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| | File | m3/32-body-data/32p-drug-prod/product-1/32p4-contr-excip/excipient-1/validation-analyt-procedures.pdf |
| | Comment | 3.2.P4 のコメント参照。 |
| 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-specification.pdf |
| | Comment | 3.2.P4 のコメント参照。 |
| 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 |

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| | 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 | 以下にどのように多重ファイルを用いるか、各分析方法に関する個別ファイルを添付するかに関して例を示す。このレベルより下位ではCTDの番号付けが定義されていない(例えば、3.2.P.5.2.1)。 |
| 101 | Number | |
| | Title | <i>Analytical Procedure – 1</i> |
| | 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 | <i>Analytical Procedure – 2</i> |
| | 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 | <i>Analytical Procedure – 3</i> |
| | 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 | 以下にどのように多重ファイルを用いるか、各分析方法に関する個別ファイルを添付するかに関して例を示す。このレベルより下位ではCTDの番号付けが定義されていない(例えば、3.2.P.5.3.1)。 |
| 105 | Number | |
| | Title | <i>Validation of Analytical Procedures – 1</i> |
| | 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 | <i>Validation of Analytical Procedures – 2</i> |

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| | 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-2.pdf |
| | Comment | |
| 107 | Number | |
| | Title | <i>Validation of Analytical Procedures – 3</i> |
| | 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-3.pdf |
| | Comment | |
| 108 | Number | 3.2.P.5.4 |
| | Title | Batch Analyses (name, dosage form) |
| | Element | m3-2-p-5-4-batch-analyses |
| | Directory | m3/32-body-data/32p-drug-prod/product-1/32p5-contr-drug-prod/32p54-batch-analys |
| | Comment | |
| 109 | Number | 3.2.P.5.4 |
| | Title | Batch Analyses (name, dosage form) |
| | Element | m3-2-p-5-4-batch-analyses |
| | File | m3/32-body-data/32p-drug-prod/product-1/32p5-contr-drug-prod/32p54-batch-analys/batch-analyses.pdf |
| | Comment | |
| 110 | Number | 3.2.P.5.5 |
| | Title | Characterisation of Impurities (name, dosage form) |
| | Element | m3-2-p-5-5-characterisation-of-impurities |
| | Directory | m3/32-body-data/32p-drug-prod/product-1/32p5-contr-drug-prod/32p55-charac-imp |
| | Comment | |
| 111 | Number | 3.2.P.5.5 |
| | Title | Characterisation of Impurities (name, dosage form) |
| | Element | m3-2-p-5-5-characterisation-of-impurities |
| | File | m3/32-body-data/32p-drug-prod/product-1/32p5-contr-drug-prod/32p55-charac-imp/characterisation-impurities.pdf |
| | Comment | |
| 112 | Number | 3.2.P.5.6 |
| | Title | Justification of Specifications (name, dosage form) |
| | Element | m3-2-p-5-6-justification-of-specifications |
| | Directory | m3/32-body-data/32p-drug-prod/product-1/32p5-contr-drug-prod/32p56-justif-spec |
| | Comment | |

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| 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-specification.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 | 多重ファイルを本項に用いる場合、ファイル名は当該文書がどの標準品に関するものであるかを示さなければならない。 |
| 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 |

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| | 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 | 本付録にはいくつかの報告書が含まれると考えられる。その構成は申請者が定める。しかし、複数の製造業者がある場合には、製造業者ごとにフォルダを作成し、ディレクトリ名で製造業者を識別できるようにすること。このレベルより下位ではCTDの番号付けが定義されていない（例えば、3.2.A.1.1）。 |
| 124 | Number | |
| | Title | <i>Facilities and Equipment Report 1</i> |
| | 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 | <i>Facilities and Equipment Report 2</i> |
| | Element | m3-2-a-1-facilities-and-equipment |
| | File | m3/32-body-data/32a-app/32a1-fac-equip/facilities-and-equipment-report-2.pdf |

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| | Comment | |
| 126 | Number | |
| | Title | <i>Facilities and Equipment Report 3</i> |
| | 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 | 非ウイルス性感染性物質については、このフォルダに報告書を入れる。ウイルス性感染性物質については、以下のサブフォルダ構造を使用すること。しかし、複数の原薬、製剤、製造業者などがある場合には、オプションごとにディレクトリを作成し、ディレクトリ名にその識別を含めること。このレベルより下位では CTD の番号付けが定義されていない（例えば、3.2.A.2.1）。 |
| 128 | Number | |
| | Title | <i>Adventitious Agents Safety Evaluation Report 1</i> |
| | 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 | <i>Adventitious Agents Safety Evaluation Report 2</i> |
| | 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 | <i>Adventitious Agents Safety Evaluation Report 3</i> |
| | 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 |

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| | Comment | 新規添加剤名はフォルダ名に含めること。複数の新規添加剤がある場合、各フォルダには異なる名前を使用し固有の名前をつける。例として、「32a3-excip-name-1」、「32a3-excip-name-2」など。 一般に、ディレクトリ/ファイル構造はモジュール 3.2.S の原薬セクションの構造に従う。こうした情報はドラッグ・マスターファイルではなく申請書に直接含める必要があるかは地域ガイダンスを参照されたい。 |
| 132 | Number | 3.2.R |
| | Title | Regional Information |
| | Element | m3-2-r-regional-information |
| | Directory | m3/32-body-data/32r-reg-info |
| | Comment | 品質に関する概括資料の文書構成に関しては M4 構成文書 Granularity Annex の該当する項を参照すること。 |
| 133 | Number | 3.3 |
| | Title | Literature References |
| | Element | m3-3-literature-references |
| | Directory | m3/33-lit-ref |
| | Comment | 通常、参考文献のコピーは個々のファイル（すなわち文献ごとに 1 ファイル）として提出する。このレベルより下位では CTD の番号付けが定義されていない（例えば、3.3.1）。 |
| 134 | Number | |
| | Title | <i>Reference 1</i> |
| | Element | m3-3-literature-references |
| | File | m3/33-lit-ref/reference-1.pdf |
| | Comment | |
| 135 | Number | |
| | Title | <i>Reference 2</i> |
| | Element | m3-3-literature-references |
| | File | m3/33-lit-ref/reference-2.pdf |
| | Comment | |
| 136 | Number | |
| | Title | <i>Reference 3</i> |
| | Element | m3-3-literature-references |
| | File | m3/33-lit-ref/reference-3.pdf |
| | Comment | |

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| 137 | Number | 4 |
| | Title | Nonclinical Study Reports |
| | Element | m4-nonclinical-study-reports |
| | Directory | m4 |
| | Comment | |
| 138 | Number | 4.2 |
| | Title | Study Reports |
| | Element | m4-2-study-reports |
| | Directory | m4/42-stud-rep |
| | Comment | |
| 139 | Number | 4.2.1 |
| | Title | Pharmacology |
| | Element | m4-2-1-pharmacology |
| | Directory | m4/42-stud-rep/421-pharmacol |
| | Comment | |
| 140 | Number | 4.2.1.1 |
| | Title | Primary Pharmacodynamics |
| | Element | m4-2-1-1-primary-pharmacodynamics |
| | Directory | m4/42-stud-rep/421-pharmacol/4211-prim-pd |
| | Comment | |
| 141 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-1-1-primary-pharmacodynamics |
| | File | m4/42-stud-rep/421-pharmacol/4211-prim-pd/ <i>study-report-1.pdf</i> |
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| | Comment | <p><u>このコメントはモジュール4の全試験報告書に適用される。</u></p> <p>一般にモジュール4の各試験報告書について、1つのファイルを提供する。しかし、がん原性試験のように大きい試験報告書の場合は、申請者は複数のファイルとして提出することもできる。その場合、報告書の本文を1ファイルとし、付録は1つまたは複数のファイルとする。複数ファイルの方式を採用する場合、ライフサイクルのあらゆる時点において、関連情報に変更があった際には、<u>ファイル一式の置換を行うべきである</u>。複数ファイルの方式を採用する場合、試験報告書のレベルにディレクトリを作成し、関連するファイルをそのディレクトリに含めることを推奨する。追加的なグラフィックファイルを、PDFファイルに直接挿入することにより、ファイル管理を容易にすることも可能である。あるいはグラフィックファイルを個別に扱ってもよい。</p> <p><u>個々の試験およびファイルには特定のCTD番号を付与しない。</u></p> |
| 142 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-1-1-primary-pharmacodynamics |
| | File | m4/42-stud-rep/421-pharmacol/4211-prim-pd/ <i>study-report-2.pdf</i> |
| | Comment | |
| 143 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-1-1-primary-pharmacodynamics |
| | File | m4/42-stud-rep/421-pharmacol/4211-prim-pd/ <i>study-report-3.pdf</i> |
| | 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 | <i>Study Report 1</i> |
| | Element | m4-2-1-2-secondary-pharmacodynamics |
| | File | m4/42-stud-rep/421-pharmacol/4212-sec-pd/ <i>study-report-1.pdf</i> |
| | Comment | |
| 146 | Number | |
| | Title | <i>Study Report 2</i> |

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| | Element | m4-2-1-2-secondary-pharmacodynamics |
| | File | m4/42-stud-rep/421-pharmacol/4212-sec-pd/study-report-2.pdf |
| | Comment | |
| 147 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-1-2-secondary-pharmacodynamics |
| | File | m4/42-stud-rep/421-pharmacol/4212-sec-pd/study-report-3.pdf |
| | Comment | |
| 148 | Number | 4.2.1.3 |
| | Title | Safety Pharmacology |
| | Element | m4-2-1-3-safety-pharmacology |
| | Directory | m4/42-stud-rep/421-pharmacol/4213-safety-pharmacol |
| | Comment | |
| 149 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-1-3-safety-pharmacology |
| | File | m4/42-stud-rep/421-pharmacol/4213-safety-pharmacol/study-report-1.pdf |
| | Comment | |
| 150 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-1-3-safety-pharmacology |
| | File | m4/42-stud-rep/421-pharmacol/4213-safety-pharmacol/study-report-2.pdf |
| | Comment | |
| 151 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-1-3-safety-pharmacology |
| | File | m4/42-stud-rep/421-pharmacol/4213-safety-pharmacol/study-report-3.pdf |
| | Comment | |
| 152 | Number | 4.2.1.4 |
| | Title | Pharmacodynamic Drug Interactions |
| | Element | m4-2-1-4-pharmacodynamic-drug-interactions |
| | Directory | m4/42-stud-rep/421-pharmacol/4214-pd-drug-interact |
| | Comment | |

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| 153 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-1-4-pharmacodynamic-drug-interactions |
| | File | m4/42-stud-rep/421-pharmacol/4214-pd-drug-interact/ <i>study-report-1.pdf</i> |
| | Comment | |
| 154 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-1-4-pharmacodynamic-drug-interactions |
| | File | m4/42-stud-rep/421-pharmacol/4214-pd-drug-interact/ <i>study-report-2.pdf</i> |
| | Comment | |
| 155 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-1-4-pharmacodynamic-drug-interactions |
| | File | m4/42-stud-rep/421-pharmacol/4214-pd-drug-interact/ <i>study-report-3.pdf</i> |
| | Comment | |
| 156 | Number | 4.2.2 |
| | Title | Pharmacokinetics |
| | Element | m4-2-2-pharmacokinetics |
| | Directory | m4/42-stud-rep/422-pk |
| | Comment | |
| 157 | Number | 4.2.2.1 |
| | Title | Analytical Methods and Validation Reports (if separate reports are available) |
| | Element | m4-2-2-1-analytical-methods-and-validation-reports |
| | Directory | m4/42-stud-rep/422-pk/4221-analyt-met-val |
| | Comment | |
| 158 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-2-1-analytical-methods-and-validation-reports |
| | File | m4/42-stud-rep/422-pk/4221-analyt-met-val/ <i>study-report-1.pdf</i> |
| | Comment | |
| 159 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-2-1-analytical-methods-and-validation-reports |

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| | File | m4/42-stud-rep/422-pk/4221-analyt-met-val/study-report-2.pdf |
| | Comment | |
| 160 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-2-1-analytical-methods-and-validation-reports |
| | File | m4/42-stud-rep/422-pk/4221-analyt-met-val/study-report-3.pdf |
| | Comment | |
| 161 | Number | 4.2.2.2 |
| | Title | Absorption |
| | Element | m4-2-2-2-absorption |
| | Directory | m4/42-stud-rep/422-pk/4222-absorp |
| | Comment | |
| 162 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-2-2-absorption |
| | File | m4/42-stud-rep/422-pk/4222-absorp/study-report-1.pdf |
| | Comment | |
| 163 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-2-2-absorption |
| | File | m4/42-stud-rep/422-pk/4222-absorp/study-report-2.pdf |
| | Comment | |
| 164 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-2-2-absorption |
| | File | m4/42-stud-rep/422-pk/4222-absorp/study-report-3.pdf |
| | Comment | |
| 165 | Number | 4.2.2.3 |
| | Title | Distribution |
| | Element | m4-2-2-3-distribution |
| | Directory | m4/42-stud-rep/422-pk/4223-distrib |
| | Comment | |
| 166 | Number | |

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| | Title | <i>Study Report 1</i> |
| | Element | m4-2-2-3-distribution |
| | File | m4/42-stud-rep/422-pk/4223-distrib/ <i>study-report-1.pdf</i> |
| | Comment | |
| 167 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-2-3-distribution |
| | File | m4/42-stud-rep/422-pk/4223-distrib/ <i>study-report-2.pdf</i> |
| | Comment | |
| 168 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-2-3-distribution |
| | File | m4/42-stud-rep/422-pk/4223-distrib/ <i>study-report-3.pdf</i> |
| | Comment | |
| 169 | Number | 4.2.2.4 |
| | Title | Metabolism |
| | Element | m4-2-2-4-metabolism |
| | Directory | m4/42-stud-rep/422-pk/4224-metab |
| | Comment | |
| 170 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-2-4-metabolism |
| | File | m4/42-stud-rep/422-pk/4224-metab/ <i>study-report-1.pdf</i> |
| | Comment | |
| 171 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-2-4-metabolism |
| | File | m4/42-stud-rep/422-pk/4224-metab/ <i>study-report-2.pdf</i> |
| | Comment | |
| 172 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-2-4-metabolism |
| | File | m4/42-stud-rep/422-pk/4224-metab/ <i>study-report-3.pdf</i> |

| | Comment | |
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| 173 | Number | 4.2.2.5 |
| | Title | Excretion |
| | Element | m4-2-2-5-excretion |
| | Directory | m4/42-stud-rep/422-pk/4225-excr |
| | Comment | |
| 174 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-2-5-excretion |
| | File | m4/42-stud-rep/422-pk/4225-excr/ <i>study-report-1.pdf</i> |
| | Comment | |
| 175 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-2-5-excretion |
| | File | m4/42-stud-rep/422-pk/4225-excr/ <i>study-report-2.pdf</i> |
| | Comment | |
| 176 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-2-5-excretion |
| | File | m4/42-stud-rep/422-pk/4225-excr/ <i>study-report-3.pdf</i> |
| | Comment | |
| 177 | Number | 4.2.2.6 |
| | Title | Pharmacokinetic Drug Interactions (nonclinical) |
| | Element | m4-2-2-6-pharmacokinetic-drug-interactions |
| | Directory | m4/42-stud-rep/422-pk/4226-pk-drug-interact |
| | Comment | |
| 178 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-2-6-pharmacokinetic-drug-interactions |
| | File | m4/42-stud-rep/422-pk/4226-pk-drug-interact/ <i>study-report-1.pdf</i> |
| | Comment | |
| 179 | Number | |
| | Title | <i>Study Report 2</i> |

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| | Element | m4-2-2-6-pharmacokinetic-drug-interactions |
| | File | m4/42-stud-rep/422-pk/4226-pk-drug-interact/study-report-2.pdf |
| | Comment | |
| 180 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-2-6-pharmacokinetic-drug-interactions |
| | File | m4/42-stud-rep/422-pk/4226-pk-drug-interact/study-report-3.pdf |
| | Comment | |
| 181 | Number | 4.2.2.7 |
| | Title | Other Pharmacokinetic Studies |
| | Element | m4-2-2-7-other-pharmacokinetic-studies |
| | Directory | m4/42-stud-rep/422-pk/4227-other-pk-stud |
| | Comment | |
| 182 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-2-7-other-pharmacokinetic-studies |
| | File | m4/42-stud-rep/422-pk/4227-other-pk-stud/study-report-1.pdf |
| | Comment | |
| 183 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-2-7-other-pharmacokinetic-studies |
| | File | m4/42-stud-rep/422-pk/4227-other-pk-stud/study-report-2.pdf |
| | Comment | |
| 184 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-2-7-other-pharmacokinetic-studies |
| | File | m4/42-stud-rep/422-pk/4227-other-pk-stud/study-report-3.pdf |
| | Comment | |
| 185 | Number | 4.2.3 |
| | Title | Toxicology |
| | Element | m4-2-3-toxicology |
| | Directory | m4/42-stud-rep/423-tox |
| | Comment | |

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| 186 | Number | 4.2.3.1 |
| | Title | Single-Dose Toxicity (in order by species, by route) |
| | Element | m4-2-3-1-single-dose-toxicity |
| | Directory | m4/42-stud-rep/423-tox/4231-single-dose-tox |
| | Comment | |
| 187 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-3-1-single-dose-toxicity |
| | File | m4/42-stud-rep/423-tox/4231-single-dose-tox/ <i>study-report-1.pdf</i> |
| | Comment | |
| 188 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-3-1-single-dose-toxicity |
| | File | m4/42-stud-rep/423-tox/4231-single-dose-tox/ <i>study-report-2.pdf</i> |
| | Comment | |
| 189 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-3-1-single-dose-toxicity |
| | File | m4/42-stud-rep/423-tox/4231-single-dose-tox/ <i>study-report-3.pdf</i> |
| | Comment | |
| 190 | Number | 4.2.3.2 |
| | Title | Repeat-Dose Toxicity (in order by species, by route, by duration, including supportive toxicokinetics evaluations) |
| | Element | m4-2-3-2-repeat-dose-toxicity |
| | Directory | m4/42-stud-rep/423-tox/4232-repeat-dose-tox |
| | Comment | |
| 191 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-3-2-repeat-dose-toxicity |
| | File | m4/42-stud-rep/423-tox/4232-repeat-dose-tox/ <i>study-report-1.pdf</i> |
| | Comment | |
| 192 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-3-2-repeat-dose-toxicity |

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| | File | m4/42-stud-rep/423-tox/4232-repeat-dose-tox/ <i>study-report-2.pdf</i> |
| | Comment | |
| 193 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-3-2-repeat-dose-toxicity |
| | File | m4/42-stud-rep/423-tox/4232-repeat-dose-tox/ <i>study-report-3.pdf</i> |
| | Comment | |
| 194 | Number | 4.2.3.3 |
| | Title | Genotoxicity |
| | Element | m4-2-3-3-genotoxicity |
| | Directory | m4/42-stud-rep/423-tox/4233-genotox |
| | Comment | |
| 195 | Number | 4.2.3.3.1 |
| | Title | In vitro |
| | Element | m4-2-3-3-1-in-vitro |
| | Directory | m4/42-stud-rep/423-tox/4233-genotox/42331-in-vitro |
| | Comment | |
| 196 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-3-3-1-in-vitro |
| | File | m4/42-stud-rep/423-tox/4233-genotox/42331-in-vitro/ <i>study-report-1.pdf</i> |
| | Comment | |
| 197 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-3-3-1-in-vitro |
| | File | m4/42-stud-rep/423-tox/4233-genotox/42331-in-vitro/ <i>study-report-2.pdf</i> |
| | Comment | |
| 198 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-3-3-1-in-vitro |
| | File | m4/42-stud-rep/423-tox/4233-genotox/42331-in-vitro/ <i>study-report-3.pdf</i> |
| | Comment | |
| 199 | Number | 4.2.3.3.2 |

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| | Title | In vivo (including supportive toxicokinetics evaluations) |
| | Element | m4-2-3-3-2-in-vivo |
| | Directory | m4/42-stud-rep/423-tox/4233-genotox/42332-in-vivo |
| | Comment | |
| 200 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-3-3-2-in-vivo |
| | File | m4/42-stud-rep/423-tox/4233-genotox/42332-in-vivo/study-report-1.pdf |
| | Comment | |
| 201 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-3-3-2-in-vivo |
| | File | m4/42-stud-rep/423-tox/4233-genotox/42332-in-vivo/study-report-2.pdf |
| | Comment | |
| 202 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-3-3-2-in-vivo |
| | File | m4/42-stud-rep/423-tox/4233-genotox/42332-in-vivo/study-report-3.pdf |
| | Comment | |
| 203 | Number | 4.2.3.4 |
| | Title | Carcinogenicity (including supportive toxicokinetics evaluations) |
| | Element | m4-2-3-4-carcinogenicity |
| | Directory | m4/42-stud-rep/423-tox/4234-carcigen |
| | Comment | |
| 204 | Number | 4.2.3.4.1 |
| | Title | Long-term studies (in order by species, including range-finding studies that cannot be appropriately included under repeat-dose toxicity or pharmacokinetics) |
| | Element | m4-2-3-4-1-long-term-studies |
| | Directory | m4/42-stud-rep/423-tox/4234-carcigen/42341-lt-stud |
| | Comment | |
| 205 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-3-4-1-long-term-studies |

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| | File | m4/42-stud-rep/423-tox/4234-carcigen/42341-lt-stud/study-report-1.pdf |
| | Comment | |
| 206 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-3-4-1-long-term-studies |
| | File | m4/42-stud-rep/423-tox/4234-carcigen/42341-lt-stud/study-report-2.pdf |
| | Comment | |
| 207 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-3-4-1-long-term-studies |
| | File | m4/42-stud-rep/423-tox/4234-carcigen/42341-lt-stud/study-report-3.pdf |
| | Comment | |
| 208 | Number | 4.2.3.4.2 |
| | Title | Short- or medium-term studies (including range-finding studies that cannot be appropriately included under repeat-dose toxicity or pharmacokinetics) |
| | Element | m4-2-3-4-2-short-or-medium-term-studies |
| | Directory | m4/42-stud-rep/423-tox/4234-carcigen/42342-smt-stud |
| | Comment | |
| 209 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-3-4-2-short-or-medium-term-studies |
| | File | m4/42-stud-rep/423-tox/4234-carcigen/42342-smt-stud/study-report-1.pdf |
| | Comment | |
| 210 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-3-4-2-short-or-medium-term-studies |
| | File | m4/42-stud-rep/423-tox/4234-carcigen/42342-smt-stud/study-report-2.pdf |
| | Comment | |
| 211 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-3-4-2-short-or-medium-term-studies |
| | File | m4/42-stud-rep/423-tox/4234-carcigen/42342-smt-stud/study-report-3.pdf |
| | Comment | |

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| 212 | Number | 4.2.3.4.3 |
| | Title | Other studies |
| | Element | m4-2-3-4-3-other-studies |
| | Directory | m4/42-stud-rep/423-tox/4234-carcigen/42343-other-stud |
| | Comment | |
| 213 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-3-4-3-other-studies |
| | File | m4/42-stud-rep/423-tox/4234-carcigen/42343-other-stud/ <i>study-report-1.pdf</i> |
| | Comment | |
| 214 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-3-4-3-other-studies |
| | File | m4/42-stud-rep/423-tox/4234-carcigen/42343-other-stud/ <i>study-report-2.pdf</i> |
| | Comment | |
| 215 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-3-4-3-other-studies |
| | File | m4/42-stud-rep/423-tox/4234-carcigen/42343-other-stud/ <i>study-report-3.pdf</i> |
| | Comment | |
| 216 | Number | 4.2.3.5 |
| | Title | Reproductive and Developmental Toxicity (including range-finding studies and supportive toxicokinetics evaluations) (if modified study designs are used, the following subheadings should be modified accordingly) |
| | Element | m4-2-3-5-reproductive-and-developmental-toxicity |
| | Directory | m4/42-stud-rep/423-tox/4235-repro-dev-tox |
| | Comment | |
| 217 | Number | 4.2.3.5.1 |
| | Title | Fertility and early embryonic development |
| | Element | m4-2-3-5-1-fertility-and-early-embryonic-development |
| | Directory | m4/42-stud-rep/423-tox/4235-repro-dev-tox/42351-fert-embryo-dev |
| | Comment | |
| 218 | Number | |
| | Title | <i>Study Report 1</i> |

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| | Element | m4-2-3-5-1-fertility-and-early-embryonic-development |
| | File | m4/42-stud-rep/423-tox/4235-repro-dev-tox/42351-fert-embryo-dev/study-report-1.pdf |
| | Comment | |
| 219 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-3-5-1-fertility-and-early-embryonic-development |
| | File | m4/42-stud-rep/423-tox/4235-repro-dev-tox/42351-fert-embryo-dev/study-report-2.pdf |
| | Comment | |
| 220 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-3-5-1-fertility-and-early-embryonic-development |
| | File | m4/42-stud-rep/423-tox/4235-repro-dev-tox/42351-fert-embryo-dev/study-report-3.pdf |
| | Comment | |
| 221 | Number | 4.2.3.5.2 |
| | Title | Embryo-fetal development |
| | Element | m4-2-3-5-2-embryo-fetal-development |
| | Directory | m4/42-stud-rep/423-tox/4235-repro-dev-tox/42352-embryo-fetal-dev |
| | Comment | |
| 222 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-3-5-2-embryo-fetal-development |
| | File | m4/42-stud-rep/423-tox/4235-repro-dev-tox/42352-embryo-fetal-dev/study-report-1.pdf |
| | Comment | |
| 223 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-3-5-2-embryo-fetal-development |
| | File | m4/42-stud-rep/423-tox/4235-repro-dev-tox/42352-embryo-fetal-dev/study-report-2.pdf |
| | Comment | |
| 224 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-3-5-2-embryo-fetal-development |
| | File | m4/42-stud-rep/423-tox/4235-repro-dev-tox/42352-embryo-fetal-dev/study-report-3.pdf |
| | Comment | |

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| 225 | Number | 4.2.3.5.3 |
| | Title | Prenatal and postnatal development, including maternal function |
| | Element | m4-2-3-5-3-prenatal-and-postnatal-development-including-maternal-function |
| | Directory | m4/42-stud-rep/423-tox/4235-repro-dev-tox/42353-pre-postnatal-dev |
| | Comment | |
| 226 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-3-5-3-prenatal-and-postnatal-development-including-maternal-function |
| | File | m4/42-stud-rep/423-tox/4235-repro-dev-tox/42353-pre-postnatal-dev/ <i>study-report-1.pdf</i> |
| | Comment | |
| 227 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-3-5-3-prenatal-and-postnatal-development-including-maternal-function |
| | File | m4/42-stud-rep/423-tox/4235-repro-dev-tox/42353-pre-postnatal-dev/ <i>study-report-2.pdf</i> |
| | Comment | |
| 228 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-3-5-3-prenatal-and-postnatal-development-including-maternal-function |
| | File | m4/42-stud-rep/423-tox/4235-repro-dev-tox/42353-pre-postnatal-dev/ <i>study-report-3.pdf</i> |
| | Comment | |
| 229 | Number | 4.2.3.5.4 |
| | Title | Studies in which the offspring (juvenile animals) are dosed and/or further evaluated |
| | Element | m4-2-3-5-4-studies-in-which-the-offspring-juvenile-animals-are-dosed-and-or-further-evaluated |
| | Directory | m4/42-stud-rep/423-tox/4235-repro-dev-tox/42354-juv |
| | Comment | |
| 230 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-3-5-4-studies-in-which-the-offspring-juvenile-animals-are-dosed-and-or-further-evaluated |
| | File | m4/42-stud-rep/423-tox/4235-repro-dev-tox/42354-juv/ <i>study-report-1.pdf</i> |
| | Comment | |
| 231 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-3-5-4-studies-in-which-the-offspring-juvenile-animals-are-dosed-and-or-further-evaluated |

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| | File | m4/42-stud-rep/423-tox/4235-repro-dev-tox/42354-juv/study-report-2.pdf |
| | Comment | |
| 232 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-3-5-4-studies-in-which-the-offspring-juvenile-animals-are-dosed-and-or-further-evaluated |
| | File | m4/42-stud-rep/423-tox/4235-repro-dev-tox/42354-juv/study-report-3.pdf |
| | Comment | |
| 233 | Number | 4.2.3.6 |
| | Title | Local Tolerance |
| | Element | m4-2-3-6-local-tolerance |
| | Directory | m4/42-stud-rep/423-tox/4236-loc-tol |
| | Comment | |
| 234 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-3-6-local-tolerance |
| | File | m4/42-stud-rep/423-tox/4236-loc-tol/study-report-1.pdf |
| | Comment | |
| 235 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-3-6-local-tolerance |
| | File | m4/42-stud-rep/423-tox/4236-loc-tol/study-report-2.pdf |
| | Comment | |
| 236 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-3-6-local-tolerance |
| | File | m4/42-stud-rep/423-tox/4236-loc-tol/study-report-3.pdf |
| | Comment | |
| 237 | Number | 4.2.3.7 |
| | Title | Other Toxicity Studies (if available) |
| | Element | m4-2-3-7-other-toxicity-studies |
| | Directory | m4/42-stud-rep/423-tox/4237-other-tox-stud |
| | Comment | |
| 238 | Number | 4.2.3.7.1 |

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| | Title | Antigenicity |
| | Element | m4-2-3-7-1-antigenicity |
| | Directory | m4/42-stud-rep/423-tox/4237-other-tox-stud/42371-antigen |
| | Comment | |
| 239 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-3-7-1-antigenicity |
| | File | m4/42-stud-rep/423-tox/4237-other-tox-stud/42371-antigen/ <i>study-report-1.pdf</i> |
| | Comment | |
| 240 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-3-7-1-antigenicity |
| | File | m4/42-stud-rep/423-tox/4237-other-tox-stud/42371-antigen/ <i>study-report-2.pdf</i> |
| | Comment | |
| 241 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-3-7-1-antigenicity |
| | File | m4/42-stud-rep/423-tox/4237-other-tox-stud/42371-antigen/ <i>study-report-3.pdf</i> |
| | Comment | |
| 242 | Number | 4.2.3.7.2 |
| | Title | Immunotoxicity |
| | Element | m4-2-3-7-2-immunotoxicity |
| | Directory | m4/42-stud-rep/423-tox/4237-other-tox-stud/42372-immunotox |
| | Comment | |
| 243 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-3-7-2-immunotoxicity |
| | File | m4/42-stud-rep/423-tox/4237-other-tox-stud/42372-immunotox/ <i>study-report-1.pdf</i> |
| | Comment | |
| 244 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-3-7-2-immunotoxicity |
| | File | m4/42-stud-rep/423-tox/4237-other-tox-stud/42372-immunotox/ <i>study-report-2.pdf</i> |

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| | Comment | |
| 245 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-3-7-2-immunotoxicity |
| | File | m4/42-stud-rep/423-tox/4237-other-tox-stud/42372-immunotox/study-report-3.pdf |
| | Comment | |
| 246 | Number | 4.2.3.7.3 |
| | Title | Mechanistic studies (if not included elsewhere) |
| | Element | m4-2-3-7-3-mechanistic-studies |
| | Directory | m4/42-stud-rep/423-tox/4237-other-tox-stud/42373-mechan-stud |
| | Comment | |
| 247 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-3-7-3-mechanistic-studies |
| | File | m4/42-stud-rep/423-tox/4237-other-tox-stud/42373-mechan-stud/study-report-1.pdf |
| | Comment | |
| 248 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-3-7-3-mechanistic-studies |
| | File | m4/42-stud-rep/423-tox/4237-other-tox-stud/42373-mechan-stud/study-report-2.pdf |
| | Comment | |
| 249 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-3-7-3-mechanistic-studies |
| | File | m4/42-stud-rep/423-tox/4237-other-tox-stud/42373-mechan-stud/study-report-3.pdf |
| | Comment | |
| 250 | Number | 4.2.3.7.4 |
| | Title | Dependence |
| | Element | m4-2-3-7-4-dependence |
| | Directory | m4/42-stud-rep/423-tox/4237-other-tox-stud/42374-dep |
| | Comment | |
| 251 | Number | |
| | Title | <i>Study Report 1</i> |

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| | Element | m4-2-3-7-4-dependence |
| | File | m4/42-stud-rep/423-tox/4237-other-tox-stud/42374-dep/study-report-1.pdf |
| | Comment | |
| 252 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-3-7-4-dependence |
| | File | m4/42-stud-rep/423-tox/4237-other-tox-stud/42374-dep/study-report-2.pdf |
| | Comment | |
| 253 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-3-7-4-dependence |
| | File | m4/42-stud-rep/423-tox/4237-other-tox-stud/42374-dep/study-report-3.pdf |
| | Comment | |
| 254 | Number | 4.2.3.7.5 |
| | Title | Metabolites |
| | Element | m4-2-3-7-5-metabolites |
| | Directory | m4/42-stud-rep/423-tox/4237-other-tox-stud/42375-metab |
| | Comment | |
| 255 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-3-7-5-metabolites |
| | File | m4/42-stud-rep/423-tox/4237-other-tox-stud/42375-metab/study-report-1.pdf |
| | Comment | |
| 256 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-3-7-5-metabolites |
| | File | m4/42-stud-rep/423-tox/4237-other-tox-stud/42375-metab/study-report-2.pdf |
| | Comment | |
| 257 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-3-7-5-metabolites |
| | File | m4/42-stud-rep/423-tox/4237-other-tox-stud/42375-metab/study-report-3.pdf |
| | Comment | |

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| 258 | Number | 4.2.3.7.6 |
| | Title | Impurities |
| | Element | m4-2-3-7-6-impurities |
| | Directory | m4/42-stud-rep/423-tox/4237-other-tox-stud/42376-imp |
| | Comment | |
| 259 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-3-7-6-impurities |
| | File | m4/42-stud-rep/423-tox/4237-other-tox-stud/42376-imp/ <i>study-report-1.pdf</i> |
| | Comment | |
| 260 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-3-7-6-impurities |
| | File | m4/42-stud-rep/423-tox/4237-other-tox-stud/42376-imp/ <i>study-report-2.pdf</i> |
| | Comment | |
| 261 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m4-2-3-7-6-impurities |
| | File | m4/42-stud-rep/423-tox/4237-other-tox-stud/42376-imp/ <i>study-report-3.pdf</i> |
| | Comment | |
| 262 | Number | 4.2.3.7.7 |
| | Title | Other |
| | Element | m4-2-3-7-7-other |
| | Directory | m4/42-stud-rep/423-tox/4237-other-tox-stud/42377-other |
| | Comment | |
| 263 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m4-2-3-7-7-other |
| | File | m4/42-stud-rep/423-tox/4237-other-tox-stud/42377-other/ <i>study-report-1.pdf</i> |
| | Comment | |
| 264 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m4-2-3-7-7-other |

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| | File | m4/42-stud-rep/423-tox/4237-other-tox-stud/42377-other/study-report-2.pdf |
| | Comment | |
| 265 | Number | |
| | Title | <i>Study Report 3</i> |
| | 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 | 通常、参考文献の写しは、個別のファイル（例えば、各参考文献ごと）として提出されるべきである。 |
| 267 | Number | |
| | Title | <i>Reference 1</i> |
| | Element | m4-3-literature-references |
| | File | m4/43-lit-ref/reference-1.pdf |
| | Comment | |
| 268 | Number | |
| | Title | <i>Reference 2</i> |
| | Element | m4-3-literature-references |
| | File | m4/43-lit-ref/reference-2.pdf |
| | Comment | |
| 269 | Number | |
| | Title | <i>Reference 3</i> |
| | Element | m4-3-literature-references |
| | File | m4/43-lit-ref/reference-3.pdf |
| | Comment | |

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| 270 | Number | 5 |
| | Title | Clinical Study Reports |
| | Element | m5-clinical-study-reports |
| | Directory | m5 |
| | Comment | |
| 271 | Number | 5.2 |
| | Title | Tabular Listing of all Clinical Studies |
| | Element | m5-2-tabular-listing-of-all-clinical-studies |
| | Directory | m5/52-tab-list |
| | Comment | |
| 272 | Number | 5.2 |
| | Title | Tabular Listing of all Clinical Studies |
| | Element | m5-2-tabular-listing-of-all-clinical-studies |
| | File | m5/52-tab-list/tabular-listing.pdf |
| | Comment | |
| 273 | Number | 5.3 |
| | Title | Clinical Study Reports |
| | Element | m5-3-clinical-study-reports |
| | Directory | m5/53-clin-stud-rep |
| | Comment | |
| 274 | Number | 5.3.1 |
| | Title | Reports of Biopharmaceutic Studies |
| | Element | m5-3-1-reports-of-biopharmaceutic-studies |
| | Directory | m5/53-clin-stud-rep/531-rep-biopharm-stud |
| | Comment | |
| 275 | Number | 5.3.1.1 |
| | Title | Bioavailability (BA) Study Reports |
| | Element | m5-3-1-1-bioavailability-study-reports |
| | Directory | m5/53-clin-stud-rep/531-rep-biopharm-stud/5311-ba-stud-rep |
| | Comment | |
| 276 | Number | |
| | Title | <i>Study Report 1</i> |

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| | 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 | このコメントはモジュール5の全試験報告書に適用される。 申請者は試験報告書を複数ファイル（概要、本文及び適切な付録）として提供すること。付録は、ICH E3 ガイドラインに記述された臨床試験報告書の内容と様式に従って構成すること。複数のファイル方式を採る場合に、ライフサイクルのあらゆる時点において、関連情報に変更があった際には、 <u>ファイル一式の置換を行うべきである。各試験に対してディレクトリを作成し、試験報告書に関連するファイルはそのディレクトリ内で整理すること。</u> 個々の試験およびファイルには特定の CTD 番号を付与しない。 |
| 277 | Number | |
| | Title | <i>Study Report 2</i> |
| | 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 | <i>Study Report 3</i> |
| | 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 | <i>Study Report 1</i> |
| | 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 | <i>Study Report 2</i> |
| | 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 |

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| | Comment | |
| 282 | Number | |
| | Title | <i>Study Report 3</i> |
| | 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-3 |
| | Comment | |
| 283 | Number | 5.3.1.3 |
| | Title | In vitro – In vivo Correlation Study Reports |
| | Element | m5-3-1-3-in-vitro-in-vivo-correlation-study-reports |
| | Directory | m5/53-clin-stud-rep/531-rep-biopharm-stud/5313-in-vitro-in-vivo-corr-stud-rep |
| | Comment | |
| 284 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m5-3-1-3-in-vitro-in-vivo-correlation-study-reports |
| | Directory | m5/53-clin-stud-rep/531-rep-biopharm-stud/5313-in-vitro-in-vivo-corr-stud-rep/study-report-1 |
| | Comment | |
| 285 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m5-3-1-3-in-vitro-in-vivo-correlation-study-reports |
| | Directory | m5/53-clin-stud-rep/531-rep-biopharm-stud/5313-in-vitro-in-vivo-corr-stud-rep/study-report-2 |
| | Comment | |
| 286 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m5-3-1-3-in-vitro-in-vivo-correlation-study-reports |
| | Directory | m5/53-clin-stud-rep/531-rep-biopharm-stud/5313-in-vitro-in-vivo-corr-stud-rep/study-report-3 |
| | Comment | |
| 287 | Number | 5.3.1.4 |
| | Title | Reports of Bioanalytical and Analytical Methods for Human Studies |
| | Element | m5-3-1-4-reports-of-bioanalytical-and-analytical-methods-for-human-studies |
| | Directory | m5/53-clin-stud-rep/531-rep-biopharm-stud/5314-bioanalyt-analyt-met |
| | Comment | |
| 288 | Number | |
| | Title | <i>Study Report 1</i> |

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| | Element | m5-3-1-4-reports-of-bioanalytical-and-analytical-methods-for-human-studies |
| | Directory | m5/53-clin-stud-rep/531-rep-biopharm-stud/5314-bioanalyt-analyt-met/study-report-1 |
| | Comment | |
| 289 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m5-3-1-4-reports-of-bioanalytical-and-analytical-methods-for-human-studies |
| | Directory | m5/53-clin-stud-rep/531-rep-biopharm-stud/5314-bioanalyt-analyt-met/study-report-2 |
| | Comment | |
| 290 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m5-3-1-4-reports-of-bioanalytical-and-analytical-methods-for-human-studies |
| | Directory | m5/53-clin-stud-rep/531-rep-biopharm-stud/5314-bioanalyt-analyt-met/study-report-3 |
| | Comment | |
| 291 | Number | 5.3.2 |
| | Title | Reports of Studies Pertinent to Pharmacokinetics using Human Biomaterials |
| | Element | m5-3-2-reports-of-studies-pertinent-to-pharmacokinetics-using-human-biomaterials |
| | Directory | m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat |
| | Comment | |
| 292 | Number | 5.3.2.1 |
| | Title | Plasma Protein Binding Study Reports |
| | Element | m5-3-2-1-plasma-protein-binding-study-reports |
| | Directory | m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/5321-plasma-prot-bind-stud-rep |
| | Comment | |
| 293 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m5-3-2-1-plasma-protein-binding-study-reports |
| | Directory | m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/5321-plasma-prot-bind-stud-rep/study-report-1 |
| | Comment | |
| 294 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m5-3-2-1-plasma-protein-binding-study-reports |
| | Directory | m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/5321-plasma-prot-bind-stud-rep/study-report-2 |
| | Comment | |

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| 295 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m5-3-2-1-plasma-protein-binding-study-reports |
| | Directory | m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/5321-plasma-prot-bind-stud-rep/ <i>study-report-3</i> |
| | Comment | |
| 296 | Number | 5.3.2.2 |
| | Title | Reports of Hepatic Metabolism and Drug Interaction Studies |
| | Element | m5-3-2-2-reports-of-hepatic-metabolism-and-drug-interaction-studies |
| | Directory | m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/5322-rep-hep-metab-interact-stud |
| | Comment | |
| 297 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m5-3-2-2-reports-of-hepatic-metabolism-and-drug-interaction-studies |
| | Directory | m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/5322-rep-hep-metab-interact-stud/ <i>study-report-1</i> |
| | Comment | |
| 298 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m5-3-2-2-reports-of-hepatic-metabolism-and-drug-interaction-studies |
| | Directory | m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/5322-rep-hep-metab-interact-stud/ <i>study-report-2</i> |
| | Comment | |
| 299 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m5-3-2-2-reports-of-hepatic-metabolism-and-drug-interaction-studies |
| | Directory | m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/5322-rep-hep-metab-interact-stud/ <i>study-report-3</i> |
| | Comment | |
| 300 | Number | 5.3.2.3 |
| | Title | Reports of Studies Using Other Human Biomaterials |
| | Element | m5-3-2-3-reports-of-studies-using-other-human-biomaterials |
| | Directory | m5/53-clin-stud-rep/532-rep-stud-pk-human-biomat/5323-stud-other-human-biomat |
| | Comment | |
| 301 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m5-3-2-3-reports-of-studies-using-other-human-biomaterials |

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| | Directory | m5/53-clin-stud-rep/532-rep-stud-pk-human-bioma/5323-stud-other-human-bioma/study-report-1 |
| | Comment | |
| 302 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m5-3-2-3-reports-of-studies-using-other-human-biomaterials |
| | Directory | m5/53-clin-stud-rep/532-rep-stud-pk-human-bioma/5323-stud-other-human-bioma/study-report-2 |
| | Comment | |
| 303 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m5-3-2-3-reports-of-studies-using-other-human-biomaterials |
| | Directory | m5/53-clin-stud-rep/532-rep-stud-pk-human-bioma/5323-stud-other-human-bioma/study-report-3 |
| | Comment | |
| 304 | Number | 5.3.3 |
| | Title | Reports of Human Pharmacokinetic (PK) Studies |
| | Element | m5-3-3-reports-of-human-pharmacokinetics-pk-studies |
| | Directory | m5/53-clin-stud-rep/533-rep-human-pk-stud |
| | Comment | |
| 305 | Number | 5.3.3.1 |
| | Title | Healthy Subject PK and Initial Tolerability Study Reports |
| | Element | m5-3-3-1-healthy-subject-pk-and-initial-tolerability-study-reports |
| | Directory | m5/53-clin-stud-rep/533-rep-human-pk-stud/5331-healthy-subj-pk-init-tol-stud-rep |
| | Comment | |
| 306 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m5-3-3-1-healthy-subject-pk-and-initial-tolerability-study-reports |
| | Directory | m5/53-clin-stud-rep/533-rep-human-pk-stud/5331-healthy-subj-pk-init-tol-stud-rep/study-report-1 |
| | Comment | |
| 307 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m5-3-3-1-healthy-subject-pk-and-initial-tolerability-study-reports |
| | Directory | m5/53-clin-stud-rep/533-rep-human-pk-stud/5331-healthy-subj-pk-init-tol-stud-rep/study-report-2 |
| | Comment | |
| 308 | Number | |

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| | Title | <i>Study Report 3</i> |
| | Element | m5-3-3-1-healthy-subject-pk-and-initial-tolerability-study-reports |
| | Directory | m5/53-clin-stud-rep/533-rep-human-pk-stud/5331-healthy-subj-pk-init-tol-stud-rep/ <i>study-report-3</i> |
| | Comment | |
| 309 | Number | 5.3.3.2 |
| | Title | Patient PK and Initial Tolerability Study Reports |
| | Element | m5-3-3-2-patient-pk-and-initial-tolerability-study-reports |
| | Directory | m5/53-clin-stud-rep/533-rep-human-pk-stud/5332-patient-pk-init-tol-stud-rep |
| | Comment | |
| 310 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m5-3-3-2-patient-pk-and-initial-tolerability-study-reports |
| | Directory | m5/53-clin-stud-rep/533-rep-human-pk-stud/5332-patient-pk-init-tol-stud-rep/ <i>study-report-1</i> |
| | Comment | |
| 311 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m5-3-3-2-patient-pk-and-initial-tolerability-study-reports |
| | Directory | m5/53-clin-stud-rep/533-rep-human-pk-stud/5332-patient-pk-init-tol-stud-rep/ <i>study-report-2</i> |
| | Comment | |
| 312 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m5-3-3-2-patient-pk-and-initial-tolerability-study-reports |
| | Directory | m5/53-clin-stud-rep/533-rep-human-pk-stud/5332-patient-pk-init-tol-stud-rep/ <i>study-report-3</i> |
| | Comment | |
| 313 | Number | 5.3.3.3 |
| | Title | Intrinsic Factor PK Study Reports |
| | Element | m5-3-3-3-intrinsic-factor-pk-study-reports |
| | Directory | m5/53-clin-stud-rep/533-rep-human-pk-stud/5333-intrin-factor-pk-stud-rep |
| | Comment | |
| 314 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m5-3-3-3-intrinsic-factor-pk-study-reports |
| | Directory | m5/53-clin-stud-rep/533-rep-human-pk-stud/5333-intrin-factor-pk-stud-rep/ <i>study-report-1</i> |

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| | Comment | |
| 315 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m5-3-3-3-intrinsic-factor-pk-study-reports |
| | Directory | m5/53-clin-stud-rep/533-rep-human-pk-stud/5333-intrin-factor-pk-stud-rep/study-report-2 |
| | Comment | |
| 316 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m5-3-3-3-intrinsic-factor-pk-study-reports |
| | Directory | m5/53-clin-stud-rep/533-rep-human-pk-stud/5333-intrin-factor-pk-stud-rep/study-report-3 |
| | Comment | |
| 317 | Number | 5.3.3.4 |
| | Title | Extrinsic Factor PK Study Reports |
| | Element | m5-3-3-4-extrinsic-factor-pk-study-reports |
| | Directory | m5/53-clin-stud-rep/533-rep-human-pk-stud/5334-extrin-factor-pk-stud-rep |
| | Comment | |
| 318 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m5-3-3-4-extrinsic-factor-pk-study-reports |
| | Directory | m5/53-clin-stud-rep/533-rep-human-pk-stud/5334-extrin-factor-pk-stud-rep/study-report-1 |
| | Comment | |
| 319 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m5-3-3-4-extrinsic-factor-pk-study-reports |
| | Directory | m5/53-clin-stud-rep/533-rep-human-pk-stud/5334-extrin-factor-pk-stud-rep/study-report-2 |
| | Comment | |
| 320 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m5-3-3-4-extrinsic-factor-pk-study-reports |
| | Directory | m5/53-clin-stud-rep/533-rep-human-pk-stud/5334-extrin-factor-pk-stud-rep/study-report-3 |
| | Comment | |
| 321 | Number | 5.3.3.5 |
| | Title | Population PK Study Reports |

| | | |
|-----|-----------|--|
| | Element | m5-3-3-5-population-pk-study-reports |
| | Directory | m5/53-clin-stud-rep/533-rep-human-pk-stud/5335-popul-pk-stud-rep |
| | Comment | |
| 322 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m5-3-3-5-population-pk-study-reports |
| | Directory | m5/53-clin-stud-rep/533-rep-human-pk-stud/5335-popul-pk-stud-rep/ <i>study-report-1</i> |
| | Comment | |
| 323 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m5-3-3-5-population-pk-study-reports |
| | Directory | m5/53-clin-stud-rep/533-rep-human-pk-stud/5335-popul-pk-stud-rep/ <i>study-report-2</i> |
| | Comment | |
| 324 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m5-3-3-5-population-pk-study-reports |
| | Directory | m5/53-clin-stud-rep/533-rep-human-pk-stud/5335-popul-pk-stud-rep/ <i>study-report-3</i> |
| | Comment | |
| 325 | Number | 5.3.4 |
| | Title | Reports of Human Pharmacodynamic (PD) Studies |
| | Element | m5-3-4-reports-of-human-pharmacodynamics-pd-studies |
| | Directory | m5/53-clin-stud-rep/534-rep-human-pd-stud |
| | Comment | |
| 326 | Number | 5.3.4.1 |
| | Title | Healthy Subject PD and PK/PD Study Reports |
| | Element | m5-3-4-1-healthy-subject-pd-and-pk-pd-study-reports |
| | Directory | m5/53-clin-stud-rep/534-rep-human-pd-stud/5341-healthy-subj-pd-stud-rep |
| | Comment | |
| 327 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m5-3-4-1-healthy-subject-pd-and-pk-pd-study-reports |
| | Directory | m5/53-clin-stud-rep/534-rep-human-pd-stud/5341-healthy-subj-pd-stud-rep/ <i>study-report-1</i> |
| | Comment | |

| | | |
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| 328 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m5-3-4-1-healthy-subject-pd-and-pk-pd-study-reports |
| | Directory | m5/53-clin-stud-rep/534-rep-human-pd-stud/5341-healthy-subj-pd-stud-rep/ <i>study-report-2</i> |
| | Comment | |
| 329 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m5-3-4-1-healthy-subject-pd-and-pk-pd-study-reports |
| | Directory | m5/53-clin-stud-rep/534-rep-human-pd-stud/5341-healthy-subj-pd-stud-rep/ <i>study-report-3</i> |
| | Comment | |
| 330 | Number | 5.3.4.2 |
| | Title | Patient PD and PK/PD Study Reports |
| | Element | m5-3-4-2-patient-pd-and-pk-pd-study-reports |
| | Directory | m5/53-clin-stud-rep/534-rep-human-pd-stud/5342-patient-pd-stud-rep |
| | Comment | |
| 331 | Number | |
| | Title | <i>Study Report 1</i> |
| | Element | m5-3-4-2-patient-pd-and-pk-pd-study-reports |
| | Directory | m5/53-clin-stud-rep/534-rep-human-pd-stud/5342-patient-pd-stud-rep/ <i>study-report-1</i> |
| | Comment | |
| 332 | Number | |
| | Title | <i>Study Report 2</i> |
| | Element | m5-3-4-2-patient-pd-and-pk-pd-study-reports |
| | Directory | m5/53-clin-stud-rep/534-rep-human-pd-stud/5342-patient-pd-stud-rep/ <i>study-report-2</i> |
| | Comment | |
| 333 | Number | |
| | Title | <i>Study Report 3</i> |
| | Element | m5-3-4-2-patient-pd-and-pk-pd-study-reports |
| | Directory | m5/53-clin-stud-rep/534-rep-human-pd-stud/5342-patient-pd-stud-rep/ <i>study-report-3</i> |
| | Comment | |
| 334 | Number | 5.3.5 |
| | Title | Reports of Efficacy and Safety Studies |
| | Element | m5-3-5-reports-of-efficacy-and-safety-studies |