

Specifications for File Format Types Using eCTD Specifications

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Revision History

| Date | Version | Summary of Changes |
|------------|---------|---|
| 2013-04-11 | 1.0 | Initial version |
| 2017-03-02 | 2.0 | Updated version, new file formats added: <ul style="list-style-type: none">• Document file types: .xls, .xlsx• Audio/Visual file types: .fla, .f4v, .mpg• Data file types: .csv• Modelling & Simulation file types: .cmp, .wks, .lbr• Modelling & Simulation Reporting file types: .lua, .sas, .r, .ctl |
| 2017-11-15 | 3.0 | Updated .doc and .docx accepted locations |

Specifications for File Format Types Using eCTD Specifications

This document provides specifications for submitting file format types using eCTD specifications. It is a list of accepted file types and the eCTD locations in which those file types should be provided.

I. General Information

Documents should be provided in PDF searchable format. Images and other document types should be rendered into PDF format and retain searchable text whenever possible. Additional information related to PDF documents is available in the FDA technical specification FDA Portable Document Format (PDF) Specifications.

II. Acceptable File Formats for Use in eCTD

In most cases, files submitted in formats below should also be provided in PDF format for archival purposes, please reference the “Archive Format Copy” column to see if an alternative version of the document should also be provided.

| File Type | File Format | Format Name | Accepted location in eCTD | Archive Format Copy | Permissible Uses |
|------------------|-------------|-----------------------------------|---------------------------|---------------------|----------------------------------|
| <i>Documents</i> | | | | | |
| | .pdf | Portable Document Format | M1 – M5 | | |
| | .doc | Microsoft Word document | M1.14, 1.16 | | |
| | .docx | Microsoft Word Open XML document | M1.14, 1.16 | | |
| | .txt | Text file | M3 - M5 | | |
| | .xls | Microsoft Excel document | M3 – M5 | PDF | |
| | .xlsx | Microsoft Excel Open XML document | M3 – M5 | PDF | |
| <i>Images</i> | | | | | |
| | .bmp | Bitmap Graphics | M1.15 | | |
| | .gif | Graphics Interchange Format | M1 - M5 | | Package Insert in draft labeling |
| | .jpg, .jpeg | Joint Photographic Experts Group | M1 – M5 | | |
| | .png | Portable Network Graphics | M1 – M5 | | |

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|------------------------|--------------------|--|----------------------------------|-------------------------------|--------------------------|
| <i>Audio/Video</i> | | | | | |
| | .au | Audio file | M1.15 | | |
| | .avi | Audio Video Interleaved | M1.15 | | |
| | .flv, .fla, .f4v | Macromedia Flash Source File | M1.15 | Playable with Adobe Acrobat* | |
| | .mpg, .mpeg | MPEG-1 | M1.15 | | |
| | .mp2 | MPEG-1 Audio Layer II, MPEG-2 Audio Layer II | M1.15 | | |
| | .mp3 | MPEG-1 Audio Layer III, MPEG-2 Audio Layer III | M1.15 | | |
| | .mp4 | MPEG-4 Part 14 | M1.15 | | |
| | .swf | Shockwave Flash file | M1.15 | Playable with Adobe Acrobat * | |
| | .wav | Waveform Audio File | M1.15 | | |
| | .wma | Windows Media Audio | M1.15 | | |
| | .wmv | Windows Media Video | M1.15 | | |
| <i>Coding Language</i> | | | | | |
| | .css | Cascading Style Sheets | M1.15, M4 – M5 | | |
| | .dtd | Document Type Definition | M1 | | \util\dtd folder |
| | .htm, .html | Hypertext Markup Language | M1.15 | | |
| | .xml | Extensible Markup Language | M1.14, M4 - M5 | | Labeling, Data |
| | .xsd | XML Schema Definition | M1, M4 - M5 | | |
| | .xsl | Extensible Stylesheet | M1, M4 - M5 | | \util\style folder, data |

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|---|-------------|-----------------------------|---------------------------|---------------------|------------------|
| | | Language | | | |
| <i>Data</i> | | | | | |
| | .csv | Comma Separated Values file | M5.3.3.5 | | CDER Only |
| | .svg | Scalable Vector Graphics | M3 – M5 | TXT | |
| | .xpt | SAS Transport file | M3 – M5 | | |
| Modelling and Simulation | | | | | |
| | .cmp | SimCYP drug model file | M5 | | CDER Only |
| | .wks | SimCYP workspace file | M5 | | CDER Only |
| | .lbr | SimCYP population file | M5 | | CDER Only |
| Modelling and Simulation Reporting | | | | | |
| | .lua | SimCYP PD script | M5 | | CDER Only |
| | .sas | SAS Script file | M3-M5 | | |
| | .r | R Script file | M3 – M5 | | CDER Only |
| | .ctl | NONMEM model control stream | M5 | | CDER Only |

*Playable with Adobe Acrobat without the need for additional plug-in

References:

References are available on the eCTD Web Page: <http://www.fda.gov/ectd>

ICH M2 EWG technical specification, Electronic Common Technical Document Specification

FDA Guidance for Industry, Providing Regulatory Submissions in Electronic Format — Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications

Portable Document Format (PDF) Specifications

eCTD Backbone Files Specification for Module 1 (versions 1.3 and 2.3)

eCTD Backbone File Specification for Modules 2 through 5 3.2.2

The eCTD Backbone File Specification for Study Tagging Files 2.6.1

Specifications for File Format Types Using eCTD Specifications
Draft Guidance for Industry: Providing Regulatory Submissions in Electronic and Non-
Electronic Format – Promotional Labeling and Advertising Materials for Human
Prescription Drugs

Study Data Technical Conformance Guide

Questions may be sent to:

CDER: ESUB@fda.hhs.gov

CBER: ESUBPREP@fda.hhs.gov

Data-related questions: eDATA@fda.hhs.gov