





Manual

EURSvalidator

Version 1.4 SP1



EURSvalidator - About









Version 1.4.00 SP1 Build 05

EURSvalidator

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- Registration Management 
- Submission Management 
- Labeling Management 
- Pharmacovigilance Management 
- Document Management 
- Project Management 

Ok



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1 Installation

Please follow the EXTEDO Installation Guide carefully

“Installation Instructions for EURSvalidator”

The installation steps:

1. Installation of the application: Setup-Wizard guides you through the installation.
2. The provided validation sets require no license file. For other validation sets: License helper collects the necessary information. For receiving the license files, please send this information to EXTEDO. Copy the files into the installation folder.



2 EURSvalidator Application

The installation creates a start menu entry and a desktop icon.

Double click the desktop icon to **Start the Application**. Alternatively select “Start / Programs / EXTEDO / EURSvalidator”.



In case of a present license file, it is checked. **If the license is not valid the EXTEDO license helper program will be started** (see chapter 1).

If the license is valid, the main application will open and enables to work with additionally licensed validation sets.

If EURSvalidator is started without any licence file, the application will start up as well and enables to work with free available validation sets.

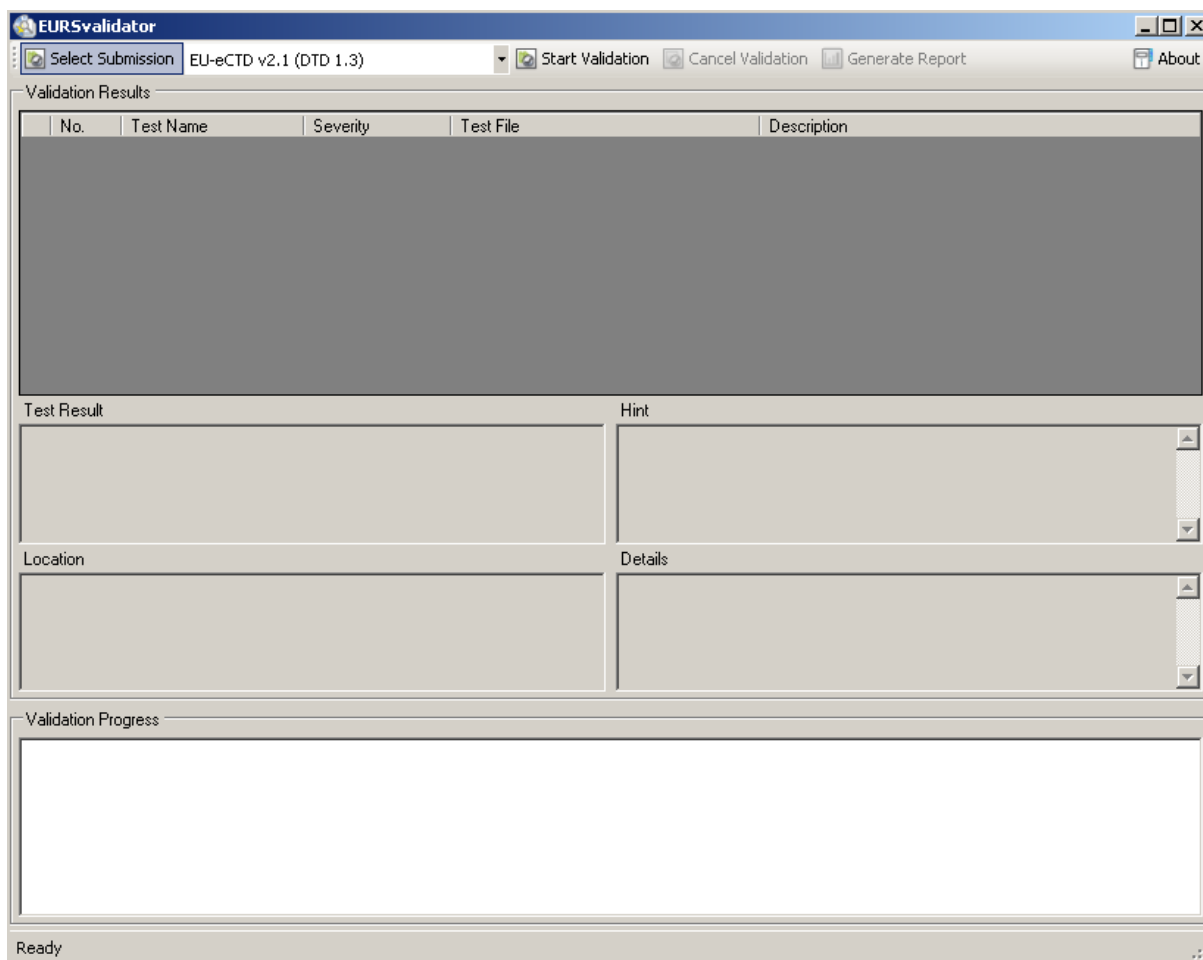


Figure 1: Main Application

The **Tool Bar** enables to control the application.

- Select Submission (see 4.1)
- Start Validation, Cancel Validation (see 4.1)
- Generate Report (see 4.5)
- About Dialog: offers program information (EXTEDO address information, Program version, eMail for Customer Support Service, Link to EXTEDO Website). Select “x” to close the “About” dialog, alternatively press the ESC key.

The **Validation Results** will be displayed in the upper part of the application (see 4.4).



The **Validation Summary** provides a brief description of the validation. During the validation the **Validation Progress** is shown here (see 4.3).

Select a particular “Validation Result”, the “Validation Details” sections may display further information.

3 **General Notes**

3.1 *Licensing*

EURSvalidator is for free and supports the validation criteria sets **CH-eCTD v1.0/v1.0.1/1.1**, **EU-eCTD 2.0** and **2.1** and **EU-NeeS 1.0**.

A support for other validation criteria sets is possible, but needs to install a licence key. Please contact your local EXTEDO representative!

3.2 *Preparing a Validation*

Before starting a validation, please ensure, the regional part information of the respective submission is noted. This is important to choose the correct validation criteria option within **EURSvalidator**, before starting a validation.

EURSvalidator does not automatically detect the respective validation set provided in your eCTD submission.

EURSvalidator proceeds a validation in every case, just as well if a wrong validation criteria set has been selected. No warning will be displayed.



4 The First Validation!

4.1 Step 1: Select Submission

Choose “**Select Submission**” from the Tool Bar. The “Select submission directory” dialog box opens. Select the **submission folder** “0000” for example.

Confirm with the “**OK**” button.


 EURS rules require a maximum path length of 180 or 230 characters. Therefore make sure that the root directory of the submission is not longer than 22 characters, e.g. (“X:\directory\12345678\”). This is a known restriction under MS-Windows systems!



Figure 2: Select Submission Directory

4.2 Step 2: Automatic DTD detection (NEW FEATURE !!)

EURSvalidator starts to detect automatically the provided DTD version of the eCTD. In case of a successful DTD detection, the following dialog is provided (example)

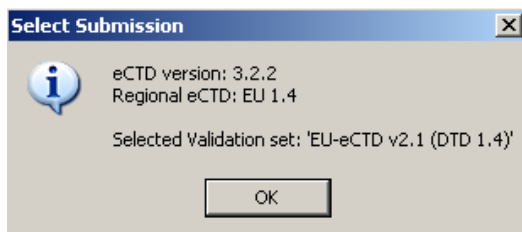


Figure 3: Successful DTD detection

Confirm with the “**OK**” button and choose “**Start Validation**” from the toolbar (continue with “Step 3”).

In case that EURSvalidator is not able to detection the provided DTD version of your eCTD submission, the following dialog is provided.

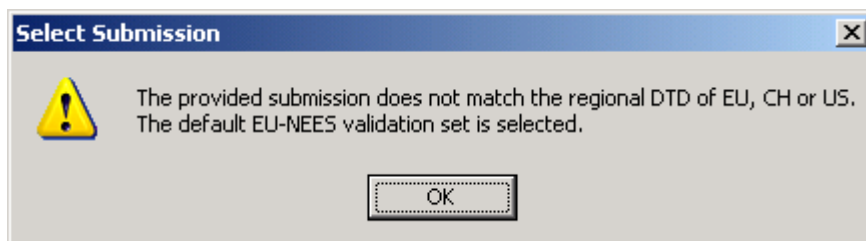


Figure 4: Failed DTD detection



Confirm with the **“OK”** button.

In such circumstances select from the provided list of validation sets the appropriate validation set

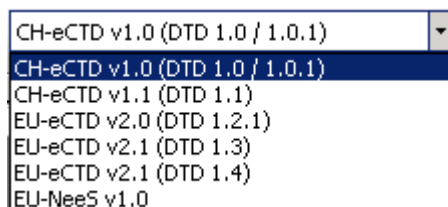


Figure 5: List of available validation set

Select a validation set and press **“Start Validation”** from the toolbar (continue with **“Step 3”**).

4.3 Step 3: Validation in Progress

Follow the **Validation Progress**:



The validation may take a long time for submissions containing documents bearing a large number of hyperlinks.

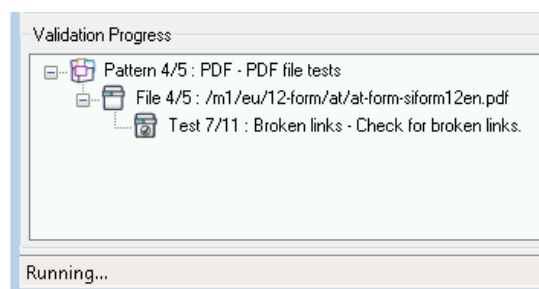


Figure 6: Validation Progress

After the validation process is finished (**“Ready”** in the Status Bar) the validity of the submission (valid / invalid) is provided in the **Validation Summary**:

Select the respective validation set from the pull-down list.

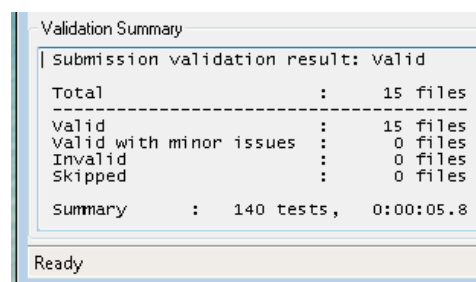


Figure 7: Validation Summary



Select **“Cancel Validation”** from the toolbar to interrupt the validation process at any time.



4.4 Step 4: Validation Results

A list of all test steps performed is available in the **Validation Results**:

No.	Test Name	Severity	Test File	Description
0001	Check ICH DTD	Success	Submission level ...	Check if ICH DTD exists in the util\dtd directory.
0002	Check EU M1 D...	Success	Submission level ...	Check if EU M1 DTD exists in the util\dtd directory.
0003_1	Check if index.xml...	Success	Submission level ...	Check if index.xml exists
0003_2	Check if eu-regio...	Success	Submission level ...	Check if eu-regional.xml exists
0004_1	Check if index.xml...	Success	Submission level ...	Check if index.xml is well-formed
0004_2	Check if eu-regio...	Success	Submission level ...	Check if eu-regional.xml is well-formed
0005	Check DTD che...	Success	Submission level ...	Check if DTD checksums are valid
0006	Check if instance...	Success	Submission level ...	Check if instance files (eAFs) are well-formed
0007	Check eAF DTD ...	Success	Submission level ...	Check if eAF DTD checksums are valid
0008	Check if util folde...	Success	Submission level ...	Check if util folder exists
0044	Unreferenced files	Success	Submission level ...	Checks if there are no unreferenced files.
0009	Check checksum...	Success	index.xml	Check if checksum-type has md5 or MD5 value

Figure 8: Validation Results

- “No.” indicates the validation test step as defined in the validation criteria.
- “Test Name” indicates the name of the validation test step.
- “Severity” indicates “success” or an error level (see chapter 4).
- “Test File” indicates the structural element that was checked.
- “Description” provides further details to the test step performed.

Click a column heading to sort the table.

Click on any cell to select the complete message. Then also the detail information is updated to allow further information regarding the selected message. Alternatively use the “up / down” keys for navigation in the table.



4.5 Step 5: Reporting

Select the “**Generate Report**” button from the toolbar. The “Report Options” dialog box is displayed.

There are 2 versions of report available:

- Short: Report contains errors only.
- Long: Report contains warnings and information also.

Select the **Report Options** and confirm with “OK” button. A PDF file is generated and opens the file in Acrobat Reader.



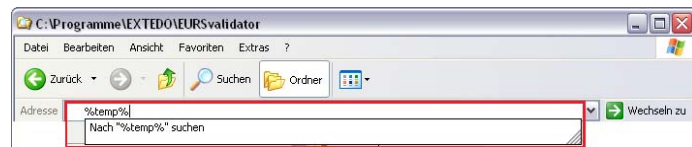
4.6 Step 6: Saving the Report File

Refer to the Windows Explorer.

Type **%temp%** into the address field.

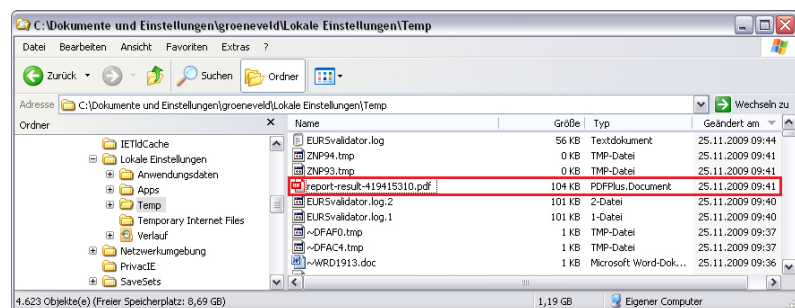
The temp directory opens, where the report file can be found.

Alternatively the **Report File** might be saved directly from Acrobat, after it has opened automatically.



Select the pdf file **report-result...** with **Adobe Reader** or **Adobe Acrobat**.

Save the file



Print the report or save the file. EURSvalidator does not store the report automatically.



5 Example for an Invalid Submission!

The **Validation Summary** indicates an invalid submission:

Validation Results

No.	Test Name	Severity	Test File	Description
0031	Maximum file size	Success	nomenclature.pdf	Check the maximum size of individual files (100 MB).
0032	Valid filename	Success	nomenclature.pdf	Check if all filename use valid characters only.
0036	PDF format	B	nomenclature.pdf	Check the format of the PDF file (PDF 1.4).
0037	Broken links	B	nomenclature.pdf	Check for broken links.
0038	Fast web access	B	nomenclature.pdf	Check if the 'Fast Web Access' flag is active.
0039	Inherit zoom	C	nomenclature.pdf	Checks whether all PDFs open in 'most recent view'.
0040	Relative hyperlinks	B	nomenclature.pdf	Checks whether all hyperlinks are relative.
0041	Protection	A	nomenclature.pdf	Checks whether the PDF is password protected.
0028	Check file format	Success	structure.pdf	Check if the file format is valid.
0029	Path length	Success	structure.pdf	Check the maximum path length of 230 characters.
0030	Filename length	Success	structure.pdf	Check the maximum file and folder name length of 64 characters.
0031	Maximum file size	Success	structure.pdf	Check the maximum size of individual files (100 MB).

Test Result
The PDF is protected by security settings or a password.

Hint
There is no security setting or password protection on any individual file.

Location
/m3/32-body-data/32s-drug-sub/activesubstance-extedoactive/32s1-gen-info

Details

Validation Summary

```
Submission validation result: Invalid
Total                :    15 files
-----
Valid                :    14 files
Valid with minor issues :    0 files
Invalid              :    1 files
Skipped              :    0 files
Summary              :   140 tests, 0:00:08.7
```

Figure 9: EURSvalidator found an Invalid Submission

Please follow this procedure to find out the problem:


1. Run through the validation results to find failed checks. They are marked with a **severity A, B, or C** (see 5.1). The element is provided where the error occurred; the No. provides the failed validation test step.



Click the heading of column “Severity” to sort the results ascending. Severity “A” will be displayed on the top of the list.

2. In the detailed views section see “Test Result” and “Hint” for further details about the error.
3. **Generate a Report** for a detailed view on the error messages:



EURSvalidator		
	Responsible:	Date/Sign:
	dmadmin	
Submission folder:	M:\Products\EURSValidator\Test_cases\EU-Rules-Test-cases\28.2-invalid-file-formats\0000	
Validation Set:	eCTD 3.2 with EU M 1.2.1 regional part Version: EU validation criteria release 2.0	
Check Result:	Invalid	

Envelope Information:

Envelope country	at
Application number	AT-001
Applicant	Extedo GmbH
Agency	Austrian Health Authority
Submission	initial-maa
Submission description	Austrian NP - correct
Procedure type	national
Invented name	Extedopirin
Sequence number	0000

Validation Report:



Status	Path/File	Severity
	(Submission)	
	Submission level tests	
	/m1/eu/12-form/at	
	at-form-siform12en.pdf	
	The PDF file contains broken links. (No. 0037)	B
	1 : [BM 2. Marketing authorisation application particulars 00000002] Bookmark, Title 2. Marketing authorisation application particulars, Action None, Page 0, Target , Zoom 0	
	10 : [BM Zhejiang Jiuzhou Pharmaceutical Co. Ltd. 00000010] Bookmark, Title Zhejiang Jiuzhou Pharmaceutical Co. Ltd., Action None, Page 0, Target , Zoom 0	

Figure 4: EURSvalidation Report



The icons indicate the Validation Result:



Validation step successfully accomplished



An error occurred, a text explains the reason, the severity of the error is indicated



A warning occurred, i.e. severity is lower than an error severity

4. Strategy for **Corrective Actions**:

1. Eliminate severity “A” first because this will to the rejection of the sequence/submission,
2. then proceed with severity “B” issues,
3. at least care for severity “C” issues.

6

Annex

6.1 EU and Swissmedic eCTD Validation Criteria

The EU eCTD Validation Criteria for DTD 1.4 are not public yet. The EURSvalidator validation set is based on V2.1, including specific modifications for the current DTD 1.4.

The EU eCTD Validation Criteria Version 2.0 can be found at [EU eCTD Validation Criteria](#) (V2.0 / July 2008)

The EU eCTD Validation Criteria Version 2.1 can be found at [EU eCTD Validation Creteria](#) (V2.1 / April 2009)

The CH eCTD Validation Criteria Version 1.0/1.0.1/1.1 can be found at [Swiss eCTD Validation Criteria](#) (V1.0 and V1.0.1 / Oct. 2009)

[Swiss eCTD Validation Criteria](#) (V1.1 / May 2010)



Prioritisation Key:	SUMMARY	
A: SERIOUS. Compliance is mandatory. Failure to comply results in an error message in the validation report, no load of eCTD into the review tool, and a replacement sequence should be requested.	A = reject sequence (applicant must submit a replacement)	
B = MEDIUM - Compliance is preferred. Failure to comply results in a warning being displayed. A degree of discretion should be applied by the agency to the feedback given to the applicant. It may be requested that the issue is resolved in a subsequent sequence.	B = accept but may request corrections (fix with a subsequent sequence)	Apply a degree of discretion. For example, if one study report is 105MB, it will not be in the interests of either the agency or the applicant to make changes. However, if the submission consists of 200 scanned reports, all over 500 MB, then the agency would have every reason to request changes.
C - LOW - Compliance is preferred. Failure to comply results in advice being displayed. Report to the applicant for future consideration. Resolution may result in the eCTD being easier to handle	C = accept but will flag errors so that they are not repeated in subsequent sequences/submissions (no fix needed)	i.e advisory only

Table 1: EURS Validation Criteria 2.0



Only submissions with severity “A” are immediately rejected by the authority. But also severities B, C will lead to an “invalid”, because you have to do corrective actions!

6.2 *NeeS validation criteria*

The NeeS Validation Criteria Version 1.0 can be found at

[EU NeeS Validation Criteria](#) (V1.0 / Aug. 2009)