

A4L Professional for SPL

Key Features

Microsoft® Word-based authoring

Multiple-file format rendering (word, xml, pdf, & graphics)

Automated FDA Resource Updater for validation rules, controlled terminology, and UNII codes

Comprehensive validation

Powerful “Word to XML” paste function

Legacy format to PLR migration support

Integrated lists of key terms, supporting fast and compliant submissions

The familiar Word environment ensures quick user adoption

Extensible to the ALiCE Edition for features such as 21CFR labeling management, Variance, Parallel Review, Compare, Cross Document Re-use, and more

Prompt and knowledgeable support from services team

SPL DIRECT - Outsourcing services reliable technologies.

SPL Authoring & Submission Creation in Microsoft® Word

A4L Professional leverages i4i’s industry leading Microsoft Word- based structured authoring platform, allowing users of all levels to easily manage the entire SPL authoring and collaboration process.

A4L simplifies the SPL authoring process by presenting the user with the familiar Word interface, as A4L works behind the scenes to create valid SPL submissions.

The screenshot displays the Microsoft Word interface with the A4L ribbon tab active. The document content includes:

Mortality was delayed in these animals, occurring 10-14 days after dosing.
In mice, rats, rabbits and dogs, significant toxicity including tonic/clonic convulsions was observed at intravenous doses of cephakillital between 125 and 300 mg/kg.

11 DESCRIPTION

ANTIBIOTICX® (cephakillital) Tablets are synthetic broad spectrum antimicrobial agents for oral administration. Cephakillital, USP, a fluorocephaloporin, is the mono monohydrate salt of 1-cyclopropyl-6-fluoro-1, 4-dihydro-4-oxo-7-(1-piperazinyl)-3-quinolinecarboxylic acid. It is a faintly yellowish to light yellow crystalline substance with a molecular weight of 385.8. Its empirical formula is $C_{17}H_{18}FN_3O_3 \cdot HCl \cdot H_2O$ and its chemical structure is as follows:

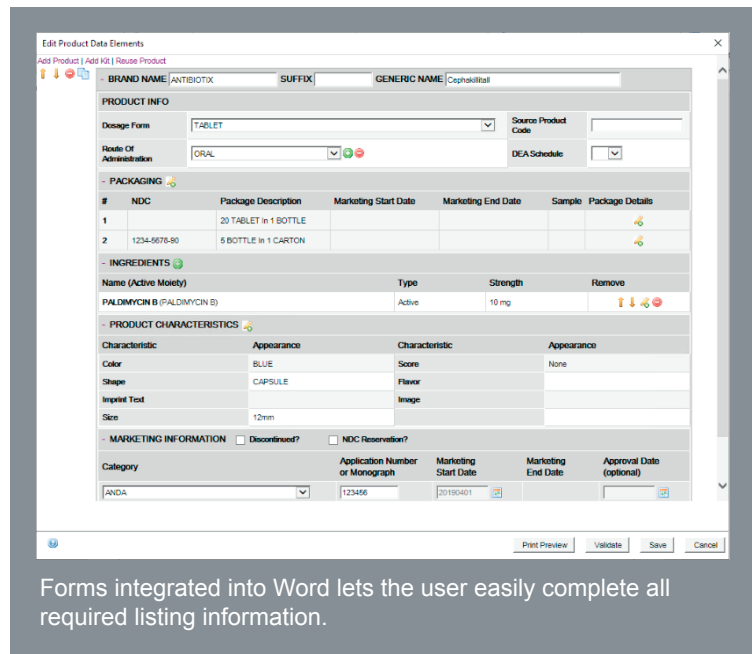
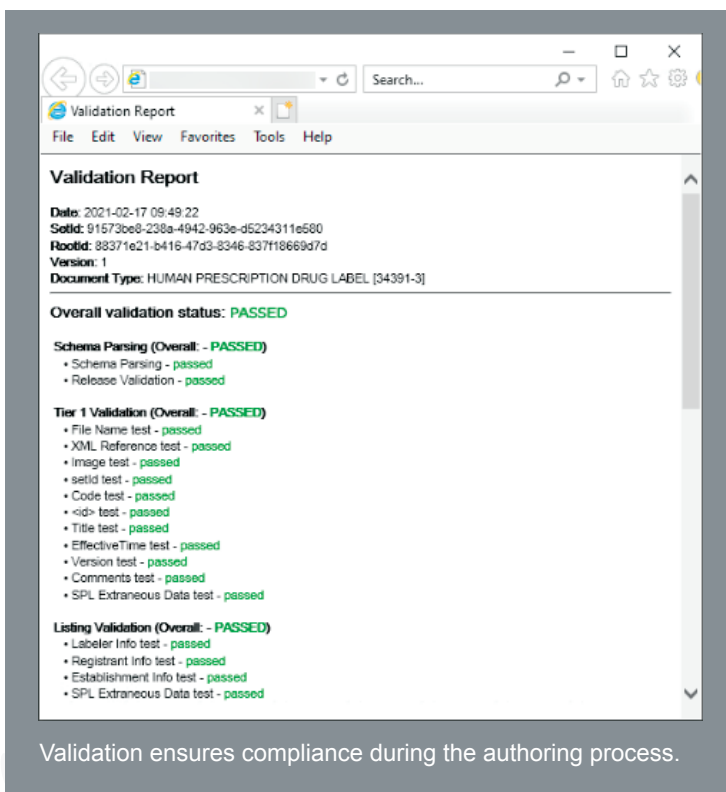
ANTIBIOTICX film-coated tablets are available in 150 mg, 250 mg, 500 mg and 850 mg (cephakillital equivalent) strengths. Cephakillital tablets are white to slightly greenish. The inactive ingredients are cornstarch, microcrystalline cellulose, silicon dioxide, crospovidone, magnesium stearate, hypromellose, titanium dioxide, polyethylene glycol and water.

Cephakillital Oral Suspension is available in 5% (5 g cephakillital in 100 mL) and 10% (10 g cephakillital in 100 mL) strengths. It is composed of cephakillital microcapsules and diluent which are mixed prior to dispensing (See DOSAGE and ADMINISTRATION for details). The components of the suspension have the following compositions:

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Compliant Drug Listings

A4L features user-friendly forms that guide the user through the definition and population of all required drug listing information. Its unique FDA Resource Updater ensures the extensive lists of FDA-controlled vocabulary, within the A4L interface, remain current as changes are made by the FDA.



Forms integrated into Word lets the user easily complete all required listing information.

Extensive Validation

A4L features a comprehensive, built-in validation engine that ensures the content is complete, consistent, and compliant with the most current regulations. The validation in A4L incorporates all of the rules outlined in the FDA's Implementation Guide, the latest Validation Procedures, and the XML Schema.

Ease of Content Migration

Migration of existing content is fast and easy. Content can be authored directly in the templates or copied and pasted from other sources – thanks to A4L's unparalleled "Word to XML" paste function. Even the most complex content, such as tables and graphics, are copied with ease into A4L.

Comprehensive Regulatory Support

A4L supports all SPL Release (R4 & R5) standards, and allows for the management of the complete Authoring, Review, Validation, and Submission process. Guided templates for creating and maintaining your Labeler Code and Establishment Registration SPLs, as well as for all product types listed below, make SPL compliance easy:

Human Prescription Drugs
Over-The-Counter (OTC)
Biological Products
Cosmetics
Dietary Supplements
Veterinary Medicines &
Medicated Feeds

Bulk Ingredients/APIs
Medical Foods
Homeopathic Drugs
Medical Devices
Establishment Registration
Labeler Code Request
Lot Distribution Report

Generic Drug Facility
Identification Submission
Identification of
CBER-Regulated Generic
Drug Facility
Risk Evaluation and Mitigation
Strategies (REMS)

The Physician's Labeling Rule

A Physician's Labeling Rule (PLR) formatted SPL can be easily created from scratch or upgraded from an existing non-PLR document. Standardized sections and boiler-plate text are automatically generated, and Highlights are uniquely arranged to ensure content compliance with the related section's text. When converting a non-PLR label to the PLR format, A4L automatically reorders sections, and guides the user in the necessary content revisions to ensure compliance.

Automated Code Management

Everything involving the management of the GUIDs (Globally Unique Identifiers), XML attributes, Ingredient Codes (UNII), and coding associated with the FDA's controlled vocabulary is automatically handled within A4L. A4L takes all technical complexities out of the SPL process, allowing authors to focus on the content while easily creating valid and compliant submissions.

Supporting Our Clients

i4i's investment in R&D ensures that A4L Professional continues to serve you as technology and regulatory requirements change. We also offer the opportunity to extend your solution, on a modular basis, to ALiCE (Authoring, Lifecycle and Collaborative Environment) – to support the broader labeling management issues such as versioning, change management, variance, and cross-departmental content “agreement”. i4i's Client Services Team has gained recognition for the swift, high-quality product support and regulatory guidance that it provides. When circumstances require additional resources on your side, the team is pleased to offer outsourcing of all registration and listing SPLs, including gateway submission services.

Leadership

Since 2004, i4i has been a key member of the SPL Working Group, where we have used our XML knowledge and industry expertise to support the FDA's SPL initiative. We remain committed to delivering comprehensive and easy-to-use authoring and content management solutions that are first to market and best-in-class to comply with FDA standards

Contact i4i

For assistance using i4i products and tools, or for more information on technical support options, please contact:

Infrastructures for Information Inc.
720 King Street West, Suite 805
Toronto, ON Canada
M5V 2T3

Phone: +1 416.504.0141
Fax: +1 416.504.1785
Email: info@i4i.com
<https://www.i4i.com>