Specifications for File Format Types Using eCTD Specifications

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: • 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
2019-08-19	4.0	Updated .doc and .docx accepted locations
2021-03-15	5.0	Updated file formats added: Modeling & Simulation file types: .cmpx, cmpz, .wksx, .wksz, ,lbrx, .lbrz, .mdb, .pbk, .opd, .psd, .spd .c, .cpp, .m, .mat, .rmd, .phxproj, .py, .jl, .cas, .dat
2021-05-28	6.0	Updated file format added: Chemical file format type: .sdf
2021-10-01	7.0	Updated file format added: Zip file format type: .zip (for grouping large sets of aECG xml files)
2022-08-12	8.0	Updated .sdf accepted locations
2023-12-01	9.0	Updated .docx permissible uses Updated .xml accepted locations and permissible uses Removed “CDER Only” from permissible uses for: .csv, .cas, .dat, .rmd, .r Updated file format added: Modeling & Simulation file types: .pksim5, .mbp3, .pkml, .json, .mlxtran, .mlxproperties, .pkx, .pkxproperties, smlx, .smlxproperties, .syc, .datxplore

2024-03-20	9.1	Corrected missing file format: .smlx Updated file format name for: .jl Removed recommendation to include PDF archive format copy when submitting .doc/.docx, .xls/.xlsx Updated file format added: Modeling & Simulation file types: .pumascp, .jmd, .qmd
2025-02-18	9.2	Updated file format added: Modeling & Simulation file types: .gpsqlite, .gpproject, .gpsettings
2025-08-20	9.3	Updated references section Updated file format added: Modeling & Simulation Reporting file types: .rds, .rdb, .rdx, .rdata/.rda, .md, .rd (for delivering R packages) Expanded permissible use of .zip and .html for R packages

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
Documents					
	.pdf	Portable Document Format	M1 – M5		
	.doc	Microsoft Word document	M1.14, 1.16		
			M2.3, M2.7		ANDA
	.docx	Microsoft Word Open XML document	M1.14, 1.16		
			M2.3		ANDA
			M2.7		ANDA, BLA, NDA
	.txt	Text file	M3 - M5		
	.xls	Microsoft Excel document	M3 – M5		
	.xlsx	Microsoft Excel Open XML document	M3 – M5		
Images					
	.bmp	Bitmap Graphics	M1.15		

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File Type	File Format	Format Name	Accepted location in eCTD	Archive Format Copy	Permissible Uses
	.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		
Audio/Video					
	.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		
Coding Language					
	.css	Cascading Style Sheets	M1.15, M4 – M5		
	.dtd	Document Type Definition	M1		\util\dtd folder

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	.htm, .html	Hypertext Markup Language	M1.15		
			M5		For delivering R packages
	.xml	Extensible Markup Language	M1.14, 1.16, M4 - M5		Labeling, REMS, Data
	.xsd	XML Schema Definition	M1, M4 - M5		
	.xsl	Extensible Stylesheet Language	M1, M4 - M5		\util\style folder, data
Data					
	.csv	Comma Separated Values file	M5.3.3.5		
	.svg	Scalable Vector Graphics	M3 – M5	TXT	
	.xpt	SAS Transport file	M3 – M5		
	.zip	Zip file	M5.3		For grouping large sets of aECG xml files CDER Only
			M5		For delivering R packages
Modeling and Simulation					
	.cmp, .cmpx, .cmpz	SimCYP drug model files	M5		CDER Only
	.wks, .wksx, .wksz	SimCYP workspace files	M5		CDER Only
	.lbr , .lbrx, .lbrz	SimCYP population files	M5		CDER Only
	.mdb	GastroPlus model compound file	M5		CDER Only
	.pbk	GastroPlus whole body physiology files	M5		CDER Only
	.opd	GastroPlus Tissue and/or plasma	M5		CDER Only

File Type	File Format	Format Name	Accepted location in eCTD	Archive Format Copy	Permissible Uses
		concentration vs time data file for other dosage forms			
	.psd	GastroPlus particle size distribution data file	M5		CDER Only
	.spd	GastroPlus solubility vs pH data file	M5		CDER Only
	.gpsqlite	GastroPlus model compound file	M5		CDER Only
	.gpproject	GastroPlus project file	M5		CDER Only
	.gpsettings	GastroPlus project settings file	M5		CDER Only
	.c, .cpp	C/C++ model files	M5		CDER Only
	.m, .mat	MATLAB model files	M5		CDER Only
	.rmd	R Markdown file	M5		
	.phxproj	Phoenix project file	M5		CDER Only
	.py	Python file	M5		CDER Only
	.jl	Pumas/Julia file	M5		CDER Only
	.pumascp	Pumas Analysis and Reporting File	M5		CDER Only
	.cas, .dat	ANSYS Flurent files	M5		
	.pksim5	PK-Sim project file	M5	CSV	CDER Only
	.mbp3	MoBi project file	M5	CSV	CDER Only
	.pkml	Model file	M5		CDER Only
	.json	PK-Sim project snapshots file	M5		
	.mlxtran	Monolix project file	M5		CDER Only
	.mlxproperties	Monolix plot settings	M5		CDER Only
	.pkx	PKanalix project files	M5		CDER Only
	.pkxproperties	PKanalix plot	M5		CDER Only

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		settings			
	.smlx	Simulx project files	M5		CDER Only
	.smlxproperties	Simulx plot settings	M5		CDER Only
	.syc	Sycomore project files	M5		CDER Only
	.datxplore	Datxplore project file	M5		CDER Only
Modeling and Simulation Reporting					
	.lua	SimCYP PD script	M5		CDER Only
	.sas	SAS Script file	M3-M5		
	.r	R Script file	M3 – M5		
	.ctl	NONMEM model control stream	M5		CDER Only
	.jmd	Julia Markdown File	M5		CDER Only
	.qmd	Quarto Markdown File	M5		CDER Only
	.rds	R Serialized Object File	M5		For delivering R packages
	.rdb	R Data Base File	M5		
	.rdx	R Data Index File	M5		
	.rdata or .rda	R Data File (examples only)	M5		
	.md	Markdown File	M5		
	.rd	R Documentation File	M5		
Chemical File					
	.sdf	Structure-data file	M3		

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

References:

Submission Standards for eCTD and Regional M1 pages:

- eCTD v4.0
- eCTD v3.2.2

(Both contain links to the *Portable Document Format (PDF) Specifications*)

Additional related documents available via the FDA Guidance Search page:

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