INTERNATIONAL CONFERENCE ON HARMONISATION OF TECHNICAL REQUIREMENTS FOR REGISTRATION OF PHARMACEUTICALS FOR HUMAN USE

ICH M2 EWG

Electronic Common Technical Document Specification

This specification has been developed by the ICH M2 Expert Working Group and maintained by the eCTD Implementation Working Group in accordance with the ICH Process as pertains to the M2 EWG and eCTD change control as it pertains to the eCTD IWG.

8	Number	2
	Title	Common Technical Document Summaries
	Element	m2-common-technical-document-summaries
	Directory	m2
	Comment	
9	Number	2.2
	Title	Introduction
	Element	m2-2-introduction
	Directory	m2/22-intro
	Comment	
10	Number	2.2
	Title	Introduction
	Element	m2-2-introduction
	File	m2/22-intro/introduction.pdf
	Comment	
11	Number	2.3
	Title	Quality Overall Summary
	Element	m2-3-quality-overall-summary
	Directory	m2/23-qos
	Comment	Refer to the Granularity Annex of the M4 Organisation Document for guidance on the flexibility of multiple documents for the Quality Overall Summary
12	Number	2.3
	Title	Introduction
	Element	m2-3-introduction
	File	m2/23-qos/introduction.pdf
	Comment	
13	Number	2.3.S
	Title	Drug Substance - *Name* - *Manufacturer*
	Element	m2-3-s-drug-substance
	File	m2/23-qos/drug-substance.pdf

	Comment	Refer to the Granularity Annex of the M4 Organisation Document for guidance on the flexibility of multiple documents for the Quality Overall Summary Where there are more than one drug substance and/or manufacturer, separate files can be provided for each.
14	Number	2.3.P
	Title	Drug Product -*Name*
	Element	m2-3-p-drug-product
	File	m2/23-qos/drug-product-*name*.pdf
	Comment	Refer to the Granularity Annex of the M4 Organisation Document for guidance on the flexibility of multiple documents for the Quality Overall Summary Refer to regional guidance for definition of what constitutes a drug product and the acceptability of more than one drug product in an application. Where more than one drug product is acceptable in an application, a separate file can be provided for each drug product.
15	Number	2.3.A
	Title	Appendices
	Element	m2-3-a-appendices
	File	m2/23-qos/appendices.pdf
	Comment	Refer to the Granularity Annex of the M4 Organisation Document for guidance on the flexibility of multiple documents for the Quality Overall Summary
16	Number	2.3.R
	Title	Regional Information
	Element	m2-3-r-regional-information
	File	m2/23-qos/regional-information.pdf
	Comment	Refer to the Granularity Annex of the M4 Organisation Document for guidance on the flexibility of multiple documents for the Quality Overall Summary
17	Number	2.4
	Title	Nonclinical Overview
	Element	m2-4-nonclinical-overview
	Directory	m2/24-nonclin-over
	Comment	
18	Number	2.4
	Title	Nonclinical Overview
	Element	m2-4-nonclinical-overview
	File	m2/24-nonclin-over/nonclinical-overview.pdf
	Comment	Typically, this document should consist of a single file. The CTD defines further heading levels and navigation should be provided within the document to these sub-headings.

19	Number	2.5
	Title	Clinical Overview
	Element	m2-5-clinical-overview
	Directory	m2/25-clin-over
	Comment	
20	Number	2.5
	Title	Clinical Overview
	Element	m2-5-clinical-overview
	File	m2/25-clin-over/clinical-overview.pdf
	Comment	Typically, this document should consist of a single file. The CTD defines further heading levels and navigation should be provided within the document to these sub-headings.
21	Number	2.6
	Title	Nonclinical Written and Tabulated Summaries
	Element	m2-6-nonclinical-written-and-tabulated-summaries
	Directory	m2/26-nonclin-sum
	Comment	
22	Number	2.6.1
	Title	Introduction
	Element	m2-6-1-introduction
	File	m2/26-nonclin-sum/introduction.pdf
	Comment	
23	Number	2.6.2
	Title	Pharmacology Written Summary
	Element	m2-6-2-pharmacology-written-summary
	File	m2/26-nonclin-sum/pharmacol-written-summary.pdf
	Comment	Typically, this document should consist of a single file. The CTD defines further heading levels and navigation should be provided within the document to these sub-headings.
24	Number	2.6.3
	Title	Pharmacology Tabulated Summary
	Element	m2-6-3-pharmacology-tabulated-summary
	File	m2/26-nonclin-sum/pharmacol-tabulated-summary.pdf
	Comment	Should have further navigation via bookmarks
25	Number	2.6.4

	Title	Pharmacokinetics Written Summary
	Element	m2-6-4-pharmacokinetics-written-summary
	File	m2/26-nonclin-sum/pharmkin-written-summary.pdf
	Comment	Typically, this document should consist of a single file. The CTD defines further heading levels and navigation should be provided within the document to these sub-headings.
26	Number	2.6.5
	Title	Pharmacokinetics Tabulated Summary
	Element	m2-6-5-pharmacokinetics-tabulated-summary
	File	m2/26-nonclin-sum/pharmkin-tabulated-summary.pdf
	Comment	Should have further navigation via bookmarks
27	Number	2.6.6
	Title	Toxicology Written Summary
	Element	m2-6-6-toxicology-written-summary
	File	m2/26-nonclin-sum/toxicology-written-summary.pdf
	Comment	Typically, this document should consist of a single file. The CTD defines further heading levels and navigation should be provided within the document to these sub-headings.
28	Number	2.6.7
	Title	Toxicology Tabulated Summary
	Element	m2-6-7-toxicology-tabulated-summary
	File	m2/26-nonclin-sum/toxicology-tabulated-summary.pdf
	Comment	Should have further navigation via bookmarks
29	Number	2.7
	Title	Clinical Summary
	Element	m2-7-clinical-summary
	Directory	m2/27-clin-sum
	Comment	
30	Number	2.7.1
	Title	Summary of Biopharmaceutic Studies and Associated Analytical Methods
	Element	m2-7-1-summary-of-biopharmaceutic-studies-and-associated-analytical-methods
	File	m2/27-clin-sum/summary-biopharm.pdf
	Comment	Typically, this document should consist of a single file. The CTD defines further heading levels and navigation should be provided within the document to these sub-headings.
31	Number	2.7.2
	Title	Summary of Clinical Pharmacology Studies

	Element	m2-7-2-summary-of-clinical-pharmacology-studies
	File	m2/27-clin-sum/summary-clin-pharm.pdf
	Comment	Typically, this document should consist of a single file. The CTD defines further heading levels and navigation should be provided within the document to these sub-headings.
32	Number	2.7.3
	Title	Summary of Clinical Efficacy – *Indication*
	Element	m2-7-3-summary-of-clinical-efficacy
	File	m2/27-clin-sum/summary-clin-efficacy-*indication.pdf*
	Comment	The file name should always include the indication being claimed (abbreviated if appropriate) e.g., 'summary-clin-efficacy-asthma.pdf'. Where there is more than one indication (e.g., asthma & migraine) then the first indication has a file name 'summary-clin-efficacy-asthma.pdf' and the second 'summary-clin-efficacy-migraine.pdf'. Typically, this document should consist of a single file. The CTD defines further heading levels and navigation should be provided within the document to these sub-headings. The 'indication' attribute in the backbone should be consistent with that used in the filename but can be different. For example, an 'indication' attribute value of 'Non-Small Cell Lung Cancer' could be expressed as 'NSCLC' in the filename for that document (i.e., summclineff-nsclc.pdf). There is currently no standard terminology list for 'indication' and applicants should choose these attributes carefully as they can not be easily changed during the life cycle of the application. The only way this can be accomplished currently is to delete all the leaf elements with the incorrect attribute value and provide new leaf elements for those files with the modified attribute value. Applicants should consult with the regional authority before attempting to modify these attributes to discuss the appropriateness of, and approach to be taken for, this type of change.
33	Number	2.7.4
	Title	Summary of Clinical Safety
	Element	m2-7-4-summary-of-clinical-safety
	File	m2/27-clin-sum/summary-clin-safety.pdf
	Comment	Typically, this document should consist of a single file. The CTD defines further heading levels and navigation should be provided within the document to these sub-headings.
34	Number	2.7.5
	Title	Literature References
	Element	m2-7-5-literature-references
	File	m2/27-clin-sum/literature-references.pdf
	Comment	
35	Number	2.7.6
	Title	Synopses of Individual Studies
	Element	m2-7-6-synopses-of-individual-studies

	File	m2/27-clin-sum/synopses-indiv-studies.pdf
	Comment	These synopses should already be located in the Clinical Study Reports in Module 5 and should not, therefore, be repeated in Module 2. It is considered sufficient to provide hyperlinks from the listing of the studies, located here, to the locations of the synopses in Module 5.

36	Number	3
	Title	Quality
	Element	m3-quality
	Directory	m3
	Comment	Refer to the Granularity Annex of the M4 Organisation Document for guidance on the flexibility of multiple documents for Module 3
37	Number	3.2
	Title	Body of Data
	Element	m3-2-body-of-data
	Directory	m3/32-body-data
	Comment	
38	Number	3.2.S
	Title	Drug Substance
	Element	m3-2-s-drug-substance
	Directory	m3/32-body-data/32s-drug-sub
	Comment	
39	Number	3.2.S
	Title	Drug Substance - *Drug Substance Name - Manufacturer*
	Element	m3-2-s-drug-substance
	Directory	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*
	Comment	In this section, it can be helpful if the folder name includes the name of the drug substance and manufacturer. This applies particularly when there are multiple drug substances and/or manufacturers. When naming folders, attention should be paid to the length of the name of the folder on the overall length of the full path. Abbreviations can help control the length of the path. The 'substance' and 'manufacturer' attribute values in the backbone should be consistent with that used in the folder name but can be different. For example, a 'manufacturer' attribute value of 'Company XXX, City Name, Country Name' could be expressed as 'xxx' in the folder name. There is currently no standard terminology list for these attributes and applicants should choose these attributes carefully as they can not be easily changed during the life cycle of the application. The only way this can be accomplished currently is to delete all the leaf elements with the incorrect attribute value and provide new leaf elements for those files with the modified attribute value. Applicants should consult with the regional authority before attempting to modify these attributes to discuss the appropriateness of, and approach to be taken for, this type of change.
40	Number	3.2.S.1
	Title	General Information (name, manufacturer)

	File	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s3-charac/impurities.pdf
	Comment	
54	Number	3.2.S.4
	Title	Control of Drug Substance (name, manufacturer)
	Element	m3-2-s-4-control-of-drug-substance
	Directory	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s4-contr-drug-sub
	Comment	
55	Number	3.2.S.4.1
	Title	Specification (name, manufacturer)
	Element	m3-2-s-4-1-specification
	Directory	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s4-contr-drug-sub/32s41-spec
	Comment	
56	Number	3.2.S.4.1
	Title	Specification (name, manufacturer)
	Element	m3-2-s-4-1-specification
	File	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s4-contr-drug-sub/32s41-spec/specification.pdf
	Comment	
57	Number	3.2.S.4.2
	Title	Analytical Procedures (name, manufacturer)
	Element	m3-2-s-4-2-analytical-procedures
	Directory	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s4-contr-drug-sub/32s42-analyt-proc
	Comment	The example below shows how a multiple file approach, where a separate file is provided for each analytical procedure, can be organized. CTD numbering is not defined below this level (e.g., 3.2.S.4.2.1).
58	Number	
	Title	*Analytical Procedure-1*
	Element	m3-2-s-4-2-analytical-procedures
	File	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s4-contr-drug-sub/32s42-analyt-proc/*analytical-procedure-1.pdf*
	Comment	
59	Number	
	Title	*Analytical Procedure-2*
	Element	m3-2-s-4-2-analytical-procedures
	File	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s4-contr-drug-sub/32s42-analyt-proc/*analytical-procedure-2.pdf*
	Comment	

60	Number	
	Title	*Analytical Procedure-3*
	Element	m3-2-s-4-2-analytical-procedures
	File	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s4-contr-drug-sub/32s42-analyt-proc/*analytical-procedure-3.pdf*
	Comment	
61	Number	3.2.S.4.3
	Title	Validation of Analytical Procedures
	Element	m3-2-s-4-3-validation-of-analytical-procedures (name, manufacturer)
	Directory	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s4-contr-drug-sub/32s43-val-analyt-proc
	Comment	The example below shows how a multiple file approach, where a separate file is provided for each analytical procedure, can be organized. CTD numbering is not defined below this level (e.g., 3.2.S.4.3.1).
62	Number	
	Title	*Validation of Analytical Procedure-1*
	Element	m3-2-s-4-3-validation-of-analytical-procedures
	File	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s4-contr-drug-sub/32s43-val-analyt-proc/*validation-analyt-procedure-1.pdf*
	Comment	
63	Number	
	Title	*Validation of Analytical Procedure-2*
	Element	m3-2-s-4-3-validation-of-analytical-procedures
	File	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s4-contr-drug-sub/32s43-val-analyt-proc/*validation-analyt-procedure-2.pdf*
	Comment	
64	Number	
	Title	*Validation of Analytical Procedure-3*
	Element	m3-2-s-4-3-validation-of-analytical-procedures
	File	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s4-contr-drug-sub/32s43-val-analyt-proc/*validation-analyt-procedure-3.pdf*
	Comment	
65	Number	3.2.S.4.4
	Title	Batch Analyses (name, manufacturer)
	Element	m3-2-s-4-4-batch-analyses
	Directory	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s4-contr-drug-sub/32s44-batch-analys
	Comment	
66	Number	3.2.S.4.4

	Title	Batch Analyses (name, manufacturer)
	Element	m3-2-s-4-4-batch-analyses
	File	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s4-contr-drug-sub/32s44-batch-analys/batch-analyses.pdf
	Comment	
67	Number	3.2.S.4.5
	Title	Justification of Specification (name, manufacturer)
	Element	m3-2-s-4-5-justification-of-specification
	Directory	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s4-contr-drug-sub/32s45-justif-spec
	Comment	
68	Number	3.2.S.4.5
	Title	Justification of Specification (name, manufacturer)
	Element	m3-2-s-4-5-justification-of-specification
	File	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s4-contr-drug-sub/32s45-justif-spec/justification-of-specification.pdf
	Comment	
69	Number	3.2.S.5
	Title	Reference Standards or Materials (name, manufacturer)
	Element	m3-2-s-5-reference-standards-or-materials
	Directory	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s5-ref-stand
	Comment	
70	Number	3.2.S.5
	Title	Reference Standards or Materials (name, manufacturer)
	Element	m3-2-s-5-reference-standards-or-materials
	File	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s5-ref-stand/reference-standards.pdf
	Comment	Where a multiple file approach is taken for this section, the file names should indicate which reference standard is covered in the document.
71	Number	3.2.S.6
	Title	Container Closure System (name, manufacturer)
	Element	m3-2-s-6-container-closure-system
	Directory	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s6-cont-closure-sys
	Comment	
72	Number	3.2.S.6
	Title	Container Closure System (name, manufacturer)
	Element	m3-2-s-6-container-closure-system
	File	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s6-cont-closure-sys/container-closure-system.pdf

	Comment	
73	Number	3.2.S.7
	Title	Stability (name, manufacturer)
	Element	m3-2-s-7-stability
	Directory	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s7-stab
	Comment	
74	Number	3.2.S.7.1
	Title	Stability Summary and Conclusions (name, manufacturer)
	Element	m3-2-s-7-1-stability-summary-and-conclusions
	File	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s7-stab/stability-summary.pdf
	Comment	
75	Number	3.2.S.7.2
	Title	Post-approval Stability Protocol and Stability Commitment (name, manufacturer)
	Element	m3-2-s-7-2-post-approval-stability-protocol-and-stability-commitment
	File	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s7-stab/postapproval-stability.pdf
	Comment	
76	Number	3.2.S.7.3
	Title	Stability Data (name, manufacturer)
	Element	m3-2-s-7-3-stability-data
	File	m3/32-body-data/32s-drug-sub/*substance-1-manufacturer-1*/32s7-stab/stability-data.pdf
	Comment	
77	Number	3.2.P
	Title	Drug Product (name, dosage form)
	Element	m3-2-p-drug-product
	Directory	m3/32-body-data/32p-drug-prod
	Comment	
78	Number	3.2.P
	Title	Drug Product (name, dosage form) – *Name*
	Element	m3-2-p-drug-product
	Directory	m3/32-body-data/32p-drug-prod/*product-1*

	Comment	In this section, it can be helpful if the folder name includes the name of the drug product. This applies particularly where there is more than one drug product (e.g., powder for reconstitution and diluent); the first drug product would have a folder 'powder-for-reconstitution' and the second, 'diluent'. Refer to regional guidance for definition of what constitutes a drug product and the acceptability of more than one drug product in an application. The 'product-name' attribute value in the backbone should be consistent with that used in the folder name but can be different. For example, a 'product-name' attribute value of 'Lyophilized Powder for Reconstitution' could be expressed as 'powder' in the folder name. There is currently no standard terminology list for these attributes and applicants should choose these attributes carefully as they can not be easily changed during the life cycle of the application. The only way this can be accomplished currently is to delete all the leaf elements with the incorrect attribute value and provide new leaf elements for those files with the modified attribute value. Applicants should consult with the regional authority before attempting to modify these attributes to discuss the appropriateness of, and approach to be taken for, this type of change.
79	Number	3.2.P.1
	Title	Description and Composition of the Drug Product (name, dosage form)
	Element	m3-2-p-1-description-and-composition-of-the-drug-product
	Directory	m3/32-body-data/32p-drug-prod/*product-1*/32p1-desc-comp
	Comment	
80	Number	3.2.P.1
	Title	Description and Composition of the Drug Product (name, dosage form)
	Element	m3-2-p-1-description-and-composition-of-the-drug-product
	File	m3/32-body-data/32p-drug-prod/*product-1*/32p1-desc-comp/description-and-composition.pdf
	Comment	
81	Number	3.2.P.2
	Title	Pharmaceutical Development (name, dosage form)
	Element	m3-2-p-2-pharmaceutical-development
	Directory	m3/32-body-data/32p-drug-prod/*product-1*/32p2-pharm-dev
	Comment	Refer to the M4 Organisation Document: Granularity Annex for guidance on the flexibility of multiple documents for the Pharmaceutical Development section.
82	Number	3.2.P.2
	Title	Pharmaceutical Development (name, dosage form)
	Element	m3-2-p-2-pharmaceutical-development
	File	m3/32-body-data/32p-drug-prod/*product-1*/32p2-pharm-dev/pharmaceutical-development.pdf

89	Number	3.2.P.4
	Title	Control of Excipients (name, dosage form)
	Element	m3-2-p-4-control-of-excipients
	Directory	m3/32-body-data/32p-drug-prod/*product-1*/32p4-contr-excip
	Comment	
90	Number	3.2.P.4
	Title	Control of Excipients (name, dosage form) – *Excipient*
	Element	m3-2-p-4-control-of-excipients
	Directory	m3/32-body-data/32p-drug-prod/*product-1*/32p4-contr-excip/*excipient-1*
	Comment	For a drug product containing more than one excipient, the information requested for sections 3.2.P.4.1 – 3.2.P.4.4 should be provided in its entirety for each excipient. Refer to the ICH eCTD QA and Change Requests document, Q&A No.4 for additional suggestions on structuring this section. For compendial excipient(s) without additional specification tests, it is appropriate to have all information in one file, making sure to introduce a folder for each of new documents to avoid mixing files and folders at the same level. Non-compendial excipients should follow the structure outlined below. The 'excipient' attribute value in the backbone should be consistent with that used in the folder name but can be different. There is currently no standard terminology list for these attributes and applicants should choose these attributes carefully as they can not be easily changed during the life cycle of the application. The only way this can be accomplished currently is to delete all the leaf elements with the incorrect attribute value and provide new leaf elements for those files with the modified attribute value. Applicants should consult with the regional authority before attempting to modify these attributes to discuss the appropriateness of, and approach to be taken for, this type of change.
91	Number	3.2.P.4.1
	Title	Specifications (name, dosage form)
	Element	m3-2-p-4-1-specifications
	File	m3/32-body-data/32p-drug-prod/*product-1*/32p4-contr-excip/*excipient-1*/specifications.pdf
	Comment	See comment under 3.2.P.4.
92	Number	3.2.P.4.2
	Title	Analytical Procedures (name, dosage form)
	Element	m3-2-p-4-2-analytical-procedures
	File	m3/32-body-data/32p-drug-prod/*product-1*/32p4-contr-excip/*excipient-1*/analytical-procedures.pdf
	Comment	See comment under 3.2.P.4.
93	Number	3.2.P.4.3
	Title	Validation of Analytical Procedures (name, dosage form)
	Element	m3-2-p-4-3-validation-of-analytical-procedures

	File	m3/32-body-data/32p-drug-prod/*product-1*/32p4-contr-excip/*excipient-1*/validation-analyt-procedures.pdf
	Comment	See comment under 3.2.P.4.
94	Number	3.2.P.4.4
	Title	Justification of Specifications (name, dosage form)
	Element	m3-2-p-4-4-justification-of-specifications
	File	m3/32-body-data/32p-drug-prod/*product-1*/32p4-contr-excip/*excipient-1*/justification-of-specifications.pdf
	Comment	See comment under 3.2.P.4.
95	Number	3.2.P.4.5
	Title	Excipients of Human or Animal Origin (name, dosage form)
	Element	m3-2-p-4-5-excipients-of-human-or-animal-origin
	File	m3/32-body-data/32p-drug-prod/*product-1*/32p4-contr-excip/excipients-human-animal.pdf
	Comment	
96	Number	3.2.P.4.6
	Title	Novel Excipients (name, dosage form)
	Element	m3-2-p-4-6-novel-excipients
	File	m3/32-body-data/32p-drug-prod/*product-1*/32p4-contr-excip/novel-excipients.pdf
	Comment	
97	Number	3.2.P.5
	Title	Control of Drug Product (name, dosage form)
	Element	m3-2-p-5-control-of-drug-product
	Directory	m3/32-body-data/32p-drug-prod/*product-1*/32p5-contr-drug-prod
	Comment	
98	Number	3.2.P.5.1
	Title	Specification(s) (name, dosage form)
	Element	m3-2-p-5-1-specifications
	Directory	m3/32-body-data/32p-drug-prod/*product-1*/32p5-contr-drug-prod/32p51-spec
	Comment	
99	Number	3.2.P.5.1
	Title	Specification(s) (name, dosage form)
	Element	m3-2-p-5-1-specifications
	File	m3/32-body-data/32p-drug-prod/*product-1*/32p5-contr-drug-prod/32p51-spec/specifications.pdf
	Comment	
100	Number	3.2.P.5.2

	Title	Analytical Procedures (name, dosage form)
	Element	m3-2-p-5-2-analytical-procedures
	Directory	m3/32-body-data/32p-drug-prod/*product-1*/32p5-contr-drug-prod/32p52-analyt-proc
	Comment	The example below shows how a multiple file approach, where a separate file is provided for each analytical procedure, may be organized. CTD numbering is not defined below this level (e.g., 3.2.P.5.2.1).
101	Number	
	Title	*Analytical Procedure – 1*
	Element	m3-2-p-5-2-analytical-procedures
	File	m3/32-body-data/32p-drug-prod/*product-1*/32p5-contr-drug-prod/32p52-analyt-proc/*analytical-procedure-1.pdf*
	Comment	
102	Number	
	Title	*Analytical Procedure – 2*
	Element	m3-2-p-5-2-analytical-procedures
	File	m3/32-body-data/32p-drug-prod/*product-1*/32p5-contr-drug-prod/32p52-analyt-proc/*analytical-procedure-2.pdf*
	Comment	
103	Number	
	Title	*Analytical Procedure – 3*
	Element	m3-2-p-5-2-analytical-procedures
	File	m3/32-body-data/32p-drug-prod/*product-1*/32p5-contr-drug-prod/32p52-analyt-proc/*analytical-procedure-3.pdf*
	Comment	
104	Number	3.2.P.5.3
	Title	Validation of Analytical Procedures (name, dosage form)
	Element	m3-2-p-5-3-validation-of-analytical-procedures
	Directory	m3/32-body-data/32p-drug-prod/*product-1*/32p5-contr-drug-prod/32p53-val-analyt-proc
	Comment	The example below shows how a multiple file approach, where a separate file is provided for each analytical procedure, may be organized. CTD numbering is not defined below this level (e.g., 3.2.P.5.3.1).
105	Number	
	Title	*Validation of Analytical Procedures – 1*
	Element	m3-2-p-5-3-validation-of-analytical-procedures
	File	m3/32-body-data/32p-drug-prod/*product-1*/32p5-contr-drug-prod/32p53-val-analyt-proc/*validation-analytical-procedures-1.pdf*
	Comment	
106	Number	
	Title	*Validation of Analytical Procedures – 2*

113	Number	3.2.P.5.6
	Title	Justification of Specifications (name, dosage form)
	Element	m3-2-p-5-6-justification-of-specifications
	File	m3/32-body-data/32p-drug-prod/*product-1*/32p5-contr-drug-prod/32p56-justif-spec/justification-of-specifications.pdf
	Comment	
114	Number	3.2.P.6
	Title	Reference Standards or Materials (name, dosage form)
	Element	m3-2-p-6-reference-standards-or-materials
	Directory	m3/32-body-data/32p-drug-prod/*product-1*/32p6-ref-stand
	Comment	
115	Number	3.2.P.6
	Title	Reference Standards or Materials (name, dosage form)
	Element	m3-2-p-6-reference-standards-or-materials
	File	m3/32-body-data/32p-drug-prod/*product-1*/32p6-ref-stand/reference-standards.pdf
	Comment	When a multiple file approach is taken for this section, the file names should indicate which reference standard is covered in the document.
116	Number	3.2.P.7
	Title	Container Closure System (name, dosage form)
	Element	m3-2-p-7-container-closure-system
	Directory	m3/32-body-data/32p-drug-prod/*product-1*/32p7-cont-closure-sys
	Comment	
117	Number	3.2.P.7
	Title	Container Closure System (name, dosage form)
	Element	m3-2-p-7-container-closure-system
	File	m3/32-body-data/32p-drug-prod/*product-1*/32p7-cont-closure-sys/container-closure-system.pdf
	Comment	
118	Number	3.2.P.8
	Title	Stability (name, dosage form)
	Element	m3-2-p-8-stability
	Directory	m3/32-body-data/32p-drug-prod/*product-1*/32p8-stab
	Comment	
119	Number	3.2.P.8.1
	Title	Stability Summary and Conclusion (name, dosage form)
	Element	m3-2-p-8-1-stability-summary-and-conclusion

	File	m3/32-body-data/32p-drug-prod/*product-1*/32p8-stab/stability-summary.pdf
	Comment	
120	Number	3.2.P.8.2
	Title	Post-approval Stability Protocol and Stability Commitment (name, dosage form)
	Element	m3-2-p-8-2-post-approval-stability-protocol-and-stability-commitment
	File	m3/32-body-data/32p-drug-prod/*product-1*/32p8-stab/postapproval-stability.pdf
	Comment	
121	Number	3.2.P.8.3
	Title	Stability Data (name, dosage form)
	Element	m3-2-p-8-3-stability-data
	File	m3/32-body-data/32p-drug-prod/*product-1*/32p8-stab/stability-data.pdf
	Comment	
122	Number	3.2.A
	Title	Appendices
	Element	m3-2-a-appendices
	Directory	m3/32-body-data/32a-app
	Comment	
123	Number	3.2.A.1
	Title	Facilities and Equipment (name, manufacturer)
	Element	m3-2-a-1-facilities-and-equipment
	Directory	m3/32-body-data/32a-app/32a1-fac-equip
	Comment	Several reports are likely to be included in this appendix. The organisation is left to the applicant to define. However, where there is more than one manufacturer a folder should be created for each manufacturer and the identity of the manufacturer included in the directory name. CTD numbering is not defined below this level (e.g., 3.2.A.1.1).
124	Number	
	Title	*Facilities and Equipment Report 1*
	Element	m3-2-a-1-facilities-and-equipment
	File	m3/32-body-data/32a-app/32a1-fac-equip*/facilities-and-equipment-report-1.pdf*
	Comment	
125	Number	
	Title	*Facilities and Equipment Report 2*
	Element	m3-2-a-1-facilities-and-equipment
	File	m3/32-body-data/32a-app/32a1-fac-equip/*facilities-and-equipment-report-2.pdf*

	Comment	
126	Number	
	Title	*Facilities and Equipment Report 3*
	Element	m3-2-a-1-facilities-and-equipment
	File	m3/32-body-data/32a-app/32a1-fac-equip/*facilities-and-equipment-report-3.pdf*
	Comment	
127	Number	3.2.A.2
	Title	Adventitious Agents Safety Evaluation (name, dosage form, manufacturer)
	Element	m3-2-a-2-adventitious-agents-safety-evaluation
	Directory	m3/32-body-data/32a-app/32a2-advent-agent
	Comment	Nonviral adventitious agents reports should be placed in this folder. For viral adventitious agents the following sub-folder structure should be used. However, where there is more than one drug substance, drug product, manufacturer etc., a directory should be created for each option and its identity included in the directory name. CTD numbering is not defined below this level (e.g., 3.2.A.2.1).
128	Number	
	Title	*Adventitious Agents Safety Evaluation Report 1*
	Element	m3-2-a-2-adventitious-agents-safety-evaluation
	File	m3/32-body-data/32a-app/32a2-advent-agent/*adventitious-agents-report-1.pdf*
	Comment	
129	Number	
	Title	*Adventitious Agents Safety Evaluation Report 2*
	Element	m3-2-a-2-adventitious-agents-safety-evaluation
	File	m3/32-body-data/32a-app/32a2-advent-agent/*adventitious-agents-report-2.pdf*
	Comment	
130	Number	
	Title	*Adventitious Agents Safety Evaluation Report 3*
	Element	m3-2-a-2-adventitious-agents-safety-evaluation
	File	m3/32-body-data/32a-app/32a2-advent-agent/*adventitious-agents-report-3.pdf*
	Comment	
131	Number	3.2.A.3
	Title	Excipients – *Name*
	Element	m3-2-a-3-excipients
	Directory	m3/32-body-data/32a-app/32a3-excip-*name-1*

	Comment	The name of any novel excipient should be included in the folder name. If there is more than one novel excipient then each folder should have unique identification through the use of different names e.g., '32a3-excip-*name-1'* and '32a3-excip-*name-2'*. The directory/file structure would typically follow that of the drug substance section in Module 3.2.S. Refer to regional guidances for the need for such information to be included in the submission directly as opposed to its inclusion in a Drug Master File.
132	Number	3.2.R
	Title	Regional Information
	Element	m3-2-r-regional-information
	Directory	m3/32-body-data/32r-reg-info
	Comment	Refer to the M4 Organisation Document: Granularity Annex for the approach to take with this section.
133	Number	3.3
	Title	Literature References
	Element	m3-3-literature-references
	Directory	m3/33-lit-ref
	Comment	Copies of literature references should ordinarily be submitted as individual files (i.e., one for each reference). CTD numbering is not defined below this level (e.g., 3.3.1).
134	Number	
	Title	*Reference 1*
	Element	m3-3-literature-references
	File	m3/33-lit-ref/*reference-1.pdf*
	Comment	
135	Number	
	Title	*Reference 2*
	Element	m3-3-literature-references
	File	m3/33-lit-ref/*reference-2.pdf*
	Comment	
136	Number	
	Title	*Reference 3*
	Element	m3-3-literature-references
	File	m3/33-lit-ref/*reference-3.pdf*
	Comment	

	Comment	This comment is applicable to all study reports in Module 4. A single file can be provided for each study report document in Module 4. However, where the study report is large (e.g., a carcinogenicity study) the applicant can choose to submit the report as more than one file. In this case the text portion of the report should be one file and the appendices can be one or more files. In choosing the level of granularity for these reports, the applicant should consider that, when relevant information is changed at any point in the product's life cycle, replacements of complete files should be provided. Where submission as a collection of multiple files is used it is recommended that a directory is created at the study report level and the relevant files included within the directory. It is possible to have the additional graphical file(s) inserted directly into the PDF file, thus making management of the file easier. Alternatively, the applicant can choose to manage graphical files independently. Individual studies and files do not have specific CTD numbers.
142	Number	
	Title	*Study Report 2*
	Element	m4-2-1-1-primary-pharmacodynamics
	File	m4/42-stud-rep/421-pharmacol/4211-prim-pd/*study-report-2.pdf*
	Comment	
143	Number	
	Title	*Study Report 3*
	Element	m4-2-1-1-primary-pharmacodynamics
	File	m4/42-stud-rep/421-pharmacol/4211-prim-pd/*study-report-3.pdf*
	Comment	
144	Number	4.2.1.2
	Title	Secondary Pharmacodynamics
	Element	m4-2-1-2-secondary-pharmacodynamics
	Directory	m4/42-stud-rep/421-pharmacol/4212-sec-pd
	Comment	
145	Number	
	Title	*Study Report 1*
	Element	m4-2-1-2-secondary-pharmacodynamics
	File	m4/42-stud-rep/421-pharmacol/4212-sec-pd/*study-report-1.pdf*
	Comment	
146	Number	

	Element	m4-2-3-7-7-other
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42377-other/*study-report-2.pdf*
	Comment	
265	Number	
	Title	*Study Report 3*
	Element	m4-2-3-7-7-other
	File	m4/42-stud-rep/423-tox/4237-other-tox-stud/42377-other/*study-report-3.pdf*
	Comment	
266	Number	4.3
	Title	Literature References
	Element	m4-3-literature-references
	Directory	m4/43-lit-ref
	Comment	Copies of literature references should ordinarily be submitted as individual files (i.e., one for each reference).
267	Number	
	Title	*Reference 1*
	Element	m4-3-literature-references
	File	m4/43-lit-ref/*reference-1.pdf*
	Comment	
268	Number	
	Title	*Reference 2*
	Element	m4-3-literature-references
	File	m4/43-lit-ref/*reference-2.pdf*
	Comment	
269	Number	
	Title	*Reference 3*
	Element	m4-3-literature-references
	File	m4/43-lit-ref/*reference-3.pdf*
	Comment	

	Element	m5-3-1-1-bioavailability-study-reports
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5311-ba-stud-rep/*study-report-1*
	Comment	This comment is applicable to all study reports in Module 5. The applicants should ordinarily provide the study reports as multiple files (a synopsis, a main body and appropriate appendices). Appendices should be organized in accordance with the ICH E3 guideline, which describes the content and format of the clinical study report. In choosing the level of granularity for reports the applicant should consider that, when relevant information is changed at any point in the product's life cycle, replacements of complete files should be provided. A directory should be created for each study and the files associated with the study report should be organized within the directory. Individual studies and files do not have specific CTD numbers.
277	Number	
	Title	*Study Report 2*
	Element	m5-3-1-1-bioavailability-study-reports
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5311-ba-stud-rep/*study-report-2*
	Comment	
278	Number	
	Title	*Study Report 3*
	Element	m5-3-1-1-bioavailability-study-reports
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5311-ba-stud-rep/*study-report-3*
	Comment	
279	Number	5.3.1.2
	Title	Comparative BA and Bioequivalence (BE) Study Reports
	Element	m5-3-1-2-comparative-ba-and-bioequivalence-study-reports
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5312-compar-ba-be-stud-rep
	Comment	
280	Number	
	Title	*Study Report 1*
	Element	m5-3-1-2-comparative-ba-and-bioequivalence-study-reports
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5312-compar-ba-be-stud-rep/*study-report-1*
	Comment	
281	Number	
	Title	*Study Report 2*
	Element	m5-3-1-2-comparative-ba-and-bioequivalence-study-reports
	Directory	m5/53-clin-stud-rep/531-rep-biopharm-stud/5312-compar-ba-be-stud-rep/*study-report-2*

	Directory	m5/53-clin-stud-rep/535-rep-effic-safety-stud
	Comment	
335	Number	5.3.5
	Title	Reports of Efficacy and Safety Studies - *Indication Name*
	Element	m5-3-5-reports-of-efficacy-and-safety-studies
	Directory	m5/53-clin-stud-rep/535-rep-effic-safety-stud/*indication-1*
	Comment	The folder name should always include the indication being claimed, for example, 'asthma' (abbreviated if appropriate). Where there is more than one indication (e.g., asthma and migraine), then the first indication has a folder 'asthma' and the second 'migraine'. The 'indication' attribute in the backbone should be consistent with that used in the folder name but can be different. For example, an 'indication' attribute value of 'Non-Small Cell Lung Cancer' could be expressed as 'NSCLC' in the folder name. There is currently no standard terminology list for 'indication' and applicants should choose the 'indication' attributes carefully as they can not be easily changed during the life cycle of the application. The only way this can be accomplished currently is to delete all the leaf elements with the incorrect attribute value and provide new leaf elements for those files with the modified attribute value. Applicants should consult with the regional authority before attempting to modify these attributes to discuss the appropriateness of, and approach to be taken for, this type of change.
336	Number	5.3.5.1
	Title	Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication
	Element	m5-3-5-1-study-reports-of-controlled-clinical-studies-pertinent-to-the-claimed-indication
	Directory	m5/53-clin-stud-rep/535-rep-effic-safety-stud/*indication-1*/5351-stud-rep-contr
	Comment	
337	Number	
	Title	*Study Report 1*
	Element	m5-3-5-1-study-reports-of-controlled-clinical-studies-pertinent-to-the-claimed-indication
	Directory	m5/53-clin-stud-rep/535-rep-effic-safety-stud/*indication-1*/5351-stud-rep-contr/*study-report-1*
	Comment	
338	Number	
	Title	*Study Report 2*
	Element	m5-3-5-1-study-reports-of-controlled-clinical-studies-pertinent-to-the-claimed-indication
	Directory	m5/53-clin-stud-rep/535-rep-effic-safety-stud/*indication-1*/5351-stud-rep-contr/*study-report-2*
	Comment	
339	Number	
	Title	*Study Report 3*
	Element	m5-3-5-1-study-reports-of-controlled-clinical-studies-pertinent-to-the-claimed-indication
	Directory	m5/53-clin-stud-rep/535-rep-effic-safety-stud/*indication-1*/5351-stud-rep-contr/*study-report-3*

353	Number	5.3.7
	Title	Case Report Forms and Individual Patient Listings
	Element	m5-3-7-case-report-forms-and-individual-patient-listings
	Directory	m5/53-clin-stud-rep/537-crf-ipl
	Comment	
354	Number	
	Title	*Study 1*
	Element	m5-3-7-case-report-forms-and-individual-patient-listings
	Directory	m5/53-clin-stud-rep/537-crf-ipl/*study-1*
	Comment	
355	Number	
	Title	*Document/Dataset 1*
	Element	m5-3-7-case-report-forms-and-individual-patient-listings
	File	m5/53-clin-stud-rep/537-crf-ipl/*study-1/filename-1.pdf*
	Comment	The filename and extension should include the description of the file and appropriate file extension according to Appendix 2. Reference should be made to regional guidance for the acceptability of submission of datasets
356	Number	
	Title	*Document/Dataset 2*
	Element	m5-3-7-case-report-forms-and-individual-patient-listings
	File	m5/53-clin-stud-rep/537-crf-ipl/*study-1/filename-2.pdf*
	Comment	
357	Number	
	Title	*Document/Dataset 3*
	Element	m5-3-7-case-report-forms-and-individual-patient-listings
	File	m5/53-clin-stud-rep/537-crf-ipl/*study-1/filename-3.pdf*
	Comment	
358	Number	
	Title	*Study 2*
	Element	m5-3-7-case-report-forms-and-individual-patient-listings
	Directory	m5/53-clin-stud-rep/537-crf-ipl/*study-2*
	Comment	define element
359	Number	
	Title	*Document/Dataset 1*

366	Number	5.4
	Title	Literature References
	Element	m5-4-literature-references
	Directory	m5/54-lit-ref
	Comment	Copies of literature references should ordinarily be submitted as individual files (i.e,. one for each reference).
367	Number	
	Title	*Reference 1*
	Element	m5-4-literature-references
	File	m5/54-lit-ref/*reference-1.pdf*
	Comment	
368	Number	
	Title	*Reference 2*
	Element	m5-4-literature-references
	File	m5/54-lit-ref/*reference-2.pdf*
	Comment	
369	Number	
	Title	*Reference 3*
	Element	m5-4-literature-references
	File	m5/54-lit-ref/*reference-3.pdf*
	Comment	