novel Molecules
- ☑ Isolation & Characterization of Unknown Impurities
- ☑ Analytical Services

Upcoming Infrastructure 15,000 Sq. Ft

Get in Touch with Chemicea

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