

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

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		
	.docx	Microsoft Word Open XML document	M1.14		
	.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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File Type	File Format	Format Name	Accepted location in eCTD	Archive Format Copy	Permissible Uses
<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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File Type	File Format	Format Name	Accepted location in eCTD	Archive Format Copy	Permissible Uses
		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:

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