



SPECIFIKACE VOD PODLE LÉKOPISU

LABORATORNÍ TESTOVÁNÍ VODY

VODA PRO ANALYTICKÉ METODY

EVIDENCE ANALÝZ

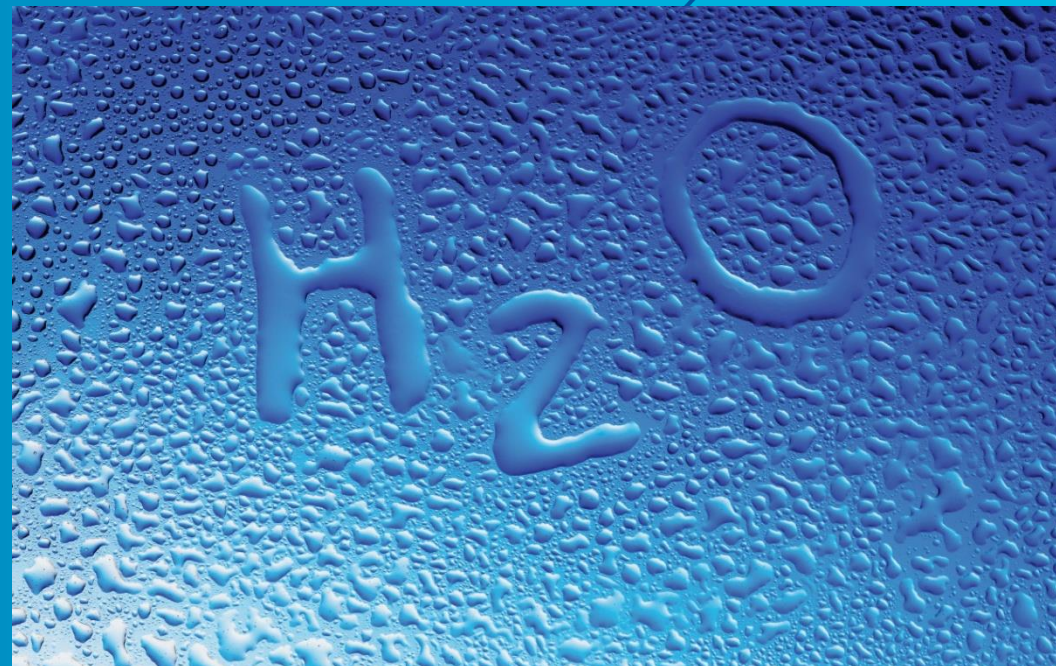
VÝSLEDKY, TRENDY A JEJICH VYHODNOCENÍ

Lukáš Dvořák, 26.11. 2021, Brno

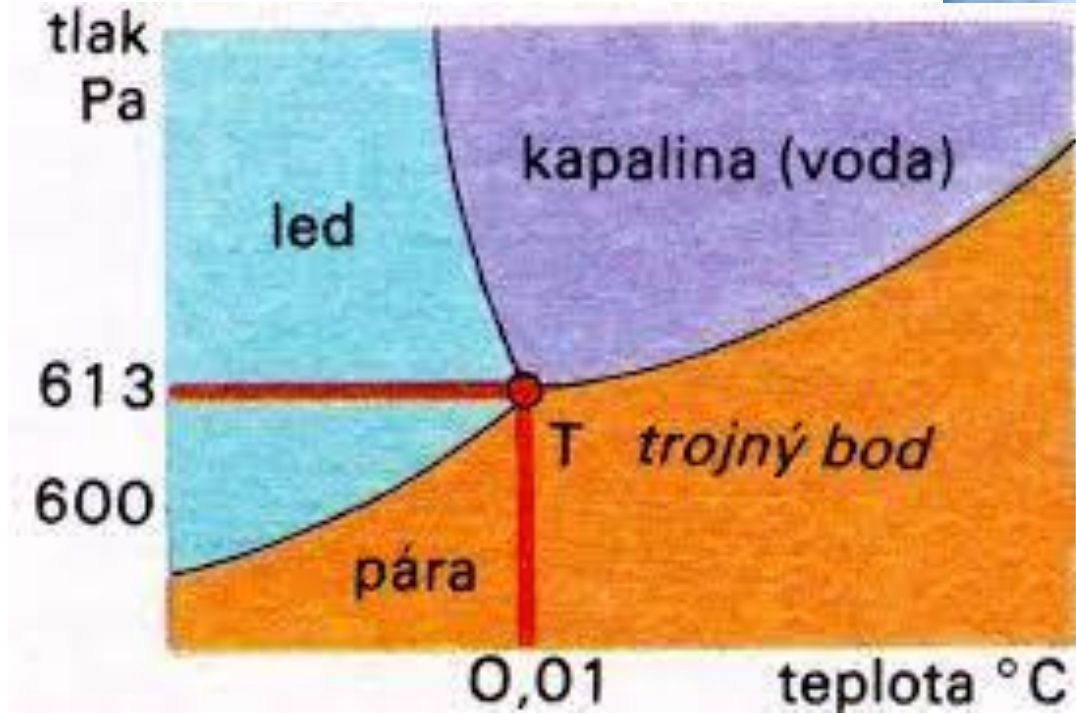
**VODA A VODNÍ SYSTÉMY VE FARMACEUTICKÉM  
PRŮMYSLU**

SPECIFIKACE VOD PODLE LÉKOPISU

LABORATORNÍ TESTOVÁNÍ VODY







# EDQM - European Directorate for the Quality of Medicines

## European Pharmacopoeia (Ph. Eur.) 10th Edition



# Specifikace vod podle lékopisu



## PUBLICATION SCHEDULE

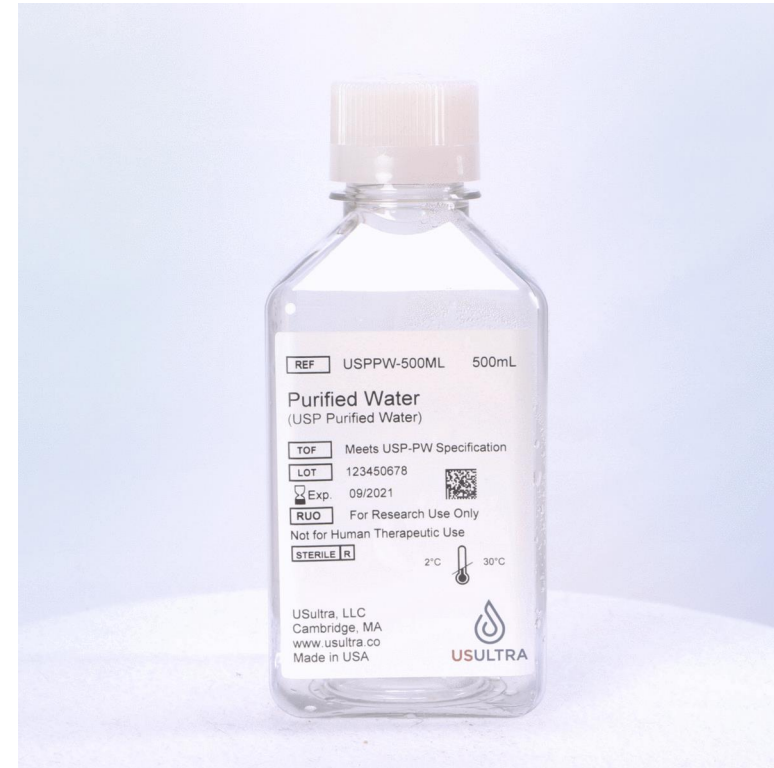
Commission Sessions		Edition/ Supplement	Publication schedule	Corrections to be taken into account as soon as possible and not later than	Implementation date
Session No.	Date				
<b>162</b>	<b>November 2018</b>	<b>10<sup>th</sup> Edition</b>	<b>July 2019</b>	<b>31 August 2019</b>	<b>1 January 2020</b>
163	March 2019	10.1	October 2019	30 November 2019	1 April 2020
164	June 2019	10.2	January 2020	29 February 2020	1 July 2020
165	November 2019	10.3	July 2020	31 August 2020	1 January 2021
166	March 2020	10.4	October 2020	30 November 2020	1 April 2021
167	June 2020	10.5	January 2021	28 February 2021	1 July 2021
168	November 2020	10.6	July 2021	31 August 2021	1 January 2022
169	March 2021	10.7	October 2021	30 November 2021	1 April 2022
170	June 2021	10.8	January 2022	28 February 2022	1 July 2022
<b>171</b>	<b>November 2021</b>	<b>11<sup>th</sup> Edition</b>	<b>July 2022</b>	<b>31 August 2022</b>	<b>1 January 2023</b>

# Lékopisná kvalita vod

VODA PRO INJEKCE (WFI)

VODA PRO PŘÍPRAVU EXTRAKTŮ

ČIŠTĚNÁ VODA (PW)



# Lékopisná specifikace vody



Parameter	Purified water (in bulk)	Water for injection (in bulk)
TOC or oxidisable substances	X	X
Conductivity	X	X
Elemental impurities	X	N/A
Nitrates	X	X
Microbiological monitoring	X	X
Aluminium	manufacture of dialysis solutions	manufacture of dialysis solutions
Bacterial endotoxins	manufacture of dialysis solutions	X
	Purified water (in container)	Water for injection (in container)
Acidity or alkalinity	X	X
Oxidisable substances	X	X
Chlorides	X	X
Sulphates	X	X
Ammonium	X	X
Calcium and Magnesium	X	X
Residue on evaporation	X	X
Microbiological contamination	X	X
Particulate contamination	N/A	X
Sterility	N/A	X



# Specifikace vody – vybrané metody

## Vodivost & Elementární nečistoty

## WATER FOR INJECTIONS

### Aqua ad iniectabile

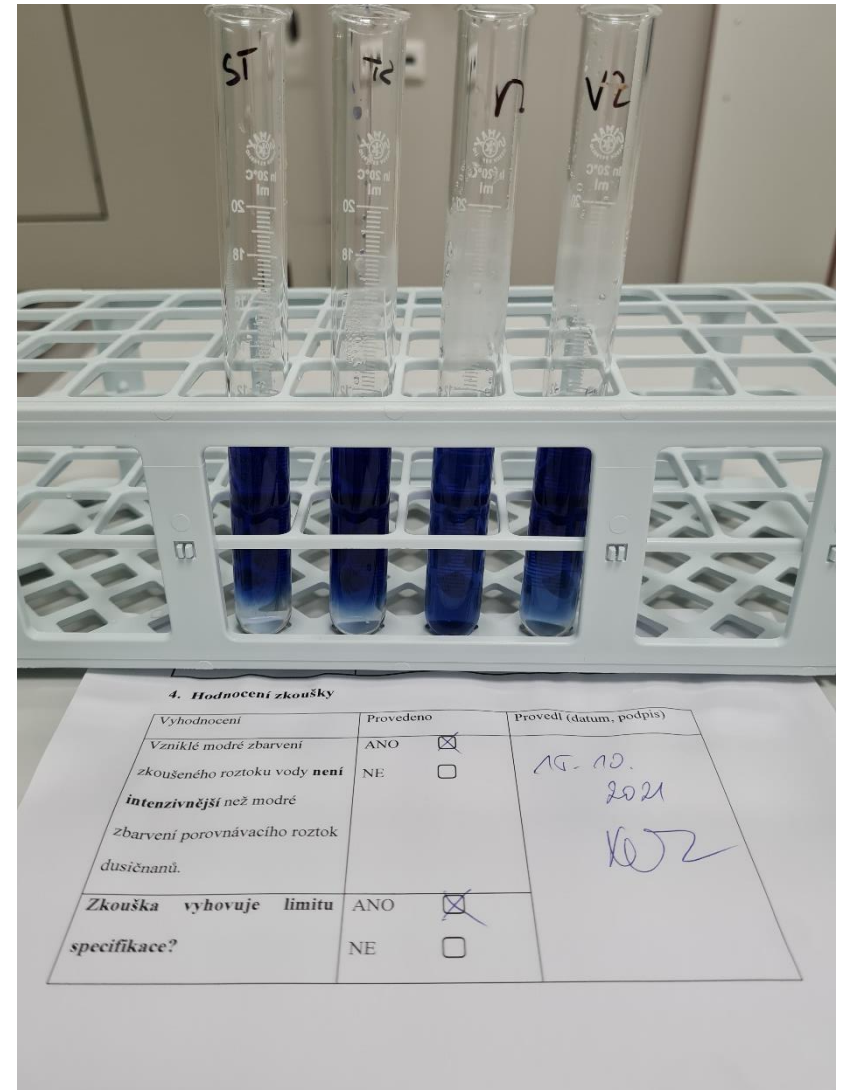
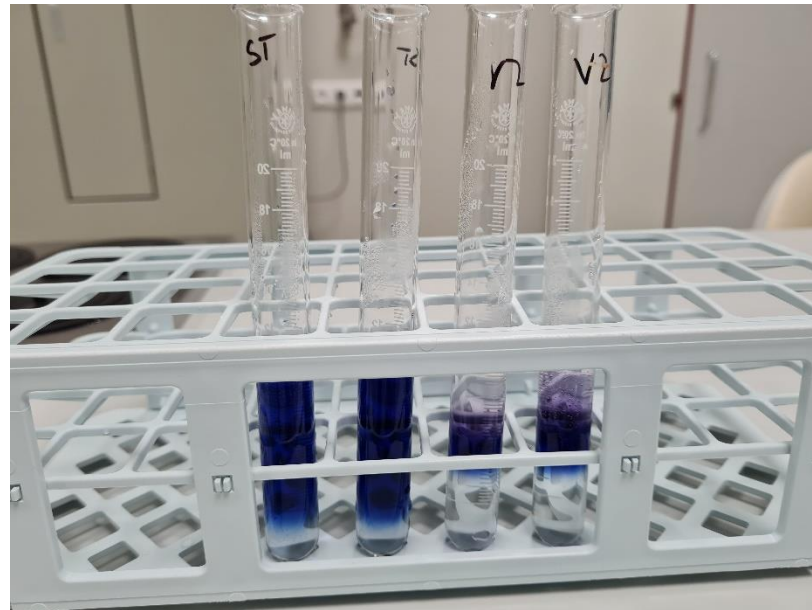
Temperature (°C)	Conductivity ( $\mu\text{S}\cdot\text{cm}^{-1}$ )
0	0.6
5	0.8
10	0.9
15	1.0
20	1.1
25	1.3
30	1.4

## WATER, PURIFIED

### Aqua purificata

Temperature (°C)	Conductivity ( $\mu\text{S}\cdot\text{cm}^{-1}$ )
0	2.4
10	3.6
20	4.3
25	5.1
30	5.4

# Specifikace vody – vybrané metody Dusičnany



**VODA A VODNÍ SYSTÉMY VE FARMACEUTICKÉM  
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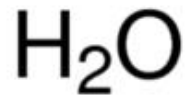
VODA PRO ANALYTICKÉ METODY



# Voda pro analytické metody



[https://www.  
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com/CZ](https://www.sigmaaldrich.com/CZ)



## Water

**CAS Number:**  
7732-18-5

**Molecular  
Weight:**  
18.02

**Beilstein Registry  
Number:**  
2050024

**Linear Formula:**  
H<sub>2</sub>O



Product Number	Product Description	SDS
<input type="checkbox"/> <a href="#">W4502</a>	Nuclease-Free Water, for Molecular Biology	<a href="#">↓</a>
<input type="checkbox"/> <a href="#">270733</a>	suitable for HPLC	<a href="#">↓</a>
<input type="checkbox"/> <a href="#">W3500</a>	sterile-filtered, BioReagent, suitable for cell culture	<a href="#">↓</a>
<input type="checkbox"/> <a href="#">1.15333</a>	for chromatography (LC-MS Grade) LiChrosolv <sup>®</sup>	<a href="#">↓</a>
<input type="checkbox"/> <a href="#">38796</a>	deionized	<a href="#">↓</a>
<input type="checkbox"/> <a href="#">00612</a>	suitable for ion chromatography	<a href="#">↓</a>
<input type="checkbox"/> <a href="#">34877-M</a>	HPLC Plus	<a href="#">↓</a>

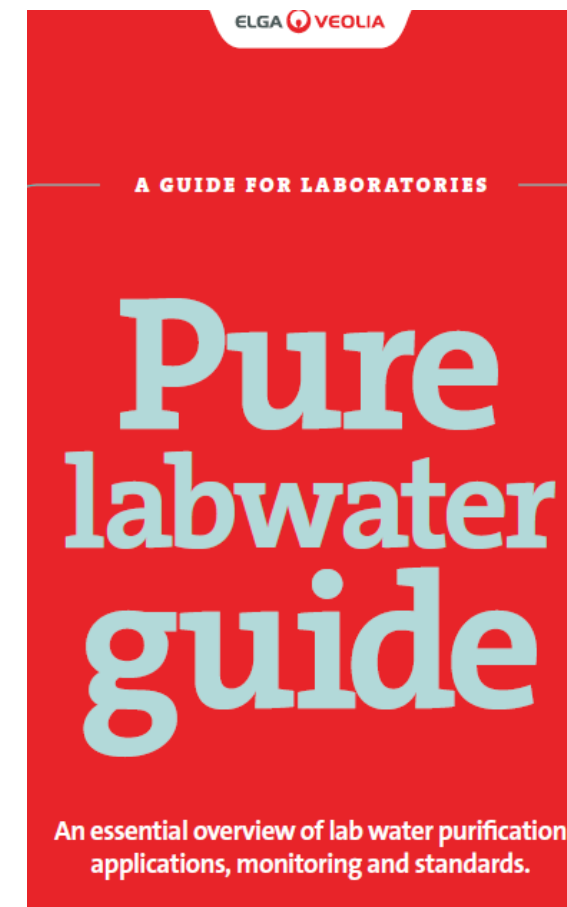
[https://www.  
sigmaaldrich.  
com/CZ](https://www.sigmaaldrich.com/CZ)

- 900682** for UHPLC, suitable for mass spectrometry (MS)
- 78533** for TOC analysis
- 1.03728** for UHPLC-MS LiChrosolv<sup>®</sup>
- 14211** ACS reagent, for ultratrace analysis
- W3513** BioPerformance Certified
- 1.00473** for inorganic trace analysis Suprapur<sup>®</sup>
- W1754** PCR Reagent
- 1.01262** Ultrapur
- 1.16754** for analysis EMSURE<sup>®</sup>
- 95289** for cell biology, sterile ultrafiltered
- 320072** ACS reagent
- 95280** tested according to Ph. Eur.

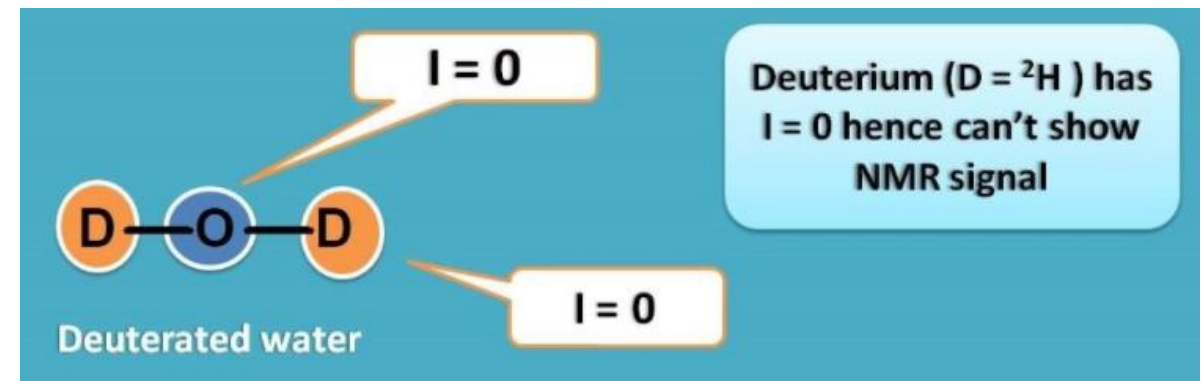
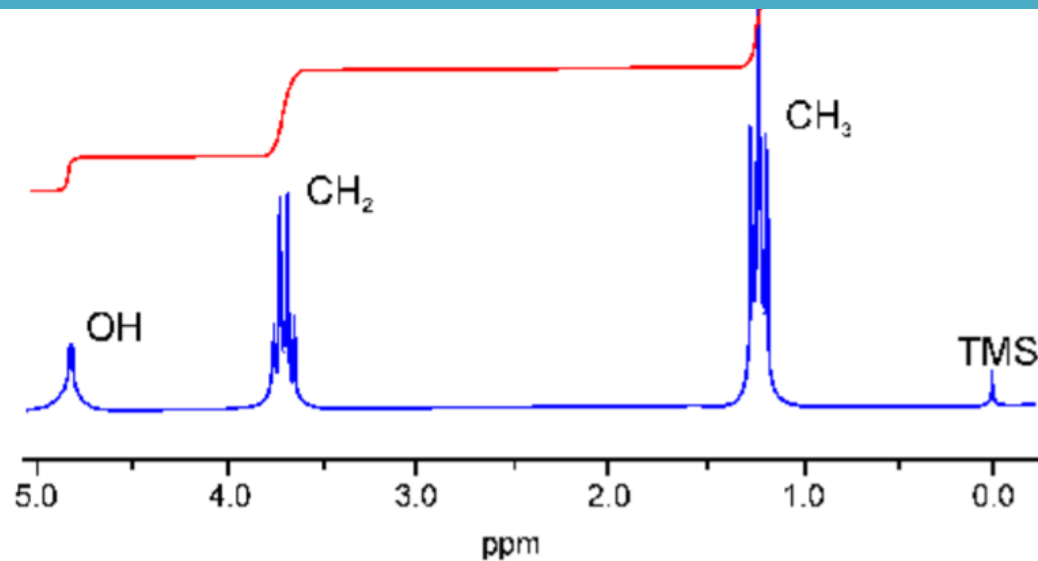
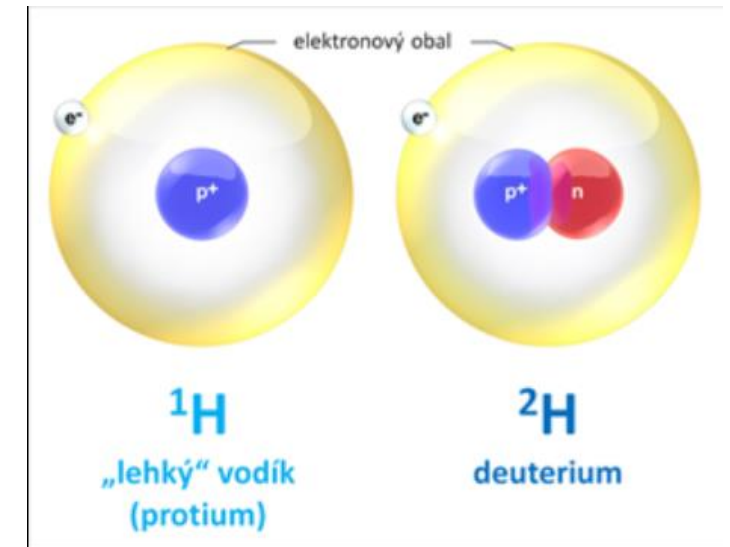


## Analytical and general applications

Technique	Sensitivity	Resistivity* MΩ-cm	TOC ppb	Filter µm	Bacteria CFU/ml	Grade of Pure Water
Electrochemistry	General	>5	<50	<0.2	NA	General lab
	High	>18	<10	<0.2	<1	Ultra pure
Feed to stills	Low	>0.05	<500	NA	NA	Primary
Feed to ultra pure water systems	General	>0.05	<50	NA	NA	Primary
	High	>1	<10	<0.2	<1	Ultra pure
Flame-AAS	General	>5	<500	<0.2	NA	General lab
GC-MS	High	>18	<3	<0.2	<1	Ultra pure
General chemistry	General	>1	<50	<0.2	<10	General lab
GF-AAS	High	>18.2	<10	<0.2	<10	Ultra pure
Glassware washing	General	>1	<50	<0.2	<10	General lab
	High	>18	<10	<0.2	<1	Ultra pure
HPLC	General	>1	<50	<0.2	<1	General lab
	High	>18	<3	<0.2	<1	Ultra pure



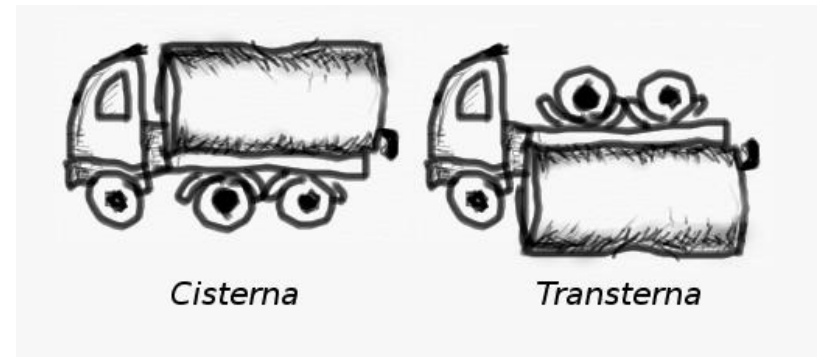
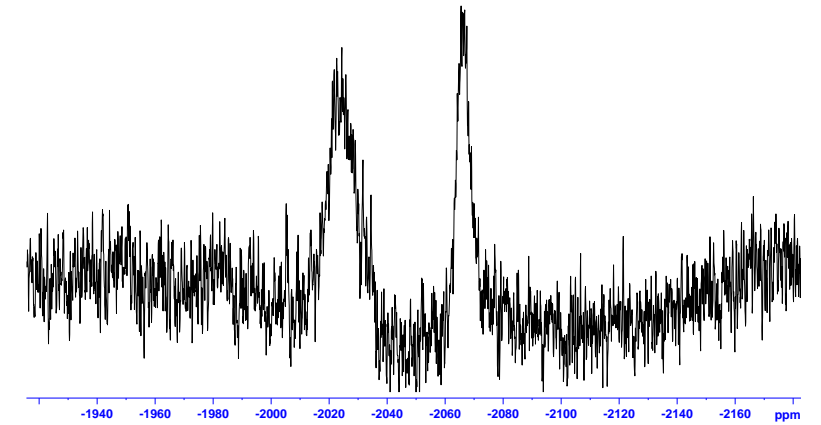
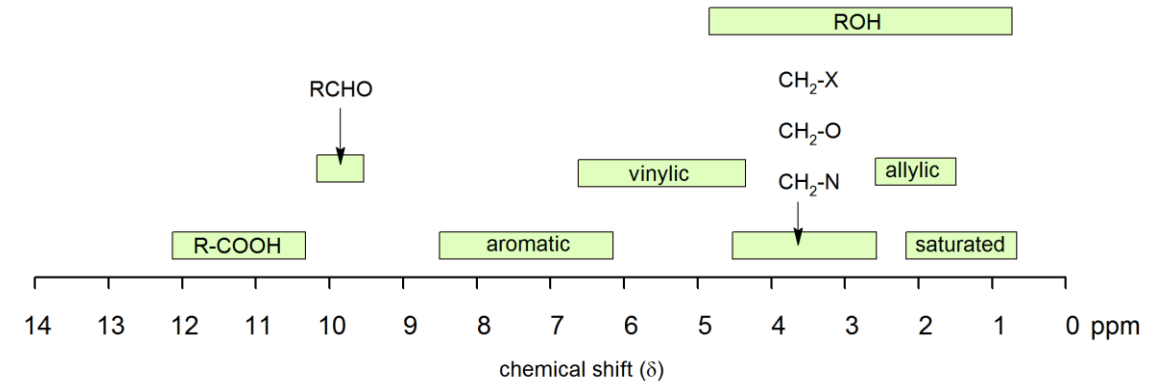
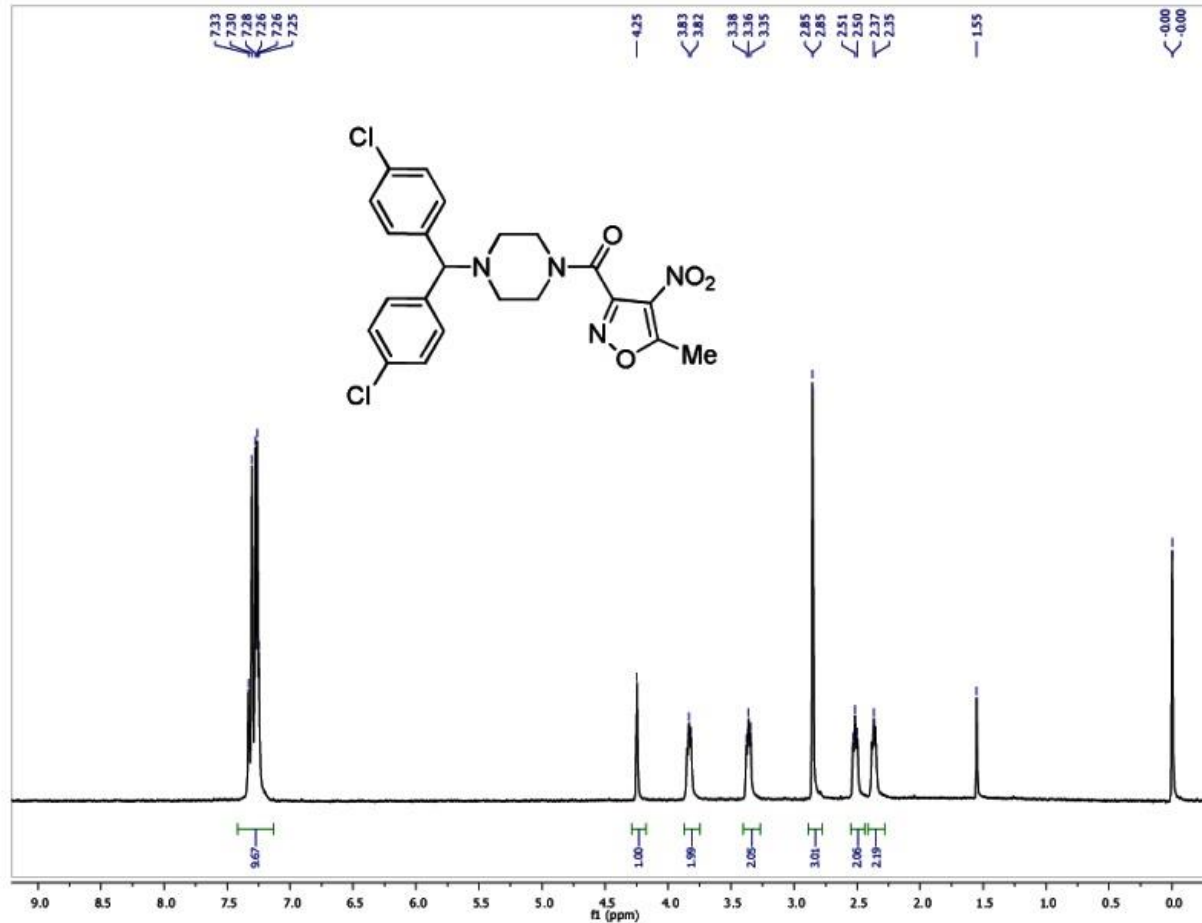
# Voda pro analytické metody NMR spektroskopie





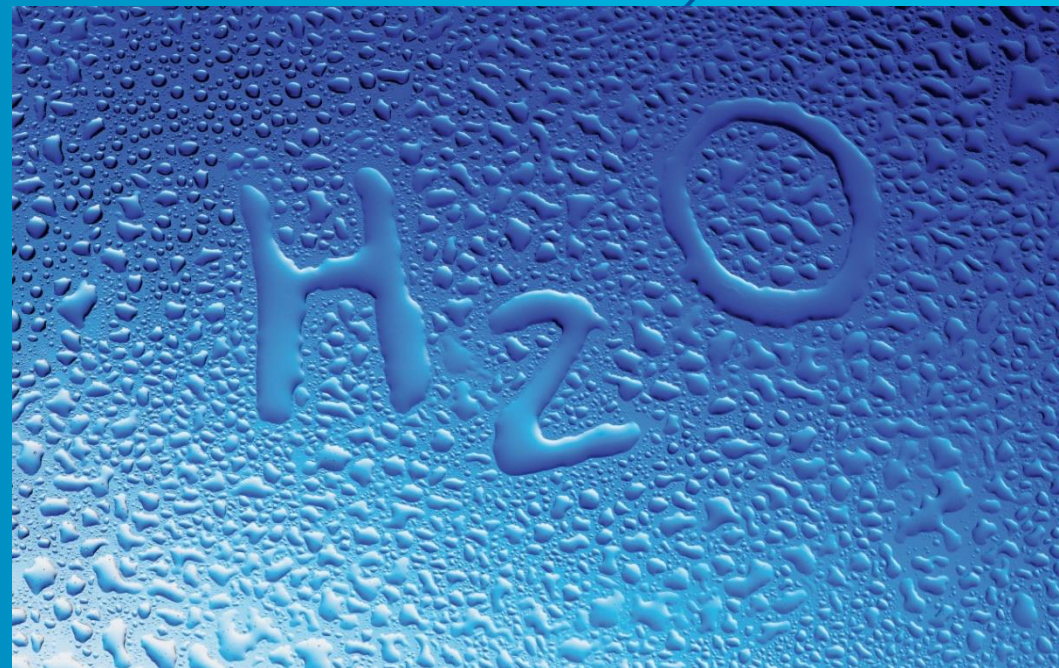
# Voda pro analytické metody

## NMR spektroskopie



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PRŮMYSLU**

**EVIDENCE ANALÝZ**





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**VÝSLEDKY, TRENDY A JEJICH VYHODNOCENÍ**



DĚKUJI ZA POZORNOST

DOTAZY?

