Guidance for Industry on Providing Regulatory Information in Electronic Format:

Non-eCTD electronic Submissions (NeeS) for human medicinal products

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Content

1 Introduction

In 2005 the Heads of Medicines Agencies agreed that all Member States would be able to accept electronic-only submissions, without accompanying paper copies, by the end of 2009. Some NCAs did not reach the target by this year but the work will continue. The benefits of moving to e-working are considered to be:

- Reduction of (internal) paper-flow (logistics and administrative burden),
- Reduction of physical archiving space,
- Facilitation of the review process.

This Guidance Document is intended to assist pharmaceutical companies with the submission of regulatory information in electronic format to the National Competent Authorities (hereafter referred to as NCAs). This document details the requirements for the submission of Non-eCTD electronic Submissions (NeeS). A separate EU guidance document covering eCTD submissions has also been published on the EMA eSubmission website.

This document has been created by the Harmonisation Group, a sub-group of the Telematics Implementation Group for electronic submissions (TIGes), and been adopted for publication by the TIGes. It is strongly recommended that all National Competent Authorities adopt this guidance as the basis for their dealings with applicants when using the NeeS format.

It should be stressed that this Guidance Document reflects the *current* situation and will be regularly updated in the light of changes in national and/or European legislation together with further experience gained within NCAs of using information submitted in electronic format. It should be emphasised that NeeS applications should be regarded as an interim format and that applicants should be actively planning their move to full eCTD submissions.

2 General considerations

2.1 Scope

2.1.1 Types of procedures

This guidance covers applications made in National, Mutual Recognition and Decentralised procedures.

2.1.2 Type of product

The product types include small molecules, herbals, vaccines, homeopathics and blood products for *human* medicinal products falling within the competence of NCAs. This includes prescription and over the counter medicines, innovative and generic product submissions.

2.1.3 Type of submission

This guidance applies to all submissions related to the authorisation and maintenance of medicinal products, including new marketing authorisations, variations, renewals, PSURs and active substance master files.

2.1.4 Exceptions

This guidance does not apply to the electronic submission of pre-MA information such as scientific advice, clinical trial applications, briefing packages and related submission correspondence.

2.2 Structure of submissions

Regulatory information must be structured in accordance with the Common Technical Document (CTD), which for paper submissions became mandatory in the European Union with effect from 1 July 2003.

For NeeS applications the eCTD folder structure is used. The breakdown of the electronic

submission should be in conformity with the ICH Granularity Document and the ICH and EU eCTD file naming conventions should be followed. (Links are found at EMA eSubmission website.)

The difference from an eCTD is that the two relevant XML files, the index.xml and eu-regional.xml for the backbone of Modules 2 to 5 and Module 1 for the EU, respectively and the util folder are not present, so navigation through a NeeS is based on electronic Tables of Content, bookmarks and hypertext links.

Typically, a NeeS application will cover all dosage forms and strengths of a product with any one invented name. In MRP/DCP, a single NeeS application should preferably be used for each procedure (e.g. UK/H/1003/001-002/DC). However, if the applicant decides to have one NeeS per strength or dosage form, this would also be acceptable but should be carefully considered in relation to transformation into eCTD at a later stage.

2.2.1 Table of Contents and bookmarks

Some NCAs have a tool with which they create their own TOCs. However, TOCs should still always be provided by the applicant. The TOCs should always be submitted in PDF format.

All documents in the NeeS dossier should be referenced from a hyperlinked Table of Contents (TOC). Hyperlinks for each document should always be provided to the first page of the appropriate file.

In the case of small dossiers (e.g. for certain variations), especially when only one module beside module 1 is concerned, it should be acceptable to only include a main TOC referring directly to the content documents. However, for larger submissions, the main TOC should always be linked to module TOCs which are then further linked to the documents in each module. The module TOCs should not include hyperlinks to documents in other modules.

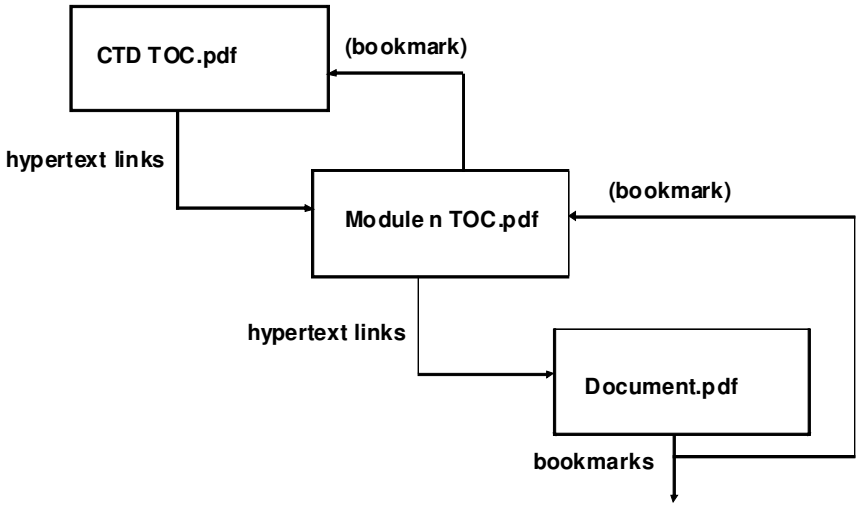
The file containing the main Table of Contents for the CTD should be named *ctd-toc.pdf* and be located in the top level folder for the NeeS submission. The files containing the module Tables of Content should be named *m1-toc.pdf*, *m2-toc.pdf*, *m3-toc.pdf*, *m4-toc.pdf* and *m5-toc.pdf* and be located in the corresponding top level module folder.

An example is presented in Annex 2. It should be noted that these are just *examples* and are provided for guidance and illustrative purposes only.

Where document TOCs are included they should be located within the same file as the rest of the document. For each document, provide bookmarks for every entry in the document's Table of Contents to the appropriate location, or where a Table of Contents does not exist, provide bookmarks to a sufficiently detailed level, typically to Level 3 or 4 headings, as considered appropriate.

An additional function might be provided to allow easy navigation back to the Table of Contents above. This can be achieved through the use of a bookmark linked back to the previous level. This additional function is not mandatory, but when provided it will facilitate the assessment.

The figure below describes diagrammatically this situation.



2.3 Submission numbering

Sequence numbers, as they are defined for eCTD submissions, are not applicable for NeeS submissions.

The use of a four digit number in the top level folder name is however recommended. The number does not have to be unique.

2.4 Moving to NeeS format applications

A NeeS format application can normally be started with any initial, variation or renewal MA application. Once the switch to this electronic format is made it is expected that further applications and responses relating to the particular medicinal product are submitted in the same electronic format or in the "up-graded" full eCTD format.

Since there is no life cycle management for NeeS, there is no need to reformat the whole dossier into NeeS format when switching from paper to NeeS, but this could be done at the applicant's discretion. It should then be clearly stated in the cover letter of the reformatted dossier that the content has not been changed, but only its format.

Applicants should not change from eCTD back to NeeS. In exceptional circumstances, if this should be needed, please contact the concerned NCAs in advance.

2.5 General Submission Considerations

2.5.1 File and folder structure

Submissions are a collection of documents and each document should be provided as a separate file. The detailed structure of the NeeS should conform to the ICH Granularity Document and EU M1 specifications. NCAs have a distinct preference for naming the root folder of the submission with the product (invented) name in lower case or procedure number followed by the subfolder, name, e.g. mydrug/0000/ or de-h-01234/0000/.

Total folder/file path should not exceed 180 characters.

2.5.2 File Naming

The eCTD file naming conventions described in the ICH M2 eCTD Specification and EU Module 1 Specification should be followed. If an applicant wishes to submit multiple files in one section, where only one highly recommended name is available, this can be achieved using a suffix to the filename, using the file name-*var*.pdf convention as described in the EU Module 1 Specification,

where the -var component has no dashes or illegal characters (e.g. pharmaceutical-development-*container*.pdf).

2.5.3 Placement of Documents

Guidance on the placement of documents within the CTD structure for particular submission types can be found in the EU-CTD Notice to Applicants.

2.6 Correspondence

In addition to the NeeS application, information may need to be exchanged to assist the processing or handling of the application. Not all such correspondence need to be included in the NeeS dossier.

Accordingly, the correspondence sent via the usual electronic means (email, Eudralink etc) only needs to be in full NeeS format if it relates directly to the content of the dossier.

2.7 Paper requirements

Paper copies of the dossier are no longer required in most NCAs. An overview of the requirements for electronic copies with or without paper is specified for each NCA at the CMDh website (eSubmissions).

The Practical guidance for the paper submission of regulatory information in support of a marketing authorisation application when using the Electronic Common Technical Document ("eCTD") as the source submission applies to NeeS submissions as well.

2.8 Hardware

NCAs will not accept any hardware (laptops, desktops, zip drives, etc.) from applicants in connection with the submission of information in electronic format. The electronic information should be directly readable and usable on NCAs hardware and software.

2.9 File formats

Detailed guidance on the specific file formats can be found in the ICH eCTD specification document and EU Module 1 specifications.

2.9.1 PDF

In general terms the majority of documents included in electronic submissions should be in PDF format.

Portable Document Format (PDF) is an open, de facto, electronic publishing standard, created by Adobe Systems Incorporated. There are several alternative suppliers of PDF software. Applicants need to check that the PDF documents meet the following key requirements:

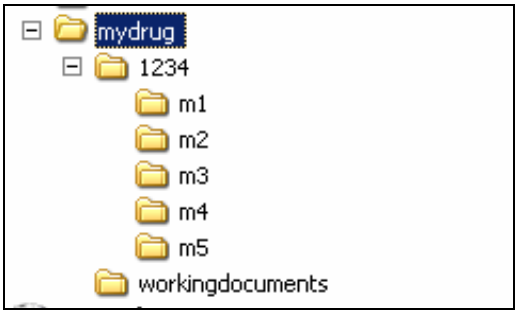
- Files should be legible with Acrobat Reader, version 5.0 or higher.
- PDF file version 1.4 only should be used except where there is an agency specific requirement for a later version for application forms.
- Documents should be generated from electronic source documents and not from scanned material, except where access to the source electronic file is unavailable or where a signature is required. See Annex 1 for further guidance on text searchable documents.

2.9.2 Extensible Mark-up Language (XML)

XML is the format for the backbone files for the eCTD but not in a NeeS dossier. Details on XML can be found in the ICH eCTD Specification Document, Appendix 7. Initiatives on the use of XML structured information are supported by NCAs and the EMA for the Product Information Management (PIM) system and e-application forms. Please refer to EMA eSubmission website for further details.

2.9.3 Other File Formats

Other file formats such as rich text (RTF) or MS Word formats may be required in addition to the PDF requirement of the NeeS by some NCAs, especially for the provision of product information documents. Please refer to the CMDh website for further details.
These files should not be added within the NeeS structure. They should be provided in a separate folder called, e.g. “workingdocuments” on the same CD/DVD containing the NeeS.



2.10 Bookmarks and hypertext links

Navigation through an electronic submission is greatly enhanced by the intelligent use of bookmarks and hypertext links. ICH guidance states “It is expected that any document that has a Table of Contents (TOC) will have bookmarks (see the eCTD specification for details). Documents without TOCs should have bookmarks included where it aids in the navigation around the document content. For example, a 4 page document summarising findings could require bookmarks to aid navigation. However, a 300 page file containing a single data listing might not require bookmarks as there is no further internal structure. Please consult regional guidance documents for further details.”

In general terms, bookmarks and hyperlinks should be used to aid navigation.

Additional details on creating bookmarks and hypertext links in PDF documents can be found in the ICH eCTD Specification, Appendix 7.

Each document should be referred to from a table of content (the overall TOC or any module TOC as applicable).

2.11 Technical validation of NeeS submissions

The technical validation of a NeeS is a separate activity to the content validation of a submission and takes place irrespective of the type of the submission. A common set of technical criteria against which all NeeS can be checked using a validation tool are published on the EMA eSubmission website.

A NeeS must pass both the technical validation and the business/content validation and errors found should be fixed by sending an updated NeeS submission.

If the applicant chooses to submit their validation report from any tool (e.g. the so called Best Report) electronically, this should be put at the root level outside the NeeS structure and not be referred to in the TOC.

2.12 Other Technical Information

2.12.1 Security issues

The physical security of the submission during transportation is the responsibility of the applicant. Once received by NCAs, security and submission integrity is the sole responsibility of the NCA.

2.12.2 Password protection

Submission or file level security is not permitted. If one-time security settings or password protection of an electronic submission is used this could constitute grounds for the rejection of the

submission. However, for some documents it might be acceptable (please refer to the NeeS Validation Criteria).

2.12.3 Virus protection

The applicant is responsible for checking the submission for viruses. Checking should be performed with an up-to-date virus checker and be confirmed in the cover letter. After receipt at NCAs, a similar internal virus check will be performed. If a virus is detected it will constitute grounds for rejection of the electronic submission.

2.12.4 Electronic signatures

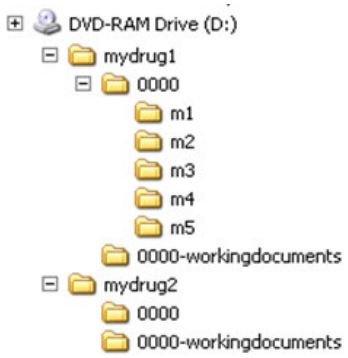
Although electronic signatures are currently accepted in the EU as being legally equivalent to handwritten signatures (Directive 1999/93/EC), some NCAs require that certain specific documents (cover letters, Application Forms) are authenticated by separate signed paper copies. Please refer to the table for electronic submission requirements at the CMDh website (eSubmissions).

2.12.5 Transmission Media

Currently CD-ROM, CD-R, DVD-R are considered acceptable media standards. Applicants should provide the electronic information on the smallest number of discs possible, taking into consideration the size of the submission.

If an individual NeeS submission is of such a size as to span several CDs, the provision of a DVD is recommended. However, if the applicant is unable to provide a DVD, and the application spans multiple CDs, then, where possible, individual CTD modules should be kept together and not be split over multiple CDs. i.e. a single CD should contain all of Module 1, another all of Module 2, etc. If one CTD module is too large to fit on one CD, then the remainder should go onto another CD, but applicants should provide multiple split modules on one CD, even if this means that additional CDs are not filled to capacity.

Typically, a separate CD/DVD should be provided for each NeeS submission. However, since grouping and worksharing of variations are regarded as one procedure they should always be provided on the same CD/DVD (see example below).



Also, when submitting several applications for the same medicinal product (trade name), it would be acceptable to provide them on a single CD/DVD.

This should always be clearly described in the cover letter and indicated on the disc (see 2.12.6).

Some NCAs have portals for upload of submissions and some submissions could also be acceptable or required to be sent by e-mail. Please refer to the CMDh website (eSubmissions).

2.12.6 Labelling of Media:

Each CD or DVD submitted with a NeeS should include the following label information, clearly presented and printed on the media:

- Format: NeeS
- The applicant's name
- The product (invented) name(s)

- The International Non-proprietary Name (INN) of the active substance(s)
- The full application number(s) (if known)
- Number of media units per full set and an indication of the place of the individual CD/DVD within this set (e.g. 1(5), 2(5), etc.
- The submission type(s) of each NeeS submission(s) contained on the CD/DVD (e.g. Initial Application, Variation Type II)

2.12.7 Procedure for sending electronic information

Some NCAs are able to accept NeeS submitted via their portals. Generally only small (<100MB) applications can be handled this way. Applicants should check with individual NCAs for details of this process. If submissions are uploaded via a portal no data corruption should occur as a result of the process.

In all other cases the NeeS submission should be sent to the address referred to in the Notice to Applicants, Volume 2A Chapter 7.

Electronic media sets should be submitted at the same time as any required paper documentation. The electronic media should be packed adequately to prevent damage and the package should include a cover letter. The cover letter should include as a minimum, the information specified in the CMDh Guidance document and a template is published on the same webpage that could be use.

2.12.8 Archiving and working copies

Please refer to the table for electronic submission requirements at the CMDh website (eSubmissions) for details of the number of copies of electronic submissions required for archiving and review purposes. Many NCAs destroy discs after data has been uploaded into their systems. Where an NCA requires the disc to be archived they may have additional requirements. Note: The current standard to burn CDs/DVDs is UDF, which has replaced the former ISO standard 9660.

3 Module specific information

3.1 Module 1.2: Administrative Information (Application Forms)

The application form should always be provided as a PDF file within the NeeS structure and for some NCAs also be provided as a signed paper copy or submitted through a portal. Please refer to the CMDh website (eSubmissions) for details.
For this specific PDF file a newer version than PDF version 1.4 may be appropriate and acceptable in accordance with the NeeS validation criteria.

3.2 Module 1.3.1: Product Information

For NeeS applications product information should be supplied as PDF files within the NeeS structure but many NCAs require an RTF/Word file in addition to facilitate assessment (see also section 2.9.3). Please refer to the CMDh website (eSubmissions) for details.

During the translation phase in MRP and DCP, it is acceptable to provide the product information documents outside the NeeS structure. The same would apply for product information in national procedures.

3.3 Module 1-responses

The organisation of the submission of electronic information in response to a list of questions from NCAs should follow the same basic principles as the first submission. The written response should be submitted following the EU recommended response folder and file structure. In this case the written response document should be placed in a folder named for example mydrug/0000/m1/eu/responses. Appropriate navigation in the submission should follow the same concepts as described in section 2.2.1.

Annex 1. Guidance on Text Searchable Documents

1. General

Applicants are requested to ensure that all submissions contain the maximum amount of text searchable content. Documents with searchable text will aid the assessor, or any other user, in searching for specific terms and also in copying and pasting information into another document, such as an assessment report.

We recognize that not all documents need to be text searchable. This short document provides some guidance about what must be text searchable and the ways to ensure that files are created appropriately.

1.1 Creating Text Searchable Files

PDF files with searchable text can be created by all PDF tools from a source file in a text format (e.g. MS Word, SAS, MS PowerPoint, Rich Text Files, etc.). When created in this way, the file will usually be the smallest in size (measured in kilobytes or megabytes) that they can be.

If the only version of a document available is in paper, then scanning to PDF and using an Optical Character Recognition (OCR) routine is the only way to create searchable text. PDF files created in this way tend to be much larger in size, for the same number of pages (from 10 to 100 times as large), and the quality of the text that is created will almost certainly not be a 100% match to the original text. It is noted that tools for checking and correcting this text tend to be somewhat cumbersome. For these reasons, applicants are recommended to use scanning/OCR only as a last resort.

Applicants are reminded that the text produced by the OCR routine should be "hidden" behind the image of the original page so that the user can refer to the picture of the page and the text on it as final verification of the data. As a result, the applicant should ensure that, as a minimum, the text on the scanned image is legible to the user. Poor quality images should not be provided and you should note that these can only inevitably lead to poor quality OCR text.

2. Documents that must always be text searchable

(i.e. the PDF should be produced wherever possible from a text source, such as MS Word, but if sourced from a scanned original then they **must be** OCR'd.)

- Key administrative documents in Module 1 including, the cover letter, application form, product information documents
    - Applicants are reminded that some NCAs regard logging in through a portal as sufficient to establish a users identity and do not require handwritten signatures on Cover Letters and Application Forms submitted this way
    - This also covers similar documents provided in non-MAA submissions.
- Any document in Module 2 of the MAA (QOS, Preclinical Overview and Summaries, Clinical Overview and Summaries).
    - This also covers similar documents provided in non-MAA submissions.
- The main body of text and main tables in any preclinical or clinical report required to support the main claim of the application.
    - This also covers similar documents provided in non-MAA submissions.
- The main body of text in any reports, methods, analytical procedures, etc. supplied in Module 3 of the MAA
    - This also covers similar documents provided in non-MAA submissions.
- The main body of text of Periodic Safety Update Reports (PSURs)
- The main body of text of Risk Management Plans
- Any English translation of a document originally written in a foreign language (see also below)

3. Documents that do not need to be text searchable

(i.e. the PDF should be produced wherever possible from a text source, such as MS Word, but if sourced from a scanned original then there is no need for OCR.)

- Any original GMP certificate
- Any original certificate of analysis
- Any manufacturer's licences
- Any certificate's of suitability
- Any Manufacturing Authorisation
- Any document written in a foreign language where a translation is provided in English (however, the translation should be text searchable, see above)
- Any literature references sourced from journals, periodicals and books (except when these are used in a bibliographic application to support the main claims of the application).
- The blank CRF in a Clinical Study Report
- Patient data listings (when supplied)
- CRFs (when supplied)
- Any page with a signature that does not contain other information key to the understanding of the submission
- Applicants should consider providing signatures on separate pages from key text in reports, overviews, etc.

4. Further Information

If applicants are uncertain whether or not a particular document should be text searchable, they should contact their NCA for guidance.

Annex 2. Example Tables of Contents

These Tables of Contents are *examples* and are provided for illustrative and guidance purposes only. The blue underlined text illustrates where hyperlinks to the individual documents may be added.
In these examples there are some "Not applicable" documents shown. "Not applicable" documents should not appear in the dossier and nor should they be included in the TOCs.

The following is an example of a CTD TOC (main TOC)

The following are examples of module TOCs.

	be - fr - combined SPC	1.3.1
	be - nl - immediate packaging 10 mg	1.3.1
	be - nl - intermediate packaging 10 mg	1.3.1
	be - nl - outer packaging 10 mg	1.3.1
	be - nl - package leaflet 10 mg	1.3.1
	be - nl - combined SPC	1.3.1
1.3.2	Mock-up	1.3.2
	common - immediate packaging 10 mg	1.3.2
	common - intermediate packaging 10 mg	1.3.2
	common - outer packaging 10 mg	1.3.2
	common - package leaflet 10 mg	1.3.2
	be - immediate packaging 10 mg	1.3.2
	be - intermediate packaging 10 mg	1.3.2
	be - outer packaging 10 mg	1.3.2
	be - package leaflet 10 mg	1.3.2
1.3.3	Specimen	1.3.3
	common-specimen	1.3.3
	be - specimen	1.3.3
1.3.4	Consultation with target patient groups	1.3.4
	common - consultation with target patient groups	1.3.4
	be - consultation with target patient groups	1.3.4
1.3.5	Product Information already approved in the Member States	1.3.5
	common - approved package leaflet 10 mg	1.3.5
	common - approved combined SPC	1.3.5
	be - approved package leaflet 10 mg	1.3.5
	be - approved combined SPC	1.3.5
1.3.6	Braille	1.3.6
1.4	Information about Experts	1.4
1.4.1	Quality	1.4.1
1.4.2	Non-Clinical	1.4.2
1.4.3	Clinical	1.4.3
1.5	Specific Requirements for Different Types of Application	1.5
1.5.1	Information about bibliographical applications	1.5.1
1.5.2	Information for Generic, `Hybrid` or Bio-similar Applications	Not Applicable
1.5.3	(Extended) Data/Market Exclusivity	Not Applicable
1.5.4	Exceptional Circumstances	Not Applicable
1.5.5	Conditional Marketing Authorisation	Not Applicable
1.6	Environmental Risk Assessment	1.6
1.6.1	Non-GMO	1.6.1
1.6.2	GMO	Not Applicable
1.7	Information on Orphan Market Exclusivity	1.7
1.7.1	Similarity	1.7.1
1.7.2	Market Exclusivity	Not Applicable
1.8	Information on Pharmacovigilance	1.8
1.8.1	Pharmacovigilance System	1.8.1
1.8.2	Risk-management System	1.8.2
1.9	Information Relating to Clinical Trials	1.9
1.10	Information Relating to Paediatrics	1.10
Responses to Questions		Not Applicable
Additional		Not

Data		Applicable

Module 2	Common Technical Document Summaries	
2.2	Introduction	2.2
2.3.S	Drug Substance - Eurotriptan Maleate - EuroFactory	2.3.S
2.3.S.1	General Information	2.3.S.1
2.3.S.2	Manufacture	2.3.S.2
2.3.S.3	Characterisation	2.3.S.3
2.3.S.4	Control of Drug Substance	2.3.S.4
2.3.S.5	Reference Standards or Materials	2.3.S.5
2.3.S.6	Container Closure System	2.3.S.6
2.3.S.7	Stability	2.3.S.7
2.3.S	Drug Substance - Eurogreen – GreenFactory	2.3.S
2.3.S.1	General Information	2.3.S.1
2.3.S.2	Manufacture	2.3.S.2
2.3.S.3	Characterisation	2.3.S.3
2.3.S.4	Control of Drug Substance	2.3.S.4
2.3.S.5	Reference Standards or Materials	2.3.S.5
2.3.S.6	Container Closure System	2.3.S.6
2.3.S.7	Stability	2.3.S.7
2.3.P	Drug Product - Efpiate capsule - Small Factory	2.3.P
2.3.P.1	Description and Composition of the Drug Product	2.3.P.1
2.3.P.2	Pharmaceutical Development	2.3.P.2
2.3.P.3	Manufacture	2.3.P.3
2.3.P.4	Control of Excipients	2.3.P.4
2.3.P.5	Control of Drug Product	2.3.P.5
2.3.P.6	Reference Standards or Materials	2.3.P.6
2.3.P.7	Container Closure System	2.3.P.7
2.3.P.8	Stability	2.3.P.8
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2.3.A.2	Adventitious Agents Safety Evaluation - Eurogreen - GreenFactory	2.3.A.2
2.3.A.2	Adventitious Agents Safety Evaluation - Eurotriptan Maleate - EuroFactory	2.3.A.2
2.3.A.3	Novel Excipients	2.3.A.3
2.3.R	Regional Information	2.3.R
2.4	Nonclinical Overview	2.4
2.5	Clinical Overview	2.5
2.6	Nonclinical Written and Tabulated Summary	2.6
2.6.1	Introduction	2.6.1
2.6.2	Pharmacology Written Summary	2.6.2
2.6.3	Pharmacology Tabulated Summary	2.6.3
2.6.4	Pharmacokinetics Written Summary	2.6.4
2.6.5	Pharmacokinetics Tabulated Summary	2.6.5
2.6.6	Toxicology Written Summary	2.6.6
2.6.7	Toxicology Tabulated Summary	2.6.7
2.7	Clinical Summary	2.7
2.7.1	Summary of Biopharmaceutic Studies and Associated Analytical Methods	2.7.1
2.7.2	Summary of Clinical Pharmacology Studies	2.7.2
2.7.3	Summary of Clinical Efficacy	2.7.3
2.7.4	Summary of Clinical Safety	2.7.4
2.7.5	Literature References	2.7.5
2.7.6	Synopses of Individual Studies	2.7.6

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3.2	Body of Data	3.2
3.2.S	Drug Substance (eurogreen-greenfact)	3.2.S
3.2.S.1	General Information (eurogreen-greenfact)	3.2.S.1
3.2.S.1.1	Nomenclature (eurogreen-greenfact)	3.2.S.1.1
3.2.S.1.2	Structure (eurogreen-greenfact)	3.2.S.1.2
3.2.S.1.3	General Properties (eurogreen-greenfact)	3.2.S.1.3
3.2.S.2	Manufacture (eurogreen-greenfact)	3.2.S.2
3.2.S.2.1	Manufacturer(s) (eurogreen-greenfact)	3.2.S.2.1
3.2.S.2.2	Description of Manufacturing Process and Process Controls (eurogreen-greenfact)	3.2.S.2.2
3.2.S.2.3	Control of Materials (eurogreen-greenfact)	3.2.S.2.3
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Document Control

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