FORMAT CTD vs MBR1 vs MRF1

Dividers have to be included as specified in the ICH Topic M4, CTD for the Registration of Pharmaceuticals for Human Use – Organisation CTD, Annex A Granularity Document for Modules 2 to 5 (http://www.ich.org/LOB/media/MEDIA554.pdf, or http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002721.pdf)

Dividers for Module 1 must be included as specified in Part A, point 8, of the Guidance for the submission of the SA CTD/eCTD – General & Module 1

Dividers for 3.2.R must be included as specified in the Pharmaceutical & Analytical CTD/eCTD guideline, under granularity for section 3.2.R

CTD	***Information required***	***MBR1***	***MRF1***	***Conversion guidance***
Module 1	**Administrative and labelling**	**-**	**-**	**Include CTD divider - No**
1.0	**Letter of application**	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Yes Standard text to state dossier conversion? No Use current amendment letter and take schedule to 1.5.2.1
1.1	**Comprehensive table of contents**	Not part of dossier	PART 1B	Include CTD divider - **Yes** Yes, if applicable and replace with CTD TOC - reflect status (**i.e.** indicate which parts in MRF1 **(or MBR1)** and which in CTD). **The TOC serves the additional purpose of a "transition status summary".**
1.2	**Application**	-	-	**Necessary to include CTD divider? No**
1.2.1	**Application form**	MBR1 front cover	PART 1A	Include CTD divider Yes and add additional information (e.g. SMF numbers, etc).
1.2.2	**Annexes**	**-**	**-**	**Necessary to include CTD divider? No**
1.2.2.1	Proof of payment	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Yes, if applicable **for present amendment**

CTD	Information required	MBR1	MRF1	Conversion guidance
1.2.2.2	Letter of authorization for communication on behalf of applicant/PHCR	Not part of dossier	PART 1A	Include CTD divider Yes~~, if applicable~~ and move letter.
1.2.2.3	Dossier product batch information	ANNEXURE 16	PART 3H (or may not be available in the required tabular format)	Necessary to include CTD divider? Yes, if applicable. Include new info if required for type of amendment **presently being submitted.** Indicate in letter and ToC (1.1) if not required at time of registration
1.2.2.4	Electronic copy declaration	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Yes, if applicable **for present amendment**
1.2.2.5	CV of person responsible for pharmacovigilance	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Yes Must we include it as additional information? Yes
1.2.2.6	~~Copy of written confirmation from the manufacturer of the API to inform the applicant in case of modification of the manufacturing process or specifications~~ API change control	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Yes, if applicable **for present amendment**
1.2.2.7	~~Copy of~~ EMEA certificate for a Vaccine Antigen Master File (VAMF)	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Yes, if applicable **for present amendment**
1.2.2.8	~~Copy~~ of EMEA certificate for a Plasma Master File (PMF)	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Yes, if applicable **for present amendment**
1.3	**South African labeling and packaging**	**-**	**-**	**Include CTD divider No**
1.3.1	~~Proposed~~ package insert	ANNEXURE 1	PART 1C	Include CTD divider and move PI text. Yes~~, if applicable~~
1.3.2	~~Proposed~~ patient information leaflet	ANNEXURE 1	PART 1C	Include CTD divider and move PIL text. Yes~~, if applicable~~
1.3.3	Labels	ANNEXURE 1	PART 1C	Include CTD divider and move label text. Yes~~, if applicable~~

Comment [MSOffice1]: Hilde: it should always be included from the point of conversion onwards, so I deleted "if applicable" here

Comment [MSOffice2]: Hilde: it should always be included when a dossier is converted, so I deleted "if applicable" here

CTD	Information required	MBR1	MRF1	Conversion guidance
1.3.4	Braille	Not part of dossier	Not part of dossier	Necessary to include CTD divider? **No** ~~Yes, if applicable~~ Indicate in letter and ToC (1.1) if not required at time of registration
1.4	**Information about the experts**	**-**	**-**	**Include CTD divider No**
1.4.1.	Quality	Not part of dossier	Part of PART 2C	If conversion from MRF1: Include CTD divider and move information. (If conversion from MBR1: Necessary to include CTD divider? Yes, if applicable
1.4.2	Non-clinical	Not part of dossier	Part of PART 2D	If conversion from MRF1: Include CTD divider and move information. (If conversion from MBR1: Necessary to include CTD divider? Yes, if applicable
1.4.3	Clinical	Not part of dossier	Part of PART 2E	If conversion from MRF1: Include CTD divider and move information. (If conversion from MBR1: Necessary to include CTD divider? Yes, if applicable
1.5	**Specific requirements for different types of applications**	**-**	**-**	**Include CTD divider No**
1.5.1	Literature based submissions	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Yes, if applicable
1.5.2	Amendments/Variations	Not part of dossier	Amendment history table in PART 1A	Include CTD divider No and move information No still in 1.2.1
1.5.2.1	~~Amendment covering letter with~~ tabulated schedule of amendments	Not part of dossier	Not part of dossier	Include CTD divider Yes, if applicable **for present amendment** and start including the information required here from now on.

CTD	Information required	MBR1	MRF1	Conversion guidance
1.5.2.2	Medicine Register Details	Not part of dossier	Not part of dossier	Include CTD divider **Yes, if applicable for present amendment** and start including the information required here from now on.
1.5.2.3	Affidavit by Responsible Pharmacist	Not part of dossier	Not part of dossier	Include CTD divider **Yes, if applicable for present amendment** and start including the information required here from now on.
1.5.3	Proprietary name applications and changes	Not part of dossier	Not part of dossier	Include CTD divider **Yes, if applicable for present amendment** and start including the information required here from now on.
1.5.4	Genetically modified organisms	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Yes, if applicable **for present amendment**
1.6	**Environmental risk assessment**	**-**	**-**	**Necessary to include CTD divider?** Yes, optional if applicable Indicate in letter and ToC (1.1) if not required at time of registration
1.6.1	Non-GMO (genetically modified organisms)	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Optional
1.6.2	GMO	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Optional
1.7	**Good manufacturing practice**	**-**	**-**	**Necessary to include CTD divider? No**
1.7.1	Date of last inspection of each site by SA regulatory authority or other authority of a country with which South Africa aligns itself	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Yes, if applicable **for present amendment**
1.7.2	Inspection reports or equivalent document (not older than 3 years) from the local Health Authority and/or FDA, MHRA, TGA, EU, Canada, PIC/s country	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Yes, if applicable **for present amendment**

CTD	Information required	MBR1	MRF1	Conversion guidance
1.7.3	Latest GMP certificate (not older than 3 years) for manufacturer/s and packer/s or a copy of the appropriate manufacturing licence	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Yes, if applicable **for present amendment**
1.7.4	Local release	ANNEXURE 9A	PART 3F	Include CTD divider Yes, if applicable and move information
1.7.4.1	Finished Product Release Control (FPRC) tests	ANNEXURE 9A	PART 3F	Include CTD divider Optional and move information
1.7.4.2	Finished Product Release Responsibility (FPRR) criteria	ANNEXURE 9A	PART 3F	Include CTD divider Optional and move information
1.7.5	Confirmation of contract between manufacturer/s, packer/s and HCR/PHCR	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Yes, if applicable **for present amendment**
1.7.6	CPP (WHO certification scheme)			Include divider if applicable
1.7.7	Proof of registration of Responsible Pharmacist by the SAPC in terms of Act 53 (Pharmacy Act)	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Yes, if applicable **for present amendment**
1.7.8	Proof of registration by the SAPC in terms of Act 53 (Pharmacy Act) of the pharmacist signing the dossier (if different from the Responsible Pharmacist)	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Yes, if applicable **for present amendment**
1.7.9	Proof (copy) of the certificate of registration of the Applicant/PHCR as a pharmacy or a pharmacist (read with guidelines)	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Yes, if applicable **for present amendment**
1.7.10	Sample and documents	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Yes, **but only applies to new applications for registration, not conversions**
1.7.10.1	Confirmation of submission of sample	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Optional

CTD	Information required	MBR1	MRF1	Conversion guidance
1.7.10.2	Batch manufacturing record of the sample	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Optional, **but only applies to new applications for registration, not conversions**
1.7.10.3	CoA of the sample	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Optional, **but only applies to new applications for registration, not conversions**
~~1.7.10~~	~~Master documentation included in Module 3.2.P.3.3 or available for inspection~~	~~Not part of dossier~~	~~Not part of dossier~~	~~Necessary to include CTD divider? Standard text to state dossier conversion?~~
1.7.11	Certified copy of a permit to manufacture specified Schedule 5, 6 7 and 8 substances	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Yes, if applicable ~~**Standard text to state dossier conversion?**~~
1.7.12	Inspection flow diagram	ANNEXURE 11	PART 3E	Include CTD divider Yes, if applicable and move information
1.8	**Details of compliance with screening outcomes**	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Not applicable to registered product ~~**Standard text to state dossier conversion**?~~
1.9	**Individual patient data – statement of availability**	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Not if registered ~~**Standard text to state dossier conversion?**~~
1.10	Foreign regulatory status	ANNEXURE 12	PART 1D	Include CTD divider Not for 1.10; yes for 1.10.1 to 1.10.3 if applicable and move information. Is it necessary to provide an updated international registration status and provide additional approved foreign package inserts? We are of the opinion
1.10.1	List of countries in which an application for the same product as being applied for has been submitted			
1.10.2	Registration certificate or marketing authorisation			

CTD	Information required	MBR1	MRF1	Conversion guidance
1.10.3	Foreign prescribing and patient information			that this may not be useful as the dossier conversions to not go to the clinical section of the MCC. **Move/transcribe existing info and add any negative decisions only**
1.10.4	Data set similarities	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Not if registered
1.11	**Bioequivalence trial information**			**Include CTD divider Yes**
1.11.1	Study Title(s) (or brief description giving design, duration, dose and subject population of each study)	ANNEXURE 13	PART 2A	We suggest to include CTD divider at highest level only (1.11) ~~and only include TOC of previously approved information and/or standard text to state dossier conversion.~~ 1.11 is a one page tabulated summary of the info required
1.11.2	Protocol and study numbers	Refer to line 1.11.1	Refer to line 1.11.1	Refer to line 1.11.1
1.11.3	Investigational products (test and reference) details	Refer to line 1.11.1	Refer to line 1.11.1	Refer to line 1.11.1
1.11.4	confirmation that the test product formulation and manufacturing process is that being applied for	Refer to line 1.11.1	Refer to line 1.11.1	Refer to line 1.11.1
1.11.5	Proof of procurement of biostudy reference product	Refer to line 1.11.1	Refer to line 1.11.1	Refer to line 1.11.1
1.11.6	Name and address of the Research Organisation(s) / Contract Research Organisation(s) where the bioequivalence studies were conducted	Refer to line 1.11.1	Refer to line 1.11.1	Refer to line 1.11.1

CTD	Information required	MBR1	MRF1	Conversion guidance
1.11.7	Sponsor and responsible sponsor representative: name and address, contact details	Refer to line 1.11.1	Refer to line 1.11.1	Refer to line 1.11.1
1.11.8	Duration of Clinical phase: dates of dosing and last clinical procedure	Refer to line 1.11.1	Refer to line 1.11.1	Refer to line 1.11.1
1.11.9	Date of final report	Refer to line 1.11.1	Refer to line 1.11.1	Refer to line 1.11.1
1.12	**Paediatric development programme**	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Not if registered
1.13	**Risk management plan**	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Not if registered
Module 2	**CTD Summaries**	**-**	**-**	**Include CTD divider No**
2.1	**CTD Table of Contents (Modules 2 to 5)**	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Yes
2.2	**Introduction**	Not part of dossier	Not part of dossier	Necessary to include CTD divider? Yes, if applicable **When converting – Include brief explanation/summary re API, indications and data submitted for efficacy in original submission.**
2.3	**Quality Overall Summary – Introduction** **Only if 2C was included**	Not part of dossier	PART 2C	If conversion from MRF1: Include CTD divider and move information. We suggest to only include CTD divider at level 2.3. (If conversion from MBR1: Necessary to include CTD divider?) **Granularity can be at the level of 2.3 or 2.3.S, 2.3.P and 2.3.A or 2.3.S.1-7, 2.3.P.1-8 and 2.3.A.1-3. It depends on the applicant and future life cycle of product**

CTD	Information required	MBR1	MRF1	Conversion guidance
2.3.S	**Quality Overall Summary – Active Pharmaceutical Ingredients**	Refer to line 2.3.	Refer to line 2.3.	Refer to line 2.3.
2.3.S.1 – 2.3.S.7	Quality Overall Summary – Active Pharmaceutical Ingredients	Refer to line 2.3.	Refer to line 2.3.	Refer to line 2.3.
2.3.P.1 – 2.3.P.8	Quality Overall Summary – Finished Pharmaceutical Product	Refer to line 2.3.	Refer to line 2.3.	Refer to line 2.3.
2.3.A.1 – 2.3.A.3	Quality Overall Summary - Appendices	Refer to line 2.3.	Refer to line 2.3.	Refer to line 2.3.
2.4	**Non-clinical Overview** **Only if 2D was included 2.4 + 2.6**	Not part of dossier or may be in ANNEXURE 14	PART 2D	If conversion from MRF1: Include CTD divider and move information. We suggest to only include CTD divider at level 2.4. Yes if applicable
2.5.1 – 2.5.7	**Clinical Overview 2.5 + 2.7**	Refer to line 2.4.	Refer to line 2.4.	Refer to line 2.4. Divider at 2.5
2.6.1 – 2.6.7	**Non-clinical written and tabulated summaries**	Refer to line 2.4.	Refer to line 2.4.	Refer to line 2.4 Dividers at 2.6.1-7 if applicable
2.7.1 – 2.7.6	**Clinical summary** **Only if 2E was included**	Not part of dossier or may be in ANNEXURE 15	PART 2E	If conversion from MRF1: Include CTD divider and move information. We suggest to only include CTD divider at level 2.5. Yes if applicable. Dividers at 2.7.1-6 if applicable
Module 3	**Quality**	**-**	**-**	**Include CTD divider No**
3.1	**Table of contents of Module 3**	Not part of dossier	PART 1B	Include CTD divider Yes and replace with CTD Module 3 TOC
3.2	**Body of data**	**-**	**-**	**Include CTD divider No**
3.2.S	**Active pharmaceutical ingredient**	**-**	**-**	**Include CTD divider No**
3.2.S.1	General information	ANNEXURE 3	PART 3A	Include CTD divider No ~~and move information~~

CTD	Information required	MBR1	MRF1	Conversion guidance
3.2.S.1.1	Nomenclature	ANNEXURE 3	PART 3A	Include CTD divider Yes and move information
3.2.S.1.2	Structure	ANNEXURE 3	PART 3A	Include CTD divider Yes and move information
3.2.S.1.3	General properties	ANNEXURE 3	PART 3A	Include CTD divider Yes and move information
3.2.S.2	**Manufacture**	**-**	**-**	**Include CTD divider No**
3.2.S.2.1	Manufacturer(s)	ANNEXURE 3	PART 3A	Include CTD divider Yes and move information
3.2.S.2.2	Description of manufacturing process and process controls	ANNEXURE 3	PART 3A	Include CTD divider Yes and move information
3.2.S.2.3	Control of materials	Not included	Not included	Necessary to include CTD divider? Yes if applicable to **present** amendment. **Indicate in letter and ToC (1.1) if not required at time of registration**
3.2.S.2.4	Controls of critical steps and intermediates	Not included	Not included	Necessary to include CTD divider? Yes if applicable to **present** amendment. **Indicate in letter and ToC (1.1) if not required at time of registration**
3.2.S.2.5	Process validation and/or evaluation	ANNEXURE 3	PART 3A	Include CTD divider Yes, if applicable and move information
3.2.S.2.6	Manufacturing process development	ANNEXURE 3	PART 3A	Include CTD divider Yes, if applicable and move information
3.2.S.3	**Characterisation**	**-**	**-**	**Include CTD divider No**
3.2.S.3.1	Elucidation of structure and other characteristics	ANNEXURE 3	PART 3A	Include CTD divider Yes and move information
3.2.S.3.2	Impurities	ANNEXURE 3	PART 3A	Include CTD divider Yes and move information

CTD	Information required	MBR1	MRF1	Conversion guidance
3.2.S.4	**Control of active pharmaceutical ingredient**	**-**	**-**	**Include CTD divider No**
3.2.S.4.1	Specifications	ANNEXURE 4	PART 3A or PART 3C	Include CTD divider Yes and move information
3.2.S.4.2	Analytical procedures	ANNEXURE 5	PART 3A or PART 3C	Include CTD divider Yes and move information
3.2.S.4.3	Validation of analytical procedures	ANNEXURE 5	PART 3A or PART 3C	Include CTD divider Yes and move information
3.2.S.4.4	Batch analyses	Not included	Usually only CoAs	Include CTD divider Yes and move information (CoA or batch analyses report)
3.2.S.4.5	Justification of specification	Not included	Not included	Necessary to include CTD divider? Yes if applicable to **present** amendment. **Indicate in letter and ToC (1.1) if not required at time of registration**
3.2.S.5	**Reference standards or materials**	Not included	Not included	Necessary to include CTD divider? Yes if applicable to **present** amendment. **Indicate in letter and ToC (1.1) if not required at time of registration**
3.2.S.6	**Container closure system**	ANNEXURE 3	PART 3A	Include CTD divider Yes and move information
3.2.S.7	**Stability**	**-**	**-**	**Include CTD divider No**
3.2.S.7.1	Stability summary and conclusions	ANNEXURE 10 a	PART 3A	Include CTD divider Yes and move information
3.2.S.7.2	Post-approval stability protocol and stability commitment	Not included	PART 3A	Include CTD divider Yes and move information
3.2.S.7.3	Stability data	ANNEXURE 10 a	PART 3A	Include CTD divider Yes and move information
3.2.P	**Pharmaceutical product**	**-**	**-**	**Include CTD divider No**

CTD	Information required	MBR1	MRF1	Conversion guidance
3.2.P.1	**Description and composition of the pharmaceutical product**	**ANNEXURE 2**	**PART 3B**	**Include CTD divider** Yes
3.2.P.2.1-3.2.P.2.6	**Pharmaceutical development** **Only if 3H was submitted**	ANNEXURE 16, but for older products would not be included	PART 3H	Include CTD divider. We suggest to only include CTD divider at level 3.2.P.2 and copy of front page of document or TOC only. (If conversion from MBR1: Necessary to include CTD divider? Standard text to state dossier conversion?) Divider can be at 3.2.P.2 or 3.2.P.2.1-6 - It depends on the applicant and future life cycle of product
3.2.P.3	**Manufacture**	**-**	**-**	**Include CTD divider No**
3.2.P.3.1	Manufacturer(s)	ANNEXURE 11	PART 3E	Include CTD divider Yes and move information
3.2.P.3.2	Batch formula	ANNEXURE 11	PART 3E	Include CTD divider Yes and move information
3.2.P.3.3	Description of manufacturing process and process controls	ANNEXURE 11	PART 3E	Include CTD divider Yes and move information
3.2.P.3.4	Controls of critical steps and intermediates	ANNEXURE 11	PART 3E	Include CTD divider Yes and move information
3.2.P.3.5	Process validation and/or evaluation	ANNEXURE 11	PART 3E	Include CTD divider Yes and move information
3.2.P.4	**Control of inactive pharmaceutical ingredients**	**-**	**-**	**Include CTD divider No**
3.2.P.4.1	Specifications	ANNEXURE 4	PART 3C	Include CTD divider Yes and move information
3.2.P.4.2	Analytical procedures	ANNEXURE 5	PART 3C	Include CTD divider Yes and move information
3.2.P.4.3	Validation of analytical procedures	ANNEXURE 5	PART 3C	Include CTD divider Yes and move information

CTD	Information required	MBR1	MRF1	Conversion guidance
3.2.P.4.4	Justification of specifications	Not included	Not included	Necessary to include CTD divider? Yes if applicable. Indicate in letter and ToC (1.1) if not required at time of registration
3.2.P.4.5	Excipients of human or animal origin	Not included	Not included	Necessary to include CTD divider? Yes
3.2.P.4.6	Novel excipients	Not included	Not included	Necessary to include CTD divider? Yes if applicable Indicate in letter and ToC (1.1) if not required at time of registration
	4.3 – 4.6 Only if previously submitted			
3.2.P.5	**Control of pharmaceutical product**	**-**	**-**	**Include CTD divider No**
3.2.P.5.1	Specification(s)	ANNEXURE 7A	PART 3F	Include CTD divider Yes and move information
3.2.P.5.2	Analytical procedures	ANNEXURE 7B	PART 3F	Include CTD divider Yes and move information
3.2.P.5.3	Validation of analytical procedures	ANNEXURE 7B	PART 3F	Include CTD divider Yes and move information
3.2.P.5.4	Batch analyses	Not included	PART 3F Usually only CoA	Include CTD divider Yes and move information (CoA or batch analyses report)
3.2.P.5.5	Characterisation of impurities Only if included previously	Not included	PART 3F or not included	Include CTD divider Yes and move information (if included)
3.2.P.5.6	Justification of specifications Only if included previously	Not included	Not included	Necessary to include CTD divider? Yes
3.2.P.6	**Reference standards or materials** Only if included previously	Not included	Not included	Necessary to include CTD divider? Yes if applicable
3.2.P.7	**Container closure system**	ANNEXURE 8A and 8B	PART 3D	Include CTD divider Yes and move information
3.2.P.8	**Stability data**	**-**	**-**	**Include CTD divider No**

CTD	Information required	MBR1	MRF1	Conversion guidance
3.2.P.8.1	Stability summary and conclusion	ANNEXURE 10	PART 3G	Include CTD divider Yes and move information
3.2.P.8.2	Post-approval stability protocol and stability commitment	ANNEXURE 10	PART 3G	Include CTD divider Yes and move information
3.2.P.8.3	Stability data	ANNEXURE 10	PART 3G	Include CTD divider Yes and move information
3.2.A	**Appendices**	**-**	**-**	**Necessary to include CTD divider? No**
3.2.A.1	Facilities and equipment Only for biologicals	Ann??	**PART 3I**	Necessary to include CTD divider? Yes, if applicable
3.2.A.2	Adventitious agents safety evaluation Only if submitted previously	Not included	Not included	Necessary to include CTD divider? Yes, if applicable
3.2.A.3	Excipients Only if included previously	Not included	Not included	Necessary to include CTD divider? Yes, if applicable
3.2.R	**Regional information**	**-**	**-**	**Include CTD divider No**
3.2.R.1	**Pharmaceutical and biological availability**	**-**	**-**	**Include CTD divider No**
3.2.R.1 3.2.R.1.1 3.2.R.1.2 3.2.R.1.3	~~Information regarding the biostudies~~ Pharmaceutical & Biological Availability Overview Reference product/s (local and foreign) Certificates of Analysis	ANNEXURE 13	PART 2A	Include CTD divider. We suggest to only include CTD divider at level 3.2.R.1 No Dividers required at 3.2.R.1.1, 3.2.R.1.2 and 3.2.R.1.3 if applicable
3.2.R.1.4	Pharmaceutical availability studies	-	-	Include CTD divider Can include divider at 3.2.R.1.4 or at 3.2.R.1.4.1/2 if applicable. It depends on the applicant and future life cycle of product

CTD	Information required	MBR1	MRF1	Conversion guidance
3.2.R.1.4.1	Dissolution studies, data and reports	ANNEXURE 13	PART 2A	Include CTD divider. Optional if applicable Dissolution data & reports to be included if submitted previously
3.2.R.1.4.2	Other	-	-	Necessary to include CTD divider? Optional if applicable
3.2.R.2	**~~Formal declaration on process – API from different site of same parent company~~** **Parent API manufacturer with various sites**	ANNEXURE 3	PART 3A	Include CTD divider Yes, if applicable and move information
3.2.R.3	**Certificate of suitability with respect to the Ph. Eur. (CEPs)**	ANNEXURE 3	PART 3A	Include CTD divider Yes, if applicable and move information
3.2.R.4	**~~Information and data: API sourced from multiple manufacturers~~** **Multiple API manufacturers**	ANNEXURE 3	PART 3A	Include CTD divider No ~~and move information~~
3.2.R.4.1	Comparative API manufacturers study report	ANNEXURE 3	PART 3A	Include CTD divider Yes, if applicable and move information
3.2.R.4.2	~~Tabulated~~ Comparative results ~~from different manufacturing sources~~	ANNEXURE 3	PART 3A	Include CTD divider Yes, if applicable and move information
3.2.R.4.3	Confirmation of compliance with guidelines	Not included	Not included	Necessary to include CTD divider? Yes, if applicable
3.2.R.4.4	Certificates of analysis ~~for each batch of API reported on in 3.2.R.3.2~~	ANNEXURE 3	PART 3A	Include CTD divider Yes, if applicable and move information
3.2.R.5	**Medical device**	Not included	Not included	Necessary to include CTD divider? Yes, if applicable
3.2.R.6	**~~Medicinal products containing or manufactured with~~ Materials of animal and/or human origin**	ANNEXURE 4	PART 3C	Include CTD divider Yes and move information

CTD	Information required	MBR1	MRF1	Conversion guidance
3.2.R.7	**~~Executed~~ Batch records of samples ~~or confirmation that they are available for inspection~~** **Not required if registered**	Not included	Not included	Necessary to include CTD divider? Not applicable for conversions and amendment
3.2.R.8	**Other**	Not included	Not included	Necessary to include CTD divider? Not applicable for conversions and amendment
3.3	**Literature references**	Not included	Not included	Necessary to include CTD divider? Not applicable for conversions and amendment
Module 4	**Non-clinical study reports**	**ANNEXURE 14**	**PART 4**	**Include CTD divider No** **For conversion to CTD, if PART 4 doesn't have to be resubmitted, leave Module 4 out**
4.1	Table of contents of Module 4	ANNEXURE 14	PART 4	**Include CTD divider No** **~~We suggest to only include CTD divider at level 4 and copy of front pages or previous TOC only.~~**
4.2.1 – 4.2.3.7.7	Study reports	Refer to line 4.1	Refer to line 4.1	Refer to line 4.1
4.3	Literature references	Refer to line 4.1	Refer to line 4.1	Refer to line 4.1
Module 5	**Clinical study reports**	**ANNEXURE 15**	**PART 5**	**Include CTD divider No** **For conversion to CTD, if PART 5 doesn't have to be resubmitted, leave Module 5 out**
5.1	Table of contents of Module 5	ANNEXURE 15	PART 5	Include CTD divider. **No** ~~We suggest to only include CTD divider at level 5 and copy of front pages or previous TOC only.~~
5.2	Tabular listing of all clinical studies	Refer to line 5.1	Refer to line 5.1	Refer to line 5.1

CTD	Information required	MBR1	MRF1	Conversion guidance
5.3	Clinical study reports	Refer to line 5.1	Refer to line 5.1	Refer to line 5.1
5.4	Literature references	Refer to line 5.1	Refer to line 5.1	Refer to line 5.1