DACHS
Document Management for Life Science

OnTrack

This specification lists the validation rules of OnTrack PDF Validation Services.
It provides a description of PDF problems that are verified by the validation rules
and defines the corresponding eCTD Validation errors of FDA eCTD Validation Criteria
or FDA PDF Specification.

1 based on Validation-Ver-4-4-20220511.pdf published by FDA
2 based on FDA_PDF_Specifications-v4-1-FINAL-9-14-2016_fixed-2.pdf published by FDA
3 based on Specification_for_Submission_Formats_for_eCTD_v1_3.pdf published by ICH in 2 June 2021

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3.0.0
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ID	Validation Rule	Problem Description	FDA eCTD Validation Error Number [1]	FDA - PORTABLE DOCUMENT FORMAT (PDF) SPECIFICATIONS [2]	Specification for Submission Formats for eCTD v1.3 [3]
	Prerequisite				
PDF.TEXT.1	Text is searchable	The document lacks searchable text. It is either blank or contains scanned images that have not been converted with OCR (optical character recognition).	5057	N/A	chapter: 2.8
PDF.PROP.1	PDF file size does not exceed configured limit	File size exceeds 100 MB.	1238	N/A	chapter: 2.3
PDF.PROP.2	PDF contents can be processed successfully	The document's content cannot be processed, e.g., a corrupted or invalid PDF document.	3102	N/A	N/A
PDF.SEC.2	PDF is not protected by open password	The document has password protection and cannot be opened.	5050	N/A	chapter: 2.17
PDF.SEC.3	No certificate protection	The document has certificate protection and cannot be opened.	N/A	N/A	N/A
	Document Properties				
PDF.PROP.3	PDF version is correct	The PDF version is different from versions 1.4, 1.5, 1.6 or 1.7.	5035	chapter: Version	chapter: 2.2
PDF.PROP.4	"Fast Web View" option is activated	The PDF has been created without "Fast Web View" active.	5040	N/A	chapter: 2.16
PDF.SEC.1	No security (document access) restriction is set	The PDF has been created with security settings that limits the ability to select text or graphics or make other changes. This prevents agencies from copying text and taking other action to the submitted documents.	5020	chapter: Security	chapter: 2.17
PDF.FONT.1	All used fonts have been embedded	Non-standard font is used but not embedded. The result is N/A if no fonts can be detected in document (e.g., images only).	5005	chapter: Fonts	chapter: 2.4
PDF.TEXT.2	No Track Changes	The document contains tracked changes.	N/A	N/A	N/A
PDF.TEXT.3	No highlighted text	The document contains highlighted texts.	N/A	N/A	chapter: 2.4.2
	Initial View				
PDF.VIEW.1	Navigation Tab Setting	The initial view is not set as Bookmarks and Pages in the Navigation Panel nor it is not set to Pages only if there are no bookmarks.	5045	N/A	chapter: 2.15
PDF.VIEW.2	Page Layout is set to Default	The Page Layout is not set to “Default.”	5045	N/A	chapter: 2.15
PDF.VIEW.3	Magnification is set to Default	The Magnification is not set to “Default.”	5045	N/A	chapter: 2.15
PDF.VIEW.4	Document open to page 1 or TOC	The document does not open to first page or TOC.	N/A	chapter: Initial View Settings	N/A
	Pages				
PDF.PAGE.1	PDF contains only pages with the configured sizes	The PDF contains one or more pages with different size than A4 or LETTER.	N/A	N/A	chapter: 2.6
PDF.PAGE.2	First page orientation is portrait	The first page orientation is not portrait.	N/A	N/A	N/A
PDF.PAGE.3	No blank page	The document contains one or more blank pages, which could be totally blank or include just header or footer information, but no other content.	N/A	N/A	N/A
PDF.PAGE.4	Sequential page numbering	There is missing page, i.e., page numbering is not consecutive within the document and within its embedded documents.	N/A	chapter: Page Numbering	chapter: 2.14
PDF.PAGE.5	First page and headers do not indicate 'draft'	The first page or headers contain 'draft' label.	N/A	N/A	N/A
PDF.PAGE.6	No text on side margins	Text is found on the side margins.	N/A	chapter: Page Size and Margins	chapter: 2.6
PDF.PAGE.7	Correct scan resolution	Incorrect scan resolution. Expected resolution is 300 dpi.	N/A	chapter: Methods for creating PDF Documents and Images	chapter: 2.9

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PDF.PAGE.8	Cover page indicates total number of pages correctly	The number of pages in the document is not the same as on the cover page. The document is shorter or longer than announced on the cover page.	N/A	N/A	N/A
	Bookmarks				
PDF.BMRK.1	Bookmarks are expanded until the defined level	The bookmarks are not expanded until the first level, or they are overexpanded.	N/A	N/A	chapter: 2.13
PDF.BMRK.2	Number of bookmark levels does not exceed maximum limit	The bookmark level is deeper than 5. (ICH requirements allow the creation of additional levels if such bookmarks contribute to efficient navigation.)	N/A	chapter: Document Navigation	chapter: 2.13
PDF.BMRK.3	Bookmark nesting is correct	The nesting of bookmarks does not follow their natural, ascending order. E.g., section no. 2.1 should be nested under section no. 2, etc.	N/A	N/A	N/A
PDF.BMRK.4	Bookmark has title and destination	The bookmark does not have title or destination. Title which contains only a section number, without any other text, is also reported. The result is N/A if there are no bookmarks in the PDF.	5102 5110	N/A	N/A
PDF.BMRK.5	Magnification of the bookmarks is set to inherit zoom	Document with one or more bookmarks that are not set to 'Inherit Zoom'. The result is N/A if there are no bookmarks in the PDF.	5117	N/A	chapter: 2.13
PDF.BMRK.6	No multiple action bookmark	Document with one or more bookmarks containing multiple actions. The result is N/A if there are no bookmarks in the PDF.	5103	N/A	N/A
PDF.BMRK.7	There are bookmarks	There are no bookmarks in the document which contains more than 4 pages.	N/A	chapter: Document Navigation	chapter: 2.13
PDF.BMRK.8	Provide bookmarks for each item listed in TOC	There are no bookmarks for each item listed in the table of contents. Passed - if bookmarks match the TOC Failed - if there is a TOC, but no bookmarks or only partial bookmark structure N/A - if there is no TOC in the PDF	N/A	chapter: Document Navigation	chapter: 2.13
PDF.BMRK.9	First bookmark leads to first page	The first bookmark does not lead to the first page.	N/A	N/A	N/A
PDF.BMRK.10	No symbols in bookmark	The document does not contain symbols in bookmarks.	N/A	N/A	N/A
PDF.BMRK.11	Bookmark points to an existing page	The bookmark points to a nonexistent page.	5102	N/A	N/A
PDF.BMRK.12	Bookmark points to the correct page	The bookmark's target page does not contain its text.	N/A	N/A	N/A
PDF.BMRK.13	Only one bookmark points to first page	There should only be one bookmark pointing to the first page, but there are two or more.	N/A	N/A	N/A
	Hyperlinks				
PDF.HLNK.1	Internal hyperlinks blued	There is not blued internal hyperlink. Invisible hyperlinks are also reported by default (optional). The result is N/A if there is no hyperlink in the PDF.	N/A	chapter: Fonts chapter: Document Navigation	chapter: 2.13
PDF.HLNK.2	No broken reference hyperlink	The hyperlink is identified as reference, but References section does not contain the hyperlink's text.	N/A	N/A	N/A
PDF.HLNK.3	Relative paths are used in hyperlinks	The document contains one or more non-relative (absolute) hyperlinks. The result is N/A if there is no hyperlink in the PDF.	5215	chapter: Document Navigation	chapter: 2.13
PDF.HLNK.4	No external hyperlinks to websites	The document contains one or more web references in the form of hyperlinks (e.g., web links, email links). The result is N/A if there is no hyperlink in the PDF.	5205	N/A	N/A
PDF.HLNK.5	Magnification of the hyperlinks is set to inherit zoom	The document contains one or more hyperlinks that are not set to 'Inherit Zoom'. The result is N/A if there is no hyperlink in the PDF.	5217	N/A	chapter: 2.13
PDF.HLNK.6	No multiple action hyperlink	The document contains one or more hyperlinks containing multiple actions. The result is N/A if there is no hyperlink in the PDF.	5203	N/A	N/A
PDF.HLNK.7	No blue texts without hyperlinks	The document contains one or more blue texts that are not hyperlinks. The result is N/A if there is no blue text in the PDF.	N/A	chapter: Fonts	chapter: 2.4.2
PDF.HLNK.7.VV1	No blue texts without hyperlinks - ignoring text within square brackets	The document contains blue text without hyperlinks. This validation rule ignores blue text in square brackets.	N/A	N/A	N/A
PDF.HLNK.8	Hypertext linked TOC is included	There is no hypertext linked TOC in the document which contains more than 4 pages.	N/A	chapter: Document Navigation	chapter: 2.13
PDF.HLNK.9	No inactive hyperlink	The document contains one or more inactive hyperlinks.	5210	N/A	N/A
PDF.HLNK.10	Hyperlink points to an existing page	The hyperlink points to a nonexistent page.	5202	N/A	N/A
PDF.HLNK.11	Hyperlink points to the correct page	The hyperlink's target page does not contain hyperlink's text.	N/A	N/A	N/A
PDF.HLNK.12	No hyperlink points to a remote destination	The hyperlink points to a remote destination.	N/A	N/A	N/A
PDF.HLNK.13	TOC items point to their correct pages	The TOC item points to a different page than the page number specified in the TOC item, or the target page does not contain the title of the TOC item.	N/A	N/A	N/A
PDF.HLNK.14	Sequential TOC section numbering	The TOC section numbering is not sequential.	N/A	N/A	N/A
PDF.HLNK.15	Provide TOC item for each bookmark	There are no TOC items provided for each bookmark.	N/A	chapter: Document Navigation	chapter: 2.13
PDF.HLNK.16	TOC contains only hyperlinked items	The TOC item is not covered by hyperlink.	N/A	chapter: Document Navigation	N/A

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	Annotations				
PDF.ANNO.1	No comments	The document contains one or more comments.	N/A	N/A	N/A
PDF.ANNO.2	No annotations	The document contains one or more annotations.	5055	N/A	chapter: 2.1
PDF.ANNO.3	No digital signatures	The document contains one or more digital signatures.	N/A	N/A	chapter: 2.17
PDF.ANNO.4	No watermark	Watermark applied on pages.	N/A	N/A	N/A