

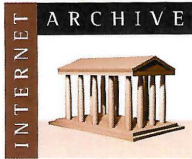
www.archive.org  
415.561.6767  
415.840-0391 e-fax

Internet Archive  
300 Funston Avenue  
San Francisco, CA 94118

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## AFFIDAVIT OF CHRISTOPHER BUTLER

1. I am the Office Manager at the Internet Archive, located in San Francisco, California. I make this declaration of my own personal knowledge.
2. The Internet Archive is a website that provides access to a digital library of Internet sites and other cultural artifacts in digital form. Like a paper library, we provide free access to researchers, historians, scholars, and the general public. The Internet Archive has partnered with and receives support from various institutions, including the Library of Congress.
3. The Internet Archive has created a service known as the Wayback Machine. The Wayback Machine makes it possible to surf more than 450 billion pages stored in the Internet Archive's web archive. Visitors to the Wayback Machine can search archives by URL (i.e., a website address). If archived records for a URL are available, the visitor will be presented with a list of available dates. The visitor may select one of those dates, and then begin surfing on an archived version of the Web. The links on the archived files, when served by the Wayback Machine, point to other archived files (whether HTML pages or images). If a visitor clicks on a link on an archived page, the Wayback Machine will serve the archived file with the closest available date to the page upon which the link appeared and was clicked.
4. The archived data made viewable and browseable by the Wayback Machine is compiled using software programs known as crawlers, which surf the Web and automatically store copies of web files, preserving these files as they exist at the point of time of capture.
5. The Internet Archive assigns a URL on its site to the archived files in the format `http://web.archive.org/web/[Year in yyyy][Month in mm][Day in dd][Time code in hh:mm:ss]/[Archived URL]`. Thus, the Internet Archive URL `http://web.archive.org/web/19970126045828/http://www.archive.org/` would be the URL for the record of the Internet Archive home page HTML file (`http://www.archive.org/`) archived on January 26, 1997 at 4:58 a.m. and 28 seconds (1997/01/26 at 04:58:28). A web browser may be set such that a printout from it will display the URL of a web page in the printout's footer. The date assigned by the Internet Archive applies to the HTML file but not to image files linked therein. Thus images that appear on a page may not have been archived on the same date as the HTML file. Likewise, if a website is designed with "frames," the date assigned by the Internet Archive applies to the frameset as a whole, and not the individual pages within each frame.
6. Attached hereto as Exhibit A are true and accurate copies of printouts of the Internet Archive's records of the HTML files or PDF files for the URLs and the dates specified in the attached coversheet of each printout.



7. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, under Section 1001 of Title 18 of the United States Code.

DATE: 5/4/20

  
Christopher Butler

# Exhibit A

<https://web.archive.org/web/20170403170533/http://www.drugsdb.eu/drug.php?d=L-cysteine%20Hydrochloride&m=Sandoz%20Inc&id=083366d6-0437-4ee0-90d4-440a5b5d03b5.xml>

# DRUGS DataBase

www.drugsDB.eu With permission of U.S. National Library of Medicine

You are here: [Home](#) > [Prescription\(RX\) Drugs](#) > [L](#) > [L-cysteine Hydrochloride \(Sandoz Inc\)](#)

[Loading](#)

<b>Name:</b>	L-cysteine Hydrochloride
<b>Manufacturer:</b>	Sandoz Inc
<b>Category:</b>	Prescription Marketed Drugs

**Prescription Marketed Drugs Alphabetically**  
[A](#) | [B](#) | [C](#) | [D](#) | [E](#) | [F](#) | [G](#) | [H](#) | [I](#) | [J](#) | [K](#) | [L](#) | [M](#) | [N](#) | [O](#) | [P](#) | [Q](#) | [R](#) | [S](#) | [T](#) | [U](#) | [V](#) | [W](#) | [X](#) | [Y](#) | [Z](#) | 0-9

**Categories:**

<a href="#">Prescription(RX) Drugs</a>
<a href="#">Over-the-counter (OTC) Drugs</a>
<a href="#">Homeopathic Drugs</a>
<a href="#">Animal Drugs</a>
<a href="#">Feedback</a>

**L-CYSTEINE HYDROCHLORIDE - cysteine hydrochloride injection, solution**  
**Sandoz Inc**

*Disclaimer: This drug has not been found by FDA to be safe and effective, and this labeling has not been approved by FDA. For further information about unapproved drugs, click here.*

**L-Cysteine Hydrochloride Injection, USP**  
**0.5 g/10 mL (50 mg/mL)**

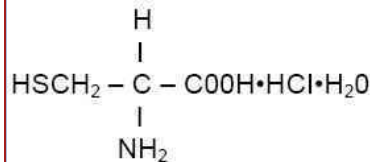
**PHARMACY BULK PACKAGE**  
**NOT FOR DIRECT INFUSION**

## DESCRIPTION

L-Cysteine Hydrochloride Injection, USP, 50 mg/mL, is a sterile, nonpyrogenic solution. Each mL contains: 50 mg of L-Cysteine Hydrochloride Monohydrate USP; Water for Injection, USP q.s.; Air replaced with Nitrogen. pH 1.0-2.5

L-Cysteine is a sulfur-containing amino acid. In premixed solutions of crystalline amino acids, cysteine is relatively unstable over time, eventually converting to insoluble cystine. To avoid such precipitation, L-Cysteine Hydrochloride Injection USP is intended to be used as an additive with crystalline Amino Acid Injections immediately prior to administration to the patient.

The structural formula of Cysteine Hydrochloride Monohydrate USP is:



**Molecular Weight** 175.63    **Molecular Formula** C<sub>3</sub>H<sub>7</sub>NO<sub>2</sub>S·HCl·H<sub>2</sub>O

## CLINICAL PHARMACOLOGY

L-Cysteine is synthesized from methionine via the trans-sulfuration pathway in the adult, but newborn infants lack the enzyme necessary to effect this conversion. Therefore, L-Cysteine is generally considered to be an essential amino acid in infants.

## INDICATIONS AND USAGE

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