

Inactive Ingredient Field Descriptions

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Inactive Ingredient

An inactive ingredient is any component of a drug product other than the active ingredient. Only inactive ingredients in the final dosage forms of drug products are included in this database.

Route

A route of administration is a way of administering a drug to a site in a patient. A comprehensive list of specific routes of administration appears in the [Data Standards Manual](#).

[\(/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/default.htm\)](/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/default.htm)

Dosage Form

A dosage form is a form in which a drug is produced and dispensed. A comprehensive list of specific routes of administration appears in the [Data Standards Manual](#).

[\(/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/default.htm\)](/Drugs/DevelopmentApprovalProcess/FormsSubmissionRequirements/ElectronicSubmissions/DataStandardsManualmonographs/default.htm)

CAS Number

The acronym "CAS" stands for "Chemical Abstracts Service," a division of the American Chemical Society that provides comprehensive electronic chemical information services. CAS assigns unique CAS Registry Numbers to chemical substances. Many inactive ingredients have CAS Registry Numbers, which are useful in searching other databases for chemical information. The CAS Registry Number itself has no chemical significance.

UNII

The acronym "UNII" stands for "Unique Ingredient Identifier"

The UNII is a part of the joint USP/FDA Substance Registration System (SRS), which has been designed to support health information technology initiatives by providing unique identifiers for substances in drugs, biologics, foods, and devices based on molecular structure and/or descriptive information. The SRS is used to generate permanent, unique, unambiguous identifiers for substances in regulated products, such as ingredients in drug products.

More information about the UNII and the SRS is available on the [Data Council SRS page](#) (</ForIndustry/DataStandards/SubstanceRegistrationSystem-UniqueIngredientIdentifierUNII/default.htm>). All chemically-related questions about the UNII or the SRS that are not answered on the FDA website should be directed [fda-srs@fda.hhs.gov \(mailto:fda-srs@fda.hhs.gov\)](mailto:fda-srs@fda.hhs.gov).

Potency Amount

The "potency amount" field specifies the maximum amount of inactive ingredient for each route/dosage form containing that ingredient. When there is no calculable potency measurement for the inactive ingredient, the "potency amount" field will be blank.

Potency Unit

The "potency unit" field specifies the unit type associated with the potency amount. This field may be blank.

Resources for You

- [Inactive Ingredient Search for Approved Drug Products: Frequently Asked Questions \(/Drugs/InformationOnDrugs/ucm080123.htm\)](#)
- [Inactive Ingredients Database Download \(/Drugs/InformationOnDrugs/ucm113978.htm\)](#)

More in [Drug Approvals and Databases](#)
(</Drugs/InformationOnDrugs/default.htm>)

[Approved Drugs \(/Drugs/InformationOnDrugs/ApprovedDrugs/default.htm\)](#)

