

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



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## Find your way in Pharmeuropa, the Knowledge database & Ph. Eur. Online: Useful hints and other practicalities

**European Pharmacopoeia Training Session on Biologicals  
4-5 February 2020**

Dr Hans-Joachim Bigalke, Head of IT and  
Publications Division, EDQM, Council of Europe

# TOPICS

- How to access?
- Pharmeuropa Online
- Ph.Eur. Online
- Knowledge database

## HOW TO ACCESS?

Specific page to EDQM databases from the EDQM website:

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

### Databases

<b>Pharmeuropa</b>  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"> <li>Texts for comments database</li> <li>Pharmeuropa archives</li> </ul>	<b>Pharmeuropa Bio &amp; Scientific Notes</b>  Pharmeuropa Bio & Scientific Notes contains all the news in the biological standardisation area and scientific articles linked to the work of the European Pharmacopoeia  <b>Knowledge</b>  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"> <li>Search Knowledge</li> <li>Latest Ph.Eur. News</li> <li>Work programme Ph.Eur.</li> </ul>
	<b>Ph. Eur. Reference Standards</b>  Search through our continuously updated database for information on Ph.Eur. Reference Standards <ul style="list-style-type: none"> <li>Search Ph.Eur. Reference Standards</li> <li>More about Ph.Eur. Standards</li> <li>Place an order</li> </ul>

Publications

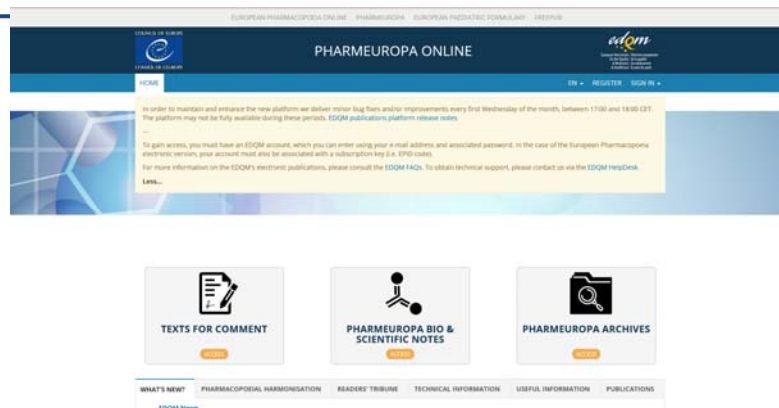
<b>EDQM Free Publications</b>  Discover the EDQM publications available for free (freepubs)  <b>European Pharmacopoeia</b>  Access to the <a href="#">Ph. Eur. 10<sup>th</sup> Edition online</a> (visiting clients) Access to the <a href="#">Ph. Eur. 9<sup>th</sup> Edition online</a> (visiting clients)
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<b>WHO ISA</b>  This database contains information on WHO International Standards for Antibiotics (ISA). <ul style="list-style-type: none"> <li>Search WHO ISA Reference Standards</li> <li>More about WHO ISA Standards</li> <li>Place an order</li> </ul>	<b>WHO ICRS</b>  This database contains information on WHO International Chemical Reference Substances (ICRS). <ul style="list-style-type: none"> <li>Search WHO ICRS Reference Standards</li> <li>More about WHO ICRS Substances</li> <li>Place an order</li> </ul>
<b>Certification</b>  Search our Certification database for information on Certificates of Suitability (CEPs) granted by the EDQM. <ul style="list-style-type: none"> <li>Search Certification Database</li> <li>Certification news</li> </ul>	<b>Standard Terms</b>  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
<b>Melclass</b>  Database on the legal classification of medicines as regards their supply conditions and details of prescription status. Search Melclass	

# TOPICS

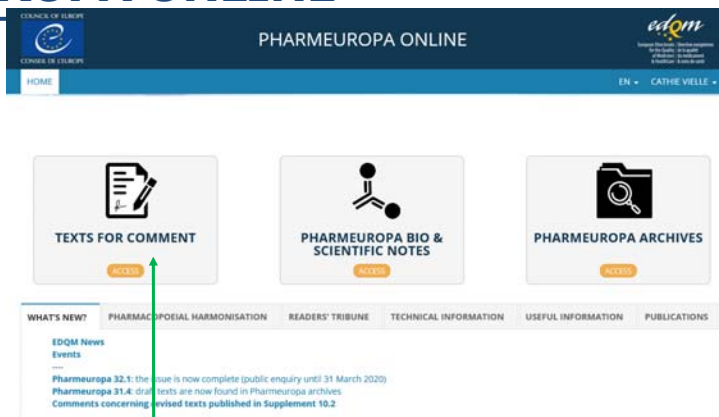
- How to access?
- **Pharmeuropa Online**
- Ph.Eur. Online
- Knowledge database

## PHARMEUROPA ONLINE



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

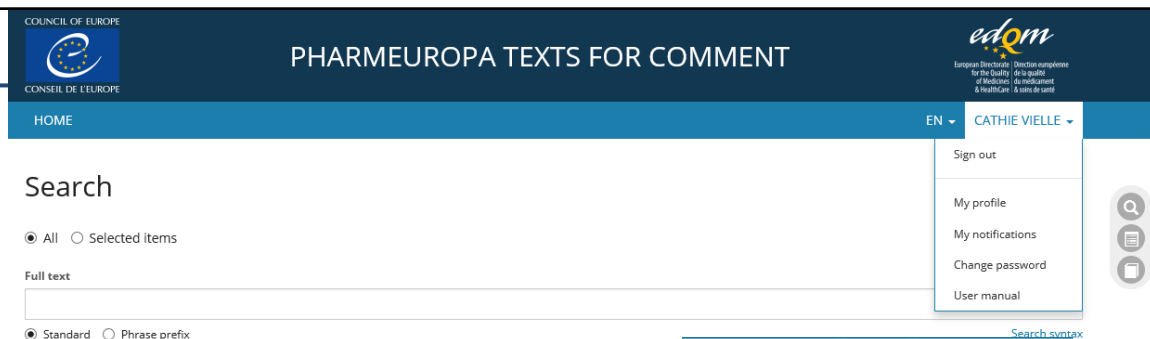
# PHARMEUROPA ONLINE



## Pharmeuropa (Texts for comments)

- The **forum** of the Ph. Eur.
- Continuous publication but ...

... 4 "issues" (with corresponding deadlines) per year.



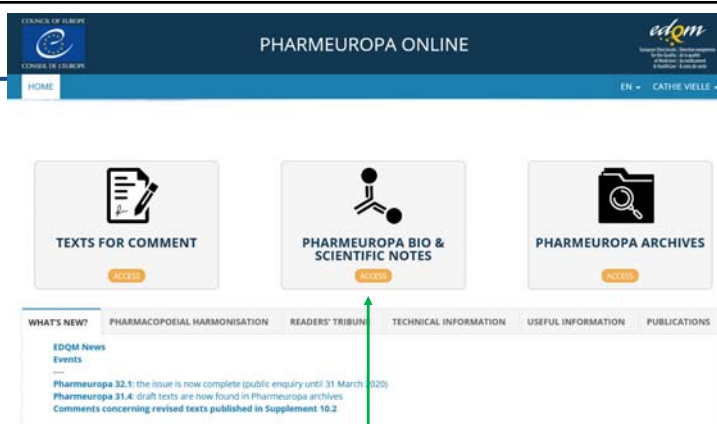
## Notes:

\* Corrections, minor revisions are not included.

\* **Comments** from the non Ph Eur countries e.g. USA through EDQM Helpdesk.



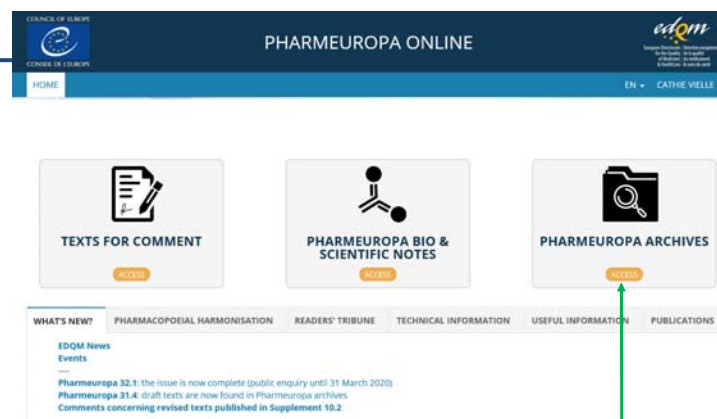
\* You can suscribe to **notifications**!



## Pharmeuropa Bio & Scientific Notes

Provides access to establishment reports of BRPs

Search engine available.




## Pharmeuropa archives

Provides access to Pharmeuropa dated back 1987


Search engine available.






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**EDQM News Events**



Pharmeuropa 32.1: the issue is now complete (public enquiry until 31 March 2020)


Pharmeuropa 31.4: draft texts are now found in Pharmeuropa archives

Comments concerning revised texts published in Supplement 10.2

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


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**Draft harmonised texts for comment**

Determination of elemental impurities (2.4.20) (until 31 December 2019)

Bulk density of powders (2.9.34) (until 31 December 2019)

Powder flow (2.9.36) (until 31 December 2019)

Croscarmellose sodium (0985) (until 31 December 2019)

**Pharmacopoeial harmonisation**

PDG state of work (April 2018)

General information



**Partners in pharmacopoeial harmonisation**


Japanese Pharmacopoeial Forum

USP Pharmacopoeial Forum

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


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**Pharmeuropa Bio & Scientific Notes and Readers' Tribune**  
Instructions for authors (February 2013)

**2014**  
Markers to ensure consistent quality of homeopathic products in Europe



**2013**  
Quality aspects of homeopathic preparations  
Quality of TCM Drugs and TCM Products


**2012**  
A consideration of the analytical requirements for fresh herbal drugs used to produce herbal drug preparations  
Monographs on mesylates: GMP and Production statement?  
Molecular weights under discussion?

**2011**  
Re-examination of the general monographs on Herbal drugs and Herbal drug preparations with reference to monographs on traditional Chinese herbal ingredients  
Comments on the article of Dr Keith Helliwell on European Pharmacopoeia monographs on extracts  
Heparins and changing regulatory requirements in the EU

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


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PUBLICATIONS

**Ph. Eur. Section 3. Materials for containers:** clarification of legal status  
**Examples of validation protocols of the alternative microbiological methods** according to chapter 5.1.6 *Alternative methods for control of microbiological quality*  
**Reverse osmosis** in Ph. Eur. monograph Water for injections (0169)  
**Bacterial endotoxins:** European Pharmacopoeia policy (revised February 2015)  
**Response and correction factors** in monographs of the European Pharmacopoeia  
**Homeopathic preparations:** changes to titles of monographs  
**Veterinary vaccines:** harmonisation with VICH Guidelines 41 and 44


**Policies, explanation to Ph. Eur. monographs**

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10<sup>th</sup> Edition

Publication schedule and general information (November 2019)

Comments concerning revised texts published in Supplement 10.2

List of texts published in Supplement 10.2

New reagents published in the European Pharmacopoeia (Supplement 10.1 included)

Comments concerning revised texts published in Supplement 10.1

List of texts published in Supplement 10.1

Comments concerning revised texts published in 10th Edition (10.0)

List of texts published in the 10<sup>th</sup> Edition

Introduction (chapter 0) of the 10<sup>th</sup> Edition (10.0)

Work of the European Pharmacopoeia

Update to work programme of the European Pharmacopoeia (June 2019)

Procedures P1, P4 and P5 for elaboration/revision of texts

List of groups of experts and ad hoc working parties

Procedure for commenting on Pharmeuropa drafts

Addresses of national authorities

Request revision of Ph. Eur. texts

Pharmeuropa Bio & Scientific Notes and Readers' Tribune

Instructions for authors (February 2013)

HelpDesk and FAQs

Free EDQM databases

Certification of suitability to the monographs of the European Pharmacopoeia

Proficiency Testing Scheme (PTS)

CombiStats: a statistical tool for the analysis of biological data

Structure of EDQM

Membership and observance of the European Pharmacopoeia Commission



✓ 10th edition

✓ Work of the Ph. Eur., procedures

✓ Procedure to comment, addresses of NA, etc.

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European Pharmacopoeia 10<sup>th</sup> Edition

Standard terms

European Pharmacopoeia reference standards

European Paediatric Formulary

Consumer health protection (cosmetics and packaging)

Blood transfusion guides

Organ, tissue and cell transplantation guides

Pharmaceuticals and pharmaceutical care

Counterfeit medical products and similar crimes

Proceedings of international conferences

Ph. Eur. Technical guides

Download the latest guides

Council of Europe

Council of Europe health-related publications

Provides access to other EDQM publications such as:

Standard terms, European Paediatric Formulary,

Proceedings of International Conferences,

Ph. Eur. technical guides...

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**Keep in touch – Don't miss an opportunity to comment on draft texts**

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## TOPICS

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- Knowledge database

## Ph. Eur. ONLINE

- New platform for the 10th edition



- Ph. Eur. electronic version is part of a new publication platform which includes the PaedForm website and Pharmeuropa

## Ph. Eur. ONLINE



- 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

- 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, Pharmeuropa)

## Ph. Eur. ONLINE

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

**PARACETAMOL**  
Paracetamolum

CC(=O)Nc1ccc(O)cc1

C<sub>9</sub>H<sub>9</sub>NO<sub>2</sub>  
[103-90-2]  
DEFINITION  
N-(4-Hydroxyphenyl)acetamide.  
Content: 99.0 per cent to 101.0 per cent (dried substance).

- **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

Q Fluorescence methylene X FOR SELECTION X Add criteria

1 - 1 of 1

Sort by Default 11 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. CHARACTERISTICS 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

- Query in 6 texts: contains "Fluorescence" & "methylene".

- possible to save queries

# 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

# TOPICS

- How to access?
- Pharmeuropa Online
- Ph.Eur. Online
- **Knowledge database**

# KNOWLEDGE DATABASE

## • How to connect?

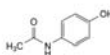
Direct link from electronic Ph. Eur.



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

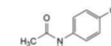
2D code in print edition



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 Pharmedropa (see Pharmedropa 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																													
Pharmedropa	28.1																												
Published in English Supplement	9.4																												
Published in French Supplement	9.4																												
On-going	Revision																												
State of work	0																												
Pharmedropa																													
Description	Revision of the test for related substances: optimisation of the LC method.																												
Chromatogram	Available																												
Additional information	Not available																												
History	<a href="#">View history</a>																												
Interchangeable (ICH_Q4B)	NO																												
Chapter 5.8 Pharmacopoeial harmonisation	NO																												
Reference standards	<table><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><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>Y0001345</td><td>Paracetamol impurity</td><td>1</td><td>15 mg</td><td>79 EUR</td><td>201600685</td></tr><tr><td></td><td>Y0001355</td><td>Paracetamol impurity</td><td>1</td><td>15 mg</td><td>79 EUR</td><td>201601115</td></tr></table>	Available since	Cat. No.	Name	Batch No.	Unit Quantity	Price	SDS Product Code		P0300000	Paracetamol	4	50 mg	79 EUR	201600685		Y0001345	Paracetamol impurity	1	15 mg	79 EUR	201600685		Y0001355	Paracetamol impurity	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																							
	Y0001345	Paracetamol impurity	1	15 mg	79 EUR	201600685																							
	Y0001355	Paracetamol impurity	1	15 mg	79 EUR	201601115																							

## On-going revision

- Aim of the revision
- State of work
- The number of the last issue of Pharmedropa 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

04/2018:0049

## PARACETAMOL

Paracetamolum

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



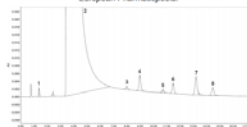
- |                |               |                |                |
|----------------|---------------|----------------|----------------|
| 1. impurity K  | 5. impurity F | 9. impurity M  | 13. impurity I |
| 2. paracetamol | 6. impurity C | 10. impurity G | 14. impurity J |
| 3. impurity A  | 7. impurity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

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

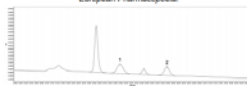
The following chromatogram is shown for information but will not be published in the European Pharmacopoeia.



- |                |               |               |               |
|----------------|---------------|---------------|---------------|
| 1. impurity K  | 3. impurity A | 5. impurity F | 7. impurity D |
| 2. paracetamol | 4. impurity B | 6. impurity C | 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:** 1<sup>st</sup> identification series updated and only IR now required; IR sample preparation deleted in accordance with current policy; 2<sup>nd</sup> 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.					
CEP	Substance Number	Substance	Certificate Holder	Certificate Number	Issue Date	Status	End date	Type
	49	Paracetamol	Rhodia Organique SAS FR 69006 Lyon	R1-CEP 1996-004-Rev 02	14/02/2005	WITHDRAWN BY HOLDER	21/06/2006	Chemistry
	49	Paracetamol	Bristol Laboratories Ltd GB HA1 2EN Harrow	R0-CEP 2001-092-Rev 02	13/10/2004	WITHDRAWN BY HOLDER	25/10/2005	Chemistry
	49	Paracetamol	NOVACYL FR 69130 Ecullly	R1-CEP 2002-214-Rev 03	19/07/2018	VALID		Chemistry
	49	Paracetamol	SRI KRISHNA PHARMACEUTICALS LIMITED IN 500 039 Hyderabad	R1-CEP 2000-144-Rev 05	24/07/2018	VALID		Chemistry
	49	Paracetamol	Hebei Jiheng (Group) Pharmaceutical Co. Ltd. CN 053 000 Hengshui City	R1-CEP 2005-032-Rev 02	05/10/2017	VALID		Chemistry
	49	Paracetamol	Weistar Industry Limited CN 313 000 Huzhou	R0-CEP 2006-156-Rev 00	17/04/2008	WITHDRAWN BY EDQM	16/04/2013	Chemistry
	49	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
	49	Paracetamol	Zhejiang Kangle Pharmaceutical Co. Ltd. CN 325 011 Wenzhou	R1-CEP 2004-309-Rev 01	06/12/2013	VALID		Chemistry
	49	Paracetamol	Indukern Chemie AG CH 8952 Schlieren	R0-CEP 2000-002-Rev 00	22/10/2001	WITHDRAWN BY EDQM	09/10/2002	Chemistry
	49	Paracetamol	Atabay Kimya Sanayi Ve Ticaret A.S. TR 34718 Kadiköy, Istanbul	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](#).

# Thank you for your attention

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