

FDA Website: Resources Available to You

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DLRUD/DRLB, Office of Compliance
CDER | US FDA

Electronic Drug Registration and Listing
Using CDER Direct – October 13, 2021

A Walkthrough of the FDA Website



- [The National Drug Code \(NDC\) Directory](#)
 - Inclusion in the NDC Directory does not indicate that FDA has verified the information provided. The content of each NDC Directory entry is the responsibility of the labeler submitting the SPL file.
 - The NDC Directory does not contain all listed drugs. It does not include animal drugs, blood products, drugs manufactured under contract or drugs that are marketed solely as part of a kit or combination product or inner layer of a multi-level packaged product not marketed individually.
 - Assignment of an NDC number does not in any way denote FDA approval of the product.

NDC Directory

National Drug Code Direct... Preprint Dashboard New tab: National Drug Code Direct... Drug Approvals and Datab... eCFR — Code of Federal R... DQCP Home

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Home > Drug Databases > NDC

National Drug Code Directory

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The National Drug Code (NDC) Directory is updated daily.
Current through: 10/2/2021

+ [NDC Application Programming Interface \(API\)](#) (Firefox and Chrome recommended)

☒ Finished Products ☐ Unfinished Products

NDC finished products search

Search the NDC database for finished drug products

Select Type

Enter at least three characters

Search Clear

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National Drug Code Directory

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The National Drug Code (NDC) Directory is updated daily.
Current through: 10/3/2021

- [NDC Application Programming Interface \(API\)](#) (Firefox and Chrome recommended)

☒ Finished Products ☐ Unfinished Products

NDC finished products search

Select Type

Proprietary Name

Application Number

Nonproprietary Name

NDC Code

Labeler

aspirin

Search Clear



NDC Directory



National Drug Code Direct... Preprod Dashboard New tab National Drug Code Direct... Drug Approvals and Datab... eCFR — Code of Federal R... DQCP Home

1 SHARE 1 TWITTER 1 LINKEDIN 1 PINTEREST EMAIL PRINT

Current through October 03, 2021

You have searched Finished drug products

Search Results: 'aspirin'

Only the first 1,000 results are displayed. Consider refining your search by entering more specific terms.

[Back to Search Page](#) | [Search Again](#)

CSV Excel

Display 50 records per page

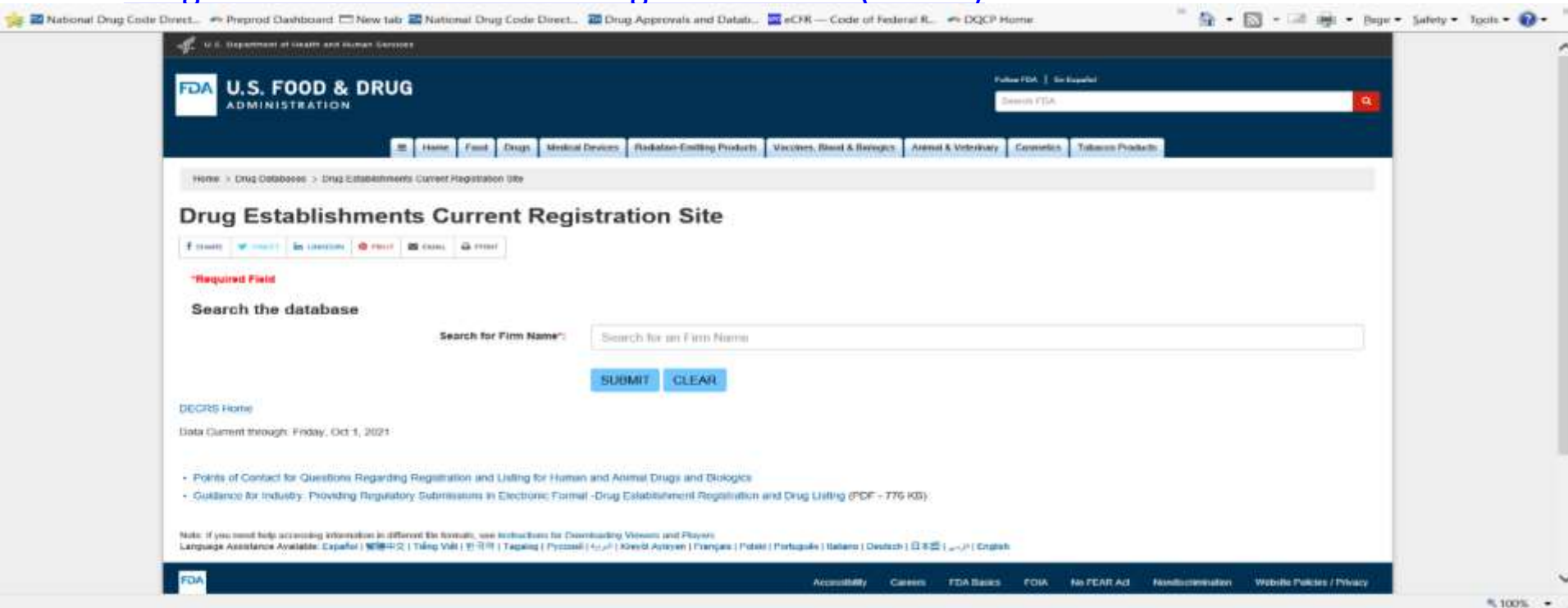
Search for text in the table:

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Appl. No.	Labeler Name	Product NDC	Nonproprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
365 everyday value aspirin	42681-7075-1	325 mg/1	TABLET, FILM COATED	ORAL	par343	Whole Foods Market, INC.	42681-7075	Aspirin	ASPIRIN	HUMAN OTC DRUG	08/23/2018	N/A	OTC MONOGRAPH NOT FINAL	180 TABLET, FILM COATED in 1 BOTTLE (42681-7075-1)
Acetaminophen 250mg Aspirin 250mg Caffeine 65mg	0363-1326-12	250 mg/1, 250 mg/1, 65 mg/1	TABLET	ORAL	par343	WALGREENS CO.	0363-1326	Acetaminophen 250mg Aspirin 250mg Caffeine 65mg	ACETAMINOPHEN, ASPIRIN, CAFFEINE	HUMAN OTC DRUG	05/24/2019	N/A	OTC MONOGRAPH NOT FINAL	120 TABLET in 1 BOTTLE (0363-1326-12)
Acetaminophen 250mg Aspirin 250mg Caffeine 65mg	0363-1326-23	250 mg/1, 250 mg/1, 65 mg/1	TABLET	ORAL	par343	WALGREENS CO.	0363-1326	Acetaminophen 250mg Aspirin 250mg Caffeine 65mg	ACETAMINOPHEN, ASPIRIN, CAFFEINE	HUMAN OTC DRUG	05/24/2019	N/A	OTC MONOGRAPH NOT FINAL	30 TABLET in 1 BOTTLE (0363-1326-23)
Acetaminophen 250mg Aspirin 250mg Caffeine 65mg	0363-1326-00	250 mg/1, 250 mg/1, 65 mg/1	TABLET	ORAL	par343	WALGREENS CO.	0363-1326	Acetaminophen 250mg Aspirin 250mg Caffeine 65mg	ACETAMINOPHEN, ASPIRIN, CAFFEINE	HUMAN OTC DRUG	05/24/2019	N/A	OTC MONOGRAPH NOT FINAL	80 TABLET in 1 BOTTLE (0363-1326-00)
Acetaminophen 250mg Aspirin 250mg Caffeine 65mg	68842-591-20	250 mg/1, 250 mg/1, 65 mg/1	TABLET	ORAL	par343	OVS Pharmacy	68842-591	Acetaminophen 250mg Aspirin 250mg Caffeine 65mg	ACETAMINOPHEN, ASPIRIN, CAFFEINE	HUMAN OTC DRUG	02/01/2021	N/A	OTC MONOGRAPH NOT FINAL	200 TABLET in 1 BOTTLE (68842-591-20)
Acetaminophen 250mg Aspirin 250mg Caffeine 65mg	68842-591-23	250 mg/1, 250 mg/1, 65 mg/1	TABLET	ORAL	par343	OVS Pharmacy	68842-591	Acetaminophen 250mg Aspirin 250mg Caffeine 65mg	ACETAMINOPHEN, ASPIRIN, CAFFEINE	HUMAN OTC DRUG	02/01/2021	N/A	OTC MONOGRAPH NOT FINAL	30 TABLET in 1 BOTTLE (68842-591-23)

100%

DECRS

- Drug Establishments Current Registration Site (DECRS)



The screenshot shows the FDA's Drug Establishments Current Registration Site (DECRS). The page header includes the FDA logo and navigation links for Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The main content area is titled "Drug Establishments Current Registration Site" and features a search bar labeled "Search for Firm Name:". Below the search bar are "SUBMIT" and "CLEAR" buttons. The page also includes a "Required Field" label, a "Search the database" section, and a "DECRS Home" link. At the bottom, there is a note about help and a language assistance section with links for Spanish, Chinese, Vietnamese, Tagalog, Russian, Korean, French, Polish, Portuguese, Italian, and German.

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Home > Drug Databases > Drug Establishments Current Registration Site

Drug Establishments Current Registration Site

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***Required Field**

Search the database

Search for Firm Name:

SUBMIT CLEAR

[DECRS Home](#)

Data Current through: Friday, Oct 1, 2021

- [Points of Contact for Questions Regarding Registration and Listing for Human and Animal Drugs and Biologics](#)
- [Guidance for Industry: Providing Regulatory Submissions in Electronic Format -Drug Establishment Registration and Drug Listing \(PDF - 776 KB\)](#)

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#)

Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | ქართული | Français | Polski | Português | Italiano | Deutsch | 日本語 | English

FDA Accessibility Careers FDA Basics FOIA No FEAR Act Food Inspection Website Policies / Privacy

DECRS

FDA

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Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

Home > Drug Database > Drug Establishments Current Registration Site

Drug Establishments Current Registration Site

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New Search

Search Results for **Abc**

CSV Excel Filter:

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Expiration Date
ABC Compounding Co., Inc.	3012553248	803284353	LABEL, MANUFACTURE, PACK	2690 Dogwood Drive, Conyers, Georgia (GA) 30013, United States (USA)	12/31/2021
ABC INDUSTRIES LLC	3013681874	561180632	MANUFACTURE	AL GHAIL, MAIN STREET, RAS AL KHAMMAH, 0427, United Arab Emirates (ARE)	12/31/2021
ABCO Laboratories	1000142677	829618279	MANUFACTURE	2450 South Watney Way, Fairfield, California (CA) 94533, United States (USA)	12/31/2021
LabChem Corp	3011238454	829684407	ANALYSIS	2015 Jaime Rodriguez Street Guanajibo Industrial Park, Mayaguez, Puerto Rico (PR) 00680, United States (USA)	12/31/2021

Showing 1 to 4 of 4 entries

Data Current through: Friday, Oct 1, 2021

[Return to Drug Firm Annual Registration Status Home Page](#)

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Pycckий | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | العربية | English

Registered Outsourcing Facilities

- [503B Facilities](#)

Registered Outsourcing Facilities

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Human Drug Compounding

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[Compounding: Inspections, Recalls, and other Actions](#)

[Information for Outsourcing](#)

Facilities Registered As Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Updated as of 9/24/2021

- [Information Concerning Outsourcing Facility Registration](#)
- [Outsourcing Facility Product Reporting Information](#)

This table lists the outsourcing facilities that have submitted registration information that has been determined to be complete by the data lock date for the latest weekly update of the table.

Content current as of:
09/29/2021

Facility Name	Contact Name and Phone Number	Initial Date of Registration as an Outsourcing Facility ¹	Date of Most Recent Registration as an Outsourcing Facility ¹	End Date of Last FDA Inspection Related to Compounding ²	Was a Form FDA-483 issued? ³	Other Action, If Any, Based on Last Inspection ^{3,4}	Intends to Compound Sterile Drugs From Bulk Drug Substances ⁵

Information for Outsourcing Facilities



- [Information for Outsourcing Facilities](#) – link to reporting

A screenshot of the FDA's Outsourcing Facility Product Report search interface. The page has a header with the title "Outsourcing Facility Product Report" and a sub-header "Outsourcing Facility Product Report search". Below the title is a blue box containing text: "Outsourcing facilities are required to provide FDA with a list of drugs they compounded during the previous six-month period upon initial registration and in June and December each year. This database contains information reported to FDA within the last two years (last four reporting periods). This information may be used to identify outsourcing facilities that have produced certain drugs. This retrospective information does not identify drugs that outsourcing facilities intend to produce in the future." Below this text is a search form with a dropdown menu labeled "Select Reporting Year" showing options for 2019-1, 2019-2, 2020-1, and 2020-2. There is also a text input field labeled "Enter all Asset Name Characters" and two buttons labeled "Search" and "Clear". The page is displayed at 100% zoom.

Outsourcing Facility Product Report

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Outsourcing facilities are required to provide FDA with a list of drugs they compounded during the previous six-month period upon initial registration and in June and December each year. This database contains information reported to FDA within the last two years (and four reporting periods). This information may be used to identify outsourcing facilities that have produced certain drugs. This retrospective information does not identify drugs that outsourcing facilities intend to produce in the future.

Outsourcing Facility Product Report search

Search the Outsourcing Facility Product Report database

2020-2

Active ingredients

aspirin

Search

Clear

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).
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Outsourcing Facility Product Report

Home > Drug Databases > Outsourcing

Outsourcing Facility Product Report

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Current through October 03, 2021

You have searched for Active Ingredients: 'aspirin'

[Back to Search Page](#)


Show 10 rows CSV Search for text in the table:

Active Ingredients	Active Ingredients Info	Dosage	Establish. Name	Package Description	WDC Package Code	Report Year
Aspirin	10 mg/1 mL	suspension	Epicor Pharma(0219531)	129 mL in 1 Bottle		2020-2

Showing 1 to 1 of 1 entries Previous 1 Next

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Points of Contact

- Points of Contact for Drug Registration and Listing

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Points of Contact for Drug Registration and Listing

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Electronic Drug Registration and Listing System (eDRLS)

Electronic Drug Registration and Listing Instructions

Electronic Registration and Listing Compliance Program

Dun and Bradstreet Verification

Points of Contact for Drug Registration and Listing

Following are points of contact for specific questions about registration and listing for human drugs, animal drugs and biologics.

Electronic Submission Gateway (ESG) account

Contact ESGHelpDesk@fda.hhs.gov for ESG technical inquiries regarding opening a new gateway account.

Examples of questions for this point of contact:

- How long does it take to open a new gateway account?
- What should I submit in my letter of non-repudiation?
- How do I obtain an x.509 digital certificate?

Structured Product Labeling (SPL)

Contact spl@fda.hhs.gov for technical help and inquiries regarding XForms.

Examples of questions for this point of contact:

- Why did I get an error message with my XForms submission? What does it mean?

Content current as of:
12/18/2020

Points of Contact contd.



- **Electronic Submission Gateway (ESG) account**
 - Contact ESGHelpDesk@fda.hhs.gov for ESG technical inquiries regarding opening a new gateway account.
- **Structured Product Labeling (SPL)**
 - Contact spl@fda.hhs.gov for technical help and inquiries regarding XForms.
- **Establishment registration status**
 - Contact edrls@fda.hhs.gov for questions and assistance with registration. See the [drug establishment current registration site](#) to check a facility's current registration.

Points of Contact contd.



- **Drug listing status**
 - See [NDC Directory](#) for human drugs and biologics listing status
 - Contact edrls@fda.hhs.gov with questions about human drug listings
 - Contact CBERSPL@fda.hhs.gov with questions about biologic listings
 - See [the electronic animal drug product listing directory](#) for animal drug listing status. Contact AskCVM@fda.hhs.gov or call 240-276-9300 with questions
 - Contact reglist@cdRH.fda.gov with questions about device registration or listing



Points of Contact contd.

- **Regulatory questions or request for general information**
- For human drugs, contact edrls@fda.hhs.gov
- For animal drugs, contact AskCVM@fda.hhs.gov or call 240-276-9300
- For biologics, contact CBERSPL@fda.hhs.gov or call 301-827-0373



SPL Resources

- [Structured Product Labeling Resources](#)
 - SPL Guidance Documents
 - SPL Terminology
 - SPL Implementation Guide and Validation Procedures
 - SPL Schema and Stylesheet information
 - GDUFA SPL Step-by-Step Instructions & Technical Specifications
 - Questions regarding SPL submissions should be directed to: spl@fda.hhs.gov.

DRLS Instructions Page

- [DRLS Instructions Page](#)
- SPL Process
- SPL Authoring Tools
- Registration, Labeler Codes, Listing
- Updating SPL submissions
- Blanket No Change Certification for product listing data

FEI Search Portal



- [FEI Search Portal](#)

The screenshot shows the FEI Search Portal homepage. At the top is the FDA U.S. Food & Drug Administration logo and a search bar. Below the logo is a navigation menu with links to Home, Food, Drugs, Medical Devices, Radiation-Emitting Products, Vaccines, Blood & Biologics, Animal & Veterinary, Cosmetics, and Tobacco Products. The main heading is 'FEI Search Portal' with a 'Help' link. Below the heading are social media sharing buttons for Facebook, Twitter, LinkedIn, Print, Email, and Print. A paragraph explains that the portal allows users to look up a FDA Establishment Identifier (FEI) based on a firm name and address or validate an address of an FEI. It also mentions that information found on the portal can be found on the FEI Portal Frequently Asked Questions (FAQ). The page is divided into two main sections: 'Existing User' and 'New User'. The 'Existing User' section has fields for 'Email' and 'Password', a 'Forgot Password' link, and a 'Login' button. The 'New User' section has a 'Create Account' button. A 'WARNING' box states that the system is a U.S. Government information system, usage may be monitored, recorded, and subject to audit, and that unauthorized use is prohibited and subject to criminal and civil penalties. It also states that use of the system indicates consent to monitoring and recording, and that anyone using the system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials. At the bottom, there is a 'Note' about downloading videos and players, and a list of language assistance options: Español, 繁體中文, Tiếng Việt, 한국어, Tagalog, Русский, العربية, Kinyòl Atyáyen, Français, Polski, Português, Italiano, Deutsch, 日本語, and English. The footer contains the FDA logo and links to Accessibility, Careers, FDA Basics, FOIA, No FEAR Act, Nondiscrimination, and Website Policies / Privacy.

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Home > FEI Search Portal

FEI Search Portal

Help

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The FEI Portal allows a user to look up a FDA Establishment Identifier (FEI) based on a firm name and address or validate an address of an FEI. Information on what the FEI Portal searches can be found on the [FEI Portal Frequently Asked Questions \(FAQ\)](#).

Existing User

Email

Password

[Forgot Password](#)

Login

New User

Create Account


WARNING: You are accessing a U.S. Government information system. The system usage may be monitored, recorded, and subject to audit. Unauthorized use of the system is prohibited and subject to criminal and civil penalties. Use of the system indicates consent to monitoring and recording, and anyone using this system expressly consents to such monitoring and is advised that if such monitoring reveals possible criminal activity, system personnel may provide the evidence of such monitoring to law enforcement officials.

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Videos and Players](#).
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Strength Conversion

- Strength Conversion in Drug Listing


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Points of Contact for Drug Registration and Listing

A drug strength or concentration of its active ingredients can be expressed in many different ways. In order to standardize the expression of active ingredients in drug listing Structured Product Labeling (SPL) submitted to FDA, the agency has adopted a series of automated validation rules to allow for certain expressions.

For example, the strength of active ingredient is not allowed to be included as a percentage value but can be a concentration of an amount of solute in an amount of solution:

- As w/w - mass (grams) of solute in mass (100 gm) of solution, like topical creams and ointments
- As w/v - mass (grams) of solute in a volume (100ml) of solution, like oral liquids
- As v/v - volume (milliliters) of solute in a volume (100ml) of solution, like alcohol

The strength data element in a listing SPL is designed to accept submissions mostly in concentrations of w/w or w/v format, when the strength of an active ingredient is expressed as a percentage. Percentages must be converted into ratios of w/w or w/v with a value in the numerator and in the denominator including the correct units of measure in order to pass the SPL validation rules.

Content current as of:
02/06/2017

100%

Resources

- [The National Drug Code \(NDC\) Directory](https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm)
 - <https://www.accessdata.fda.gov/scripts/cder/ndc/index.cfm>
- [Drug Establishments Current Registration Site \(DECRS\)](https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm)
 - <https://www.accessdata.fda.gov/scripts/cder/drls/default.cfm>
- [503B Facilities](https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities)
 - <https://www.fda.gov/drugs/human-drug-compounding/registered-outsourcing-facilities>
- [Information for Outsourcing Facilities](https://www.fda.gov/drugs/human-drug-compounding/information-outsourcing-facilities#reporting) – link to reporting
 - <https://www.fda.gov/drugs/human-drug-compounding/information-outsourcing-facilities#reporting>

Resources

- [Structured Product Labeling Resources](#)
 - <https://www.fda.gov/industry/fda-resources-data-standards/structured-product-labeling-resources>
- [DRLS Instructions Page](#)
 - <https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/electronic-drug-registration-and-listing-instructions>

Resources

- [Points of Contact for Drug Registration and Listing](https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/points-contact-drug-registration-and-listing)
 - <https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/points-contact-drug-registration-and-listing>
- [FEI Search Portal](https://www.accessdata.fda.gov/scripts/feiportal/index.cfm?action=portal.login)
- <https://www.accessdata.fda.gov/scripts/feiportal/index.cfm?action=portal.login>
- [Strength Conversion in Drug Listing](https://www.fda.gov/drugs/electronic-drug-registration-and-listing-system-edrls/strength-conversion-drug-listing)
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