

THE EUROPEAN DIRECTORATE FOR THE QUALITY OF MEDICINES & HEALTHCARE (EDQM)



Find your way in Standard terms; PharmEuropa; Knowledge database & Ph. Eur. online

2019 Training Session
"The European Pharmacopoeia"
Dr Pierre Leveau
EDQM Head of Reference Standards & Logistics Department

10 – 11 September 2019, Iselin, New Jersey, USA

TOPICS

- How to access?
- Standard Terms
- Knowledge database
- Pharmeuropa online

How to access?

HOW TO ACCESS?

Specific page to EDQM databases from the EDQM website:

<https://www.edqm.eu/en/edqm-databases-10.html>

Databases

Pharmeuropa Pharmeuropa provides: public inquiries on draft European texts or on matters of general policy, the latest official announcements on freshly adopted monographs, the latest news on Pharmacopoeial harmonisation and a readers' tribune <ul style="list-style-type: none"> • Texts for comments database • Pharmeuropa archives 	Pharmeuropa Bio & Scientific Notes Pharmeuropa Bio & Scientific Notes contains all the news in the biological standardisation area and scientific articles linked to the work of the European Pharmacopoeia
Knowledge Knowledge is a searchable database of information on a given substance or general method of analysis and also contains information such as: the monograph's revision history; the chromatogram in pdf format; the links to the reference standard catalogue number; the trade names of some reagents, such as chromatography columns and biological kits; and access to the list of Certificates of Suitability to the monographs of the European Pharmacopoeia (CEPs) that have been granted for this substance. <ul style="list-style-type: none"> • Search Knowledge • Latest Ph.Eur News • Work programme Ph.Eur 	Ph. Eur. Reference Standards Search through our continuously updated database for information on Ph.Eur. Reference Standards. <ul style="list-style-type: none"> • Search Ph.Eur. Reference Standards • More about Ph.Eur Standards • Place an order

Publications

EDQM Free Publications Discover the EDQM publications available for free (Freepubs)
European Pharmacopoeia Access to the Ph. Eur. 10th Edition online (visiting clients) Access to the Ph. Eur. 9th Edition online (visiting clients)

WHO ISA This database contains information on WHO International Standards for Antibiotics (ISA). <ul style="list-style-type: none"> • Search WHO ISA Reference Standards • More about WHO ISA Standards • Place an order 	WHO ICRS This database contains information on WHO International Chemical Reference Substances (ICRS). <ul style="list-style-type: none"> • Search WHO ICRS Reference Standards • More about WHO ICRS Substances • Place an order
Certification Search our Certification database for information on Certificates of Suitability (CEPs) granted by the EDQM. <ul style="list-style-type: none"> • Search Certification Database • Certification news 	Standard Terms The Standard Terms database contains terms and definitions to describe pharmaceutical dose forms, routes and methods of administration, containers, closures and administration devices and patient-friendly terms. Search Standard Terms Database.
Melclass Database on the legal classification of medicines as regards their supply conditions and details of prescription status. Search Melclass	

EDQM Standard Terms

Standard Terms – a brief history

- The lists of Standard Terms were initially drawn up by the European Pharmacopoeia Commission further to a request from the EU Commission
- It was recognised that a harmonised set of terms was needed across Europe to describe medicinal products
- Standard Terms are intended for use in the marketing authorisation application (MAA), summary of product characteristics (SmPC), labeling, and electronic communications... and more

Standard Terms – a brief history

- Standard Terms was originally a printed publication, first appearing as a special issue of Pharmeuropa in October 1996
- Updated versions were published every couple of years until December 2004 and replaced by an online database version in 2005
- An entirely new version of the database was released in November 2014 with major updates released in March 2016 and August 2017
- Change requests can now be accepted for assessment by the Standard Terms Working Party from authorities outside of the Ph. Eur. member states who wish to use Standard Terms themselves, in particular the ICH regions

Standard Terms – overview

- Standard Terms are controlled vocabularies that are used to describe certain attributes of a medicinal product (human and veterinary) from a regulatory perspective:
 - Pharmaceutical dose forms (i.e. dosage forms)
 - Routes or methods of administration
 - Certain important packaging items such as Containers, Closures and Administration devices
 - Combined pharmaceutical dose forms, Combined terms, Combination packs
 - Patient-friendly terms
 - Units of presentation

Standard Terms – International relevance

- EDQM Standard Terms is recognised within Europe and in other regions as the preferred terminology source for dose forms, routes of administration etc. for regulatory uses, for IDMP and for adverse event reporting (pharmacovigilance reporting)
- The scope of Standard Terms has been widened to meet the requirements of IDMP and ICSRs for pharmacovigilance, not just for marketing authorisation applications and labelling
- **IDMP: Identification of Medicinal Products**
- Project originally developed in ICH and eventually resulted in a set of 5 International Standards developed in ISO TC 215 WG 6
- Developed to meet a demand for internationally harmonised specifications for the unique identification of medicinal products

Standard Terms – International relevance

- When all of the IDMP standards are implemented, they will support the implementation of the **Individual Case Safety Report (ICSR)** standards (ISO/HL7 27953)
- ICSR standards provide a harmonised framework for adverse event reporting, and require harmonised controlled vocabularies in order that different regions can communicate effectively with each other

The overall purpose is to improve pharmacovigilance on a global scale

Standard Terms – additional features

- Application Programming Interfaces (APIs, or web services) allow external systems to interact directly with the database and extract data for use in their own systems on a regular basis, in order to ensure that they remain up to date
- A mapping feature allows owners of similar lists of controlled vocabularies to add their own terms in a separate section and map them to the equivalent Standard Term(s)
- Tagging allows the inclusion of 'non-traditional' terms that are intended not for use in marketing authorisation applications and labelling, but exclusively for other purposes, such as adverse-event reporting (e.g. terms such as 'Transplacental')

Standard Terms working procedure

- Change requests for Standard Terms can be submitted to the EDQM by national authorities only or directly to the EDQM (outside Europe)
- The Standard Terms Working Party consults on the request and, if appropriate, creates or revises a Standard Term
- A definition is included and, for some classes of terms, additional characterising information is provided
- After adoption, new or revised terms are added to the Standard Terms database in English
- Translations can then be submitted by national authorities and, after validation, appear in the Standard Terms database

Standard Terms languages

- Standard Terms are currently available in 34 languages, including several from non-EU regions:
 - Albanian, Bosnian, Bulgarian, Chinese, Croatian, Czech, Danish, Dutch, English, Estonian, Finnish, French, German, Greek, Hungarian, Icelandic, Italian, Kazakh, Latvian, Lithuanian, Macedonian, Maltese, Norwegian, Polish, Portuguese, Romanian, Russian, Serbian, Slovakian, Slovenian, Spanish, Swedish, Turkish, Ukrainian (plus Japanese for mapped ICH terms only)

Standard Terms access

- Access to Standard Terms is available free of charge
- Full instructions on how to register and create an account are available on the website

<https://standardterms.edqm.eu>

Example of a Standard Term

Powder for solution for injection

Status Term in English Tag Domain

Current Powder for solution for injection ST Human and Veterinary

DETAILS CHARACTERISTICS TRANSLATIONS LINKED TERMS SUMMARY SHEETS

Specific information tabs

Concept Code	11205000
Term	Powder for solution for injection
Definition	Solid sterile preparation consisting of one or more powders, including freeze-dried powders, intended to be dissolved in the specified liquid to obtain a solution for injection.
Concept Class	PDF
Ph. Eur. Monograph	0520
Domain	Human and Veterinary
Concept Status	Current
Version Number	2
Version creation date	2016-03-30 18:50:20
Modification made	Definition harmonised.
Language	English
Expanded code	PDF-11205000-EN-GB
Concept Creation Date	2006-03-14 00:00:00

Most important information appears under 'Details'

Status Term in English Tag Domain

Current Powder for solution for injection ST Human and Veterinary

DETAILS **CHARACTERISTICS** TRANSLATIONS LINKED TERMS SUMMARY SHEETS

This tab is specific to pharmaceutical dose forms

State of matter	Solid
Basic dose form	Powder
Administration method	Injection
Intended site	Parenteral
Release characteristics	Conventional
Transformation	Dissolution

This information is used to sort and arrange pharmaceutical dose forms

Translations

Versioning information

Current		Powder for solution for injection	ST	Human and Veterinary
DETAILS	CHARACTERISTICS	TRANSLATIONS	LINKED TERMS	SUMMARY SHEETS
English	Powder for solution for injection		2016-03-30	2
French	Poudre pour solution injectable		2006-03-14	1
Italian	Polvere per soluzione iniettabile		2006-03-14	1
Spanish	Polvo para solución inyectable		2006-03-14	1
Portuguese	Pó para solução injetável		2014-03-10	2
Romanian	Pulbere pentru soluție injectabilă		2006-03-14	1
German	Pulver zur Herstellung einer Injektionslösung		2006-03-14	1
Dutch	Poeder voor oplossing voor injectie		2006-03-14	1
Danish	Pulver til injektionsvæske, opløsning		2006-03-14	1
Norwegian	Pulver til injeksjonsvæske, oppløsning		2006-03-14	1
Icelandic	Stungulyfsstofn, lausn		2006-03-14	1

Terms are currently available in 34 languages (plus Japanese for mapped ICH terms only)

National authorities create and submit translations to the EDQM

Current		Powder for solution for injection	ST	Human and Veterinary
DETAILS	CHARACTERISTICS	TRANSLATIONS	LINKED TERMS	SUMMARY SHEETS
English	Powder for solution for injection		2016-03-30	2
French	Poudre pour solution injectable		2006-03-14	1
Italian	Polvere per soluzione iniettabile		2006-03-14	1
Spanish	Polvo para solución inyectable		2006-03-14	1
Portuguese	Pó para solução injetável		2014-03-10	2
Romanian	Pulbere pentru soluție injectabilă		2006-03-14	1
German	Pulver zur Herstellung einer Injektionslösung		2006-03-14	1
Dutch	Poeder voor oplossing voor injectie		2006-03-14	1
Danish	Pulver til injektionsvæske, opløsning		2006-03-14	1
Norwegian	Pulver til injeksjonsvæske, oppløsning		2006-03-14	1
Icelandic	Stungulyfsstofn, lausn		2006-03-14	1
Finnish	Pulver til injektionsvæske, opløsning		2006-03-14	1
Swedish	Injektionsvätska, lösning		2006-03-14	1
Polish	Injektionssuspension, Lösung		2006-03-14	1
Czech	Injektionssuspension, Lösung		2006-03-14	1
Slovak	Injektionssuspension, Lösung		2006-03-14	1
Slovenian	Injektionssuspension, Lösung		2006-03-14	1
Croatian	Injektionssuspension, Lösung		2006-03-14	1
Bulgarian	Injektionssuspension, Lösung		2006-03-14	1
Maltese	Injektionssuspension, Lösung		2006-03-14	1
Lithuanian	Injektionssuspension, Lösung		2006-03-14	1
Latvian	Injektionssuspension, Lösung		2006-03-14	1
Estonian	Injektionssuspension, Lösung		2006-03-14	1
Japanese	Injektionssuspension, Lösung		2017-03-03	1
Ukrainian	Injektionssuspension, Lösung		2006-03-14	1
Bulgarian	Injektionssuspension, Lösung		2006-03-14	1
Macedonian	Injektionssuspension, Lösung		2006-03-14	1
Czech	Injektionssuspension, Lösung		2006-03-14	1
Slovak	Injektionssuspension, Lösung		2006-03-14	1
Slovenian	Injektionssuspension, Lösung		2006-03-14	1
Croatian	Injektionssuspension, Lösung		2006-03-14	1
Bulgarian	Injektionssuspension, Lösung		2006-03-14	1
Maltese	Injektionssuspension, Lösung		2006-03-14	1
Lithuanian	Injektionssuspension, Lösung		2006-03-14	1
Latvian	Injektionssuspension, Lösung		2006-03-14	1
Estonian	Injektionssuspension, Lösung		2006-03-14	1
Japanese	Injektionssuspension, Lösung		2017-03-03	1

Current Powder for solution for injection ST Human and Veterinary

DETAILS CHARACTERISTICS TRANSLATIONS **LINKED TERMS** SUMMARY SHEETS

Combined pharmaceutical dose form

- Powder and solution for solution for injection
- Powder and solvent for solution for injection
- Powder and solvent for solution for injection/infusion
- Powder and solvent for solution for injection/skin-prick test

Combined term

- Powder and solvent for solution for injection in cartridge
- Powder and solvent for solution for injection in pre-filled pen
- Powder and solvent for solution for injection in pre-filled syringe

Patient-friendly term

- Powder for injection

Hyperlinks to related Standard Terms

Current Powder for solution for injection ST Human and Veterinary

DETAILS CHARACTERISTICS TRANSLATIONS LINKED TERMS **SUMMARY SHEETS**

- Details and translations
- All information

Summary sheets that can be downloaded in PDF format

Example of a mapped term

Intrathecal use

This tab appears when there are mapped terms

Current	Intrathecal use	ST	Human and Veterinary
DETAILS	TRANSLATIONS	MAPPINGS	SUMMARY SHEETS
Concept Code	20042000		
Term	Intrathecal use		
Definition	Injection of a medicinal product through the dura to the subarachnoid cavity.		
Concept Class	ROA		
Domain	Human and Veterinary		
Concept Status	Current		
Version Number	1		
Version creation date	2006-03-14 00:00:00		
Language	English		
Expanded code	ROA-20042000-EN-GB		
Concept Creation Date	2006-03-14 00:00:00		

Each external organisation/database has its mapped terms listed together

The screenshot shows a web interface for a term 'Intrathecal use'. At the top, there are tabs for 'DETAILS', 'TRANSLATIONS', 'MAPPINGS', and 'SUMMARY SHEETS', with 'MAPPINGS' selected. Below the tabs, there is a header for 'ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for H...) / ICH E2B Code List'. A table below lists mapped terms:

Current	Term	Date/Time	Version
Current	Intrameningeal	2019-01-24 15:54:39	1
Current	髄膜内	2019-01-24 15:54:41	1

Clicking on one of the mapped terms will take you to the entry for that particular mapped term

The ICH E2B Code List has terms in English and Japanese that are equivalent to the Standard Term 'Intrathecal use'

The screenshot shows the 'DETAILS' view for the term '髄膜内' (Japanese). The interface includes a language selector set to 'Japanese' and a domain of 'Human and Veterinary'. A table provides the following details:

Concept Code	90001203
Term	髄膜内
Concept Class	MAP
Domain	Human and Veterinary
Concept Status	Current
Version Number	1
Version creation date	2019-01-24 15:54:41
Modification made	Mapping submission
Language	Japanese
Expanded code	MAP-90001203-JA-JP
Concept Creation Date	2019-01-24 15:54:41
Source	ICH (International Council for Harmonisation of Technical Requirements for Pharmaceuticals for H...) / ICH E2B Code List
Region ID	029
Mapping With	ROA-20042000: Intrathecal use

Regional information for the term can be indicated here, including a definition, comments, and links to the external database, where available

Example of a 'non-traditional' Standard Term

Transplacental

The ST tag has been replaced with the AER tag, to indicate that it is not a traditional Standard Term but is instead intended for use in adverse-event reports

Current	Transplacental	AER	Human and Veterinary
DETAILS TRANSLATIONS SUMMARY SHEETS			
Concept Code	20083000		
Term	Transplacental		
Definition	In utero exposure of an embryo/foetus to a medicinal product administered to the pregnant mother.		
Comment	This term is not intended to describe an authorised route of administration for use in marketing authorisations, and does not cover intentional administration of a medicinal product to an embryo/foetus. It is intended for use in adverse event reporting for pharmacovigilance purposes.		
Concept Class	ROA		
Domain	Human and Veterinary		
Concept Status	Current		
Version Number	1		
Version creation date	2017-08-21 16:36:36		
Modification made	Coded Concept creation		
Language	English		
Expanded code	ROA-20083000-EN-GB		
Concept Creation Date	2017-08-21 16:36:36		
Request Authority	ICH		
EDQM's request ID	93		

This term is not intended to be used to describe an authorised route of administration. However, an official, harmonised term is necessary for AERs in order to describe exposure to a drug *in utero*, hence its inclusion as a Standard Term

Pharmeuropa online

PHARMEUROPA ONLINE



The screenshot shows the Pharmeuropa Online website. At the top, there is a navigation bar with the title 'Pharmeuropa Online' and the EDQM logo. Below the navigation bar, there are three main sections: 'Texts for comment', 'Pharmeuropa Bio & Scientific Notes', and 'Pharmeuropa archives'. A 'What's new?' section is highlighted in orange, listing recent updates: 'Texts for comment: 1 draft(s) added in the last week', 'EDQM News', 'Events', 'European Pharmacopoeia: update to work programme (June 2019)', 'European Pharmacopoeia Commission: list of texts adopted in June 2019', 'Publication schedule and general information (July 2019)', 'Comments concerning revised texts published in 10th Edition (10.0)', and 'Pharmeuropa 31.3: the issue is now complete (public enquiry until 30 September 2019)'. The bottom of the page features the EDQM and Council of Europe logos.

- Free of charge (but requires registration).
- Contains texts under public enquiry (Pharmeuropa); Bio & Scientific notes; some technical information and archives.

PHARMEUROPA ONLINE



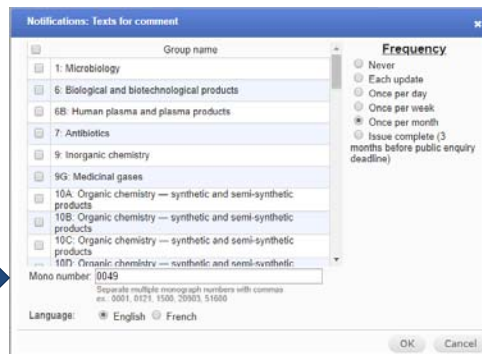
Pharmeuropa (Texts for comments)

- The **forum** of the Ph. Eur.
- Continuous publication.
- 4 "issues" (with corresponding deadlines) per year.

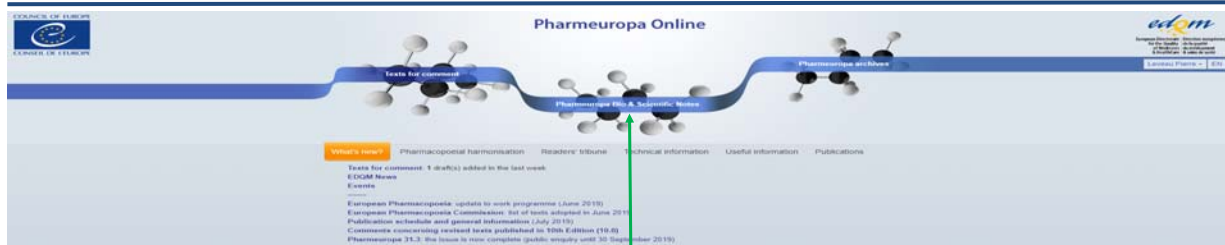
PHARMEUROPA ONLINE

Notes:

- * Corrections are not included in Pharmeuropa.
- * **Comments** from the USA: through EDQM Helpdesk.
- * You can subscribe to **notifications!**
My Account > Configure Notifications >



PHARMEUROPA ONLINE



Pharmeuropa Bio & Scientific Notes

Provides access to establishment reports of BRPs
Search engine available.

PHARMEUROPA ONLINE



Pharmeuropa archives

Provides access to Pharmeuropa dated back 1987
Search engine available.

PHARMEUROPA ONLINE



Other types of information are also available such as:

What's new?

- ✓ New texts for comment,
- ✓ List of texts adopted at the EP Commission
- ✓ Publication schedule
- ✓ Comments about texts revised in the 10th edition

PHARMEUROPA ONLINE



Other types of information are also available such as:

Pharmacopoeial harmonisation

- ✓ Draft harmonised texts for comment
- ✓ PDG state of work

PHARMEUROPA ONLINE



Other types of information are also available such as:

Reader's tribune

- ✓ You have the possibility to express opinion in response to an article in Pharmeuropa Bio & Scientific Notes

PHARMEUROPA ONLINE



Other types of information are also available such as:

Technical information

- ✓ Policies, explanation to Ph. Eur. monographs e.g. clarification of legal status: Ph. Eur. Section 3. Materials for containers and containers; response and correction factors in monographs; reverse osmosis in Ph. Eur. monograph Water for injections (0169), etc.

PHARMEUROPA ONLINE



Other types of information are also available such as:

Useful information

- ✓ 10th edition
- ✓ Work of the Ph. Eur., procedures
- ✓ Procedure to comment, addresses of NA, etc.

PHARMEUROPA ONLINE



Other types of information are also available such as:

Publications

- ✓ Provides access to other EDQM publications such as:
 - Standard terms,
 - European Paediatric Formulary,
 - Blood, organ, tissue and cell transplantation guides,
 - Proceedings of International Conferences,
 - Ph. Eur. technical guides...

Knowledge database

KNOWLEDGE DATABASE

• How to connect?

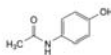
Direct link from electronic Ph. Eur.



General Notices apply to all monographs and other texts.
See the information section on general monographs.

PARACETAMOL

Paracetamolum



$C_8H_9NO_2$

[103-90-2]

DEFINITION

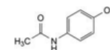
2D code in print edition



04/2018:0049

PARACETAMOL

Paracetamolum



$C_8H_9NO_2$
[103-90-2]

M_r 151.2

DEFINITION

N-(4-Hydroxyphenyl)acetamide.

Content: 99.0 per cent to 101.0 per cent (dried substance).

CHARACTERS

Appearance: white or almost white, crystalline powder.

Solubility: sparingly soluble in water, freely soluble in ethanol (96 per cent), very slightly soluble in methylene chloride.

KNOWLEDGE DATABASE

Search Database online | Knowledge Database 

Detailed view of Paracetamol.

- 0 The monograph has been authorised but work has not started yet
- 1 Work has started (first draft)
- 2 The monograph has been authorised for publication in Pharmeuropa (see Pharmeuropa number)
- 3 The monograph has been submitted for adoption to the European Pharmacopoeia Commission
- 4 The monograph has been adopted
- 5 The monograph is about to be published, or has been published

Status	In use																												
Monograph Number	00049																												
English Name	Paracetamol																												
French Name	Paracétamol																												
Latin Name	Paracetamolum																												
Pinyin Name																													
Chinese Name																													
Pharmeuropa	28.1																												
Published in English Supplement	9.4																												
Published in French Supplement	9.4																												
On-going Revision	Revision																												
State of work	0																												
Pharmeuropa																													
Description	Revision of the test for related substances: optimisation of the LC method.																												
Chromatogram	Available																												
Additional information	Not available																												
History	View history																												
Interchangeable (ICH_Q4B)	NO																												
Chapter 5.8 Pharmacopoeial harmonisation	NO																												
Reference standards	<table border="1"> <thead> <tr> <th>Available since</th> <th>Cat. No.</th> <th>Name</th> <th>Batch No.</th> <th>Unit Quantity</th> <th>Price</th> <th>SDS Product Code</th> </tr> </thead> <tbody> <tr> <td></td> <td>P0300000</td> <td>Paracetamol</td> <td>4</td> <td>50 mg</td> <td>79 EUR</td> <td>201600685</td> </tr> <tr> <td></td> <td>Y0001245</td> <td>Paracetamol impurity J</td> <td>1</td> <td>15 mg</td> <td>79 EUR</td> <td>201600685</td> </tr> <tr> <td></td> <td>Y0001255</td> <td>Paracetamol impurity K</td> <td>1</td> <td>15 mg</td> <td>79 EUR</td> <td>201601115</td> </tr> </tbody> </table>	Available since	Cat. No.	Name	Batch No.	Unit Quantity	Price	SDS Product Code		P0300000	Paracetamol	4	50 mg	79 EUR	201600685		Y0001245	Paracetamol impurity J	1	15 mg	79 EUR	201600685		Y0001255	Paracetamol impurity K	1	15 mg	79 EUR	201601115
Available since	Cat. No.	Name	Batch No.	Unit Quantity	Price	SDS Product Code																							
	P0300000	Paracetamol	4	50 mg	79 EUR	201600685																							
	Y0001245	Paracetamol impurity J	1	15 mg	79 EUR	201600685																							
	Y0001255	Paracetamol impurity K	1	15 mg	79 EUR	201601115																							

On-going revision

- Aim of the revision
- State of work
- The number of the last issue of Pharmeuropa in which a draft of the monograph was published

See next slide →

See next slide →

← RS used in the monograph

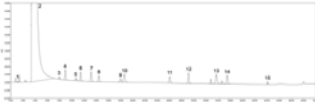
KNOWLEDGE DATABASE

EUROPEAN PHARMACOPOEIA 10 Paracetamol

042018:0049

PARACETAMOL
Paracetamolum

The following chromatogram is shown for information but will not be published in the European Pharmacopoeia.

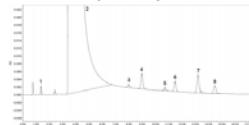


- 1. impurity K
- 2. paracetamol
- 3. impurity A
- 4. impurity B
- 5. impurity F
- 6. impurity C
- 7. impurity A
- 8. impurity E
- 9. impurity M
- 10. impurity G
- 11. impurity H
- 12. impurity L
- 13. impurity I
- 14. impurity J
- 15. impurity N

Figure 0049.-1. – Chromatogram for the test for related substances: solution of paracetamol spiked with impurities A to N at 0.01 per cent

Paracetamol EUROPEAN PHARMACOPOEIA 10

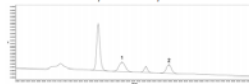
The following chromatogram is shown for information but will not be published in the European Pharmacopoeia.



- 1. impurity K
- 2. paracetamol
- 3. impurity A
- 4. impurity B
- 5. impurity F
- 6. impurity C
- 7. impurity D
- 8. impurity E

Figure 0049.-2. – Chromatogram for the test for related substances: solution of paracetamol spiked with impurities A, B, C, D, E, F and K at 50 ppm

The following chromatogram is shown for information but will not be published in the European Pharmacopoeia.



- 1. impurity I
- 2. impurity J

Figure 0049.-3. – Chromatogram for the test for related substances: solution of paracetamol spiked with impurities I and J at 10 ppm

Chromatogram

Type chromatogram is available for download.

It should be stressed that such chromatograms do not constitute a mandatory part of the corresponding monograph and **are provided for information only**.

They do not necessarily include all impurities mentioned in the monograph, are not representative for all impurity profiles of the substance and are provided solely for the convenience of the user.

KNOWLEDGE DATABASE

History

SUPPLEMENT 9.4

Identification: 1st identification series updated and only IR now required; IR sample preparation deleted in accordance with current policy; 2nd identification series updated to avoid using potassium dichromate (test D) and only a mixed melting point now described.

Related substances: new LC to take into account additional impurities.

EDITION 9.0

Heavy metals: test deleted in line with Ph. Eur. strategy on elemental impurities.

EDITION 6.0: corrected

Contains information concerning certain technical modifications to some revised/corrected texts published since Ph. Eur. 5.0.

This information complements the modifications indicated by lines in the margin in the supplements and is not necessarily exhaustive.

KNOWLEDGE DATABASE

Practical Information		Test(s)	Brand Name/Information				
		Related substances	From 9.4: Precolumn: Halo C18 is suitable; Column: Halo C18 is suitable; Dwell volume used for the development of the method = 1.07mL. Before 9.4: Lichrospher 100 RP8 and Zorbax RX C8 are suitable.				
Substance Number	Substance	Certificate Holder	Certificate Number	Issue Date	Status	End date	Type
45	Paracetamol	Rhodia Organique SAS FR 69006 Lyon	R1-CEP 1996-004-Rev 02	14/02/2005	WITHDRAWN BY HOLDER	21/06/2006	Chemistry
45	Paracetamol	Bristol Laboratories Ltd GB HA1 2EN Harrow	R0-CEP 2001-092-Rev 02	13/10/2004	WITHDRAWN BY HOLDER	25/10/2005	Chemistry
45	Paracetamol	NOVACYL FR 69130 Eculliy	R1-CEP 2002-214-Rev 03	19/07/2018	VALID		Chemistry
45	Paracetamol	SRI KRISHNA PHARMACEUTICALS LIMITED IN 500 039 Hyderabad	R1-CEP 2000-144-Rev 05	24/07/2018	VALID		Chemistry
45	Paracetamol	Hebel Jiheng (Group) Pharmaceutical Co. Ltd. CN 693 000 Hengshui City	R1-CEP 2005-032-Rev 02	05/10/2017	VALID		Chemistry
45	Paracetamol	Weistar Industry Limited CN 313 000 Huzhou	R0-CEP 2006-156-Rev 00	17/04/2008	WITHDRAWN BY EDQM	16/04/2013	Chemistry
45	Paracetamol	Rhodia Opérations S.A.S. FR 93306 Aubervilliers	R2-CEP 1992-010-Rev 02	31/08/2006	WITHDRAWN BY HOLDER	09/11/2011	Chemistry
45	Paracetamol	Zhejiang Kangle Pharmaceutical Co. Ltd. CN 325 011 Wenzhou	R1-CEP 2004-309-Rev 01	06/12/2013	VALID		Chemistry
45	Paracetamol	Indukern Chemie AG CH 8952 Schlieren	R0-CEP 2000-002-Rev 00	22/10/2001	WITHDRAWN BY EDQM	09/10/2002	Chemistry
45	Paracetamol	Atabay Kimya Sanayi Ve Ticaret A.S. TR 34718 Kadiköy, İstanbul	R1-CEP 1995-050-Rev 04	17/10/2018	VALID		Chemistry

← For guidance purposes: provides additional information to users *e.g.* column / trade names

Updated at each revision!

← If certificate(s) of suitability have been granted for the substance in question, the list of certificates is shown.

This is an excerpt from the [online List of CEP](#).

Ph. Eur. online

Ph. Eur. ONLINE

- New platform for the 10th edition



- EDQM has been using same platform for Ph. Eur. since 2007.
- The website needed modernising. We decided to redevelop the site internally using Python Programming Language.
- Ph. Eur. electronic version is part of a more global project which includes the PaedForm website and Pharmeuropa

Ph. Eur. ONLINE

- New platform for the 10th edition



- Minimum: ISOFunctional vs previous version
- Completely cumulative versions, bilingual (English and French), with new features and direct access to complementary information ([Knowledge Database](#)).
- Application fully compatible with recent Windows and Linux operating systems (Mac coming soon).

Ph. Eur. ONLINE

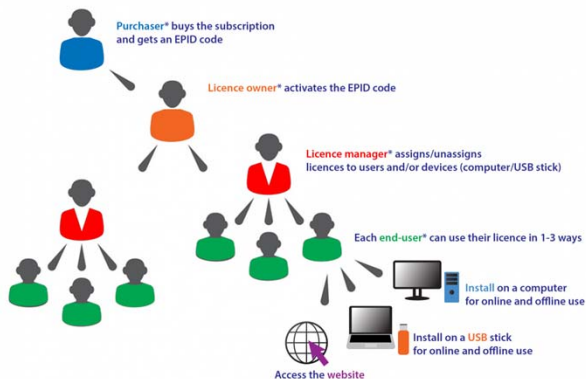
Other new features

- New subscription model
- Online version is tablet and smartphone friendly
- Direct links to texts
- Improved search query management
- Improved visibility of changes (for revised and corrected texts)
- Improved browsing
 - In the table of contents and between search results
 - Using standard browser buttons (back/forward arrows)
- Same username and password as for many other Ph. Eur. Websites as uses same authentication database (OCABR, OMCL, KnowX, PaedForm, future Pharmedropa)

Ph. Eur. ONLINE

• New management of licences

Licence model (roles)



* Each user can have 1 or more of these roles

- No more safeview plugin. Content protection is ensured by identifying users individually and preventing simultaneous access.
- Individual use: installation of the application to 1 computer and to 1 USB stick, for online or offline use, for easy access while on the move or in environments where the use of the book or the website would not be possible or would be impractical.
- Shared use: installation of the application to computers or USB sticks and use whether connected to internet or not, for example for non-nominative access in university libraries or laboratories.

Ph. Eur. ONLINE

- **NEW** possibility to use the arrows.
- New layout to access General Notices & General monographs.

← ↑

NEW possibility to use the arrows.

NEW possibility of advanced queries and saving them.

Ph. Eur. ONLINE

Table of contents

- Paracetamol
- Paraffin, hard
- Paraffin, light liquid
- Paraffin, liquid
- Paraffin, white soft
- Paraffin, yellow soft
- Paraldehyde
- Parnaparin sodium
- Paroxetine hydrochlori...
- Paroxetine hydrochlori...

Search results

fluorescence methylene FOR SELECTION Add criteria

1 - 1 of 1

Sort by: Default | Some excerpts | 50 rows

Paraffin, hard

Implementation date: 01/2008 (10.0) Text number: 1034

... solid saturated hydrocarbons generally obtained from petroleum. It may contain a suitable antioxidant. CHARACTERS Appearance: colourless or white or almost white mass; the melted substance is free from fluorescence in daylight. Solubility: practically insoluble in water; freely soluble in methylene chloride, practically insoluble in ethanol (96 per cent). IDENTIFICATION: First identification: A, C. Second identification: B, C. A: Infrared absorption spectrophotometry (2.2.34). Comparison: hard paraffin.

Save query | Tools

- Query in 5 texts; for contains "Fluorescence" & "methylene".
- ! In French query only with accent (é / è, etc.)
- Now possible to save queries

Ph. Eur. ONLINE

- Possibility to download the version on an USB stick

Downloads

APPLICATION

WINDOWS | LINUX | MAC OS (Parallels) | Downloads

OFFLINE PACKS

European Pharmacopoeia 10.0

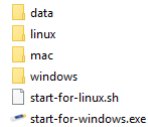
10 10.0 01/2008

Downloads menu: Sign out, My profile, My subscription keys, Services, Downloads, Change password, User manual

- "Download" menu, select the application, copy files on the USB stick, execute the .exe, enter id and code.

Ph. Eur. ONLINE

- Click on « Start-for-windows.exe »..... and start working...



- Possibility to work online and offline.
- ! Your queries could be lost on the device, please check before.

Ph. Eur. ONLINE

- Subscribers to electronic and print versions have access to Ph. Eur. archives.
 - Only subscribers with an up-to-date subscription have access
- Ph. Eur. Archives will be more dynamic than previously
- HTML versions will be moved directly to the Ph. Eur. Archives when they are no longer implemented
 - January 2020: Ph. Eur. 9.8 → Ph. Eur. Archives
 - April 2020: 10.0
 - July 2020: 10.1
 - January 2021: 10.2, etc.
- Ph. Eur. Archives will remain in PDF format

Thank you for your attention



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