

# Certificate of Analysis

## Cetylpyridinium chloride monohydrate

**PurCert Standard for GC**

(Secondary Reference Standard)

<b>Product Number</b>	PSR37855	<b>CAS No.</b>	6004-24-6
<b>Brand</b>	PureSynth	<b>Lot No.</b>	C37855T0224
<b>Molecular Formula</b>	C <sub>21</sub> H <sub>38</sub> ClN · H <sub>2</sub> O	<b>Date of Mfg.</b>	February, 2024
<b>Molecular Weight</b>	358.00 g/mol	<b>Date of Exp.</b>	January, 2027

Test	Specification	Result
Description	White Crystal	White Crystal
Assay (GC-FID)	≥ 99.5 %	99.69 %
Water (By KF)	NMT 0.200 %	0.127 %
Identification by <sup>1</sup> H NMR	Conforms to structure	Conforms
Identification by GC-MS	Conforms to molecular mass	Conforms
Identification by IR	Conforms to structure	Conforms

**\*Traceable to USP Reference Standard 1104006, Lot no: J2K032**

**Storage Condition:** Store at room temperature and keep the container tightly closed.

**Remark:** The batch complies with the prescribed quality of the above specification.

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## Assay by GC-FID

### METHOD: GC- FID conditions:

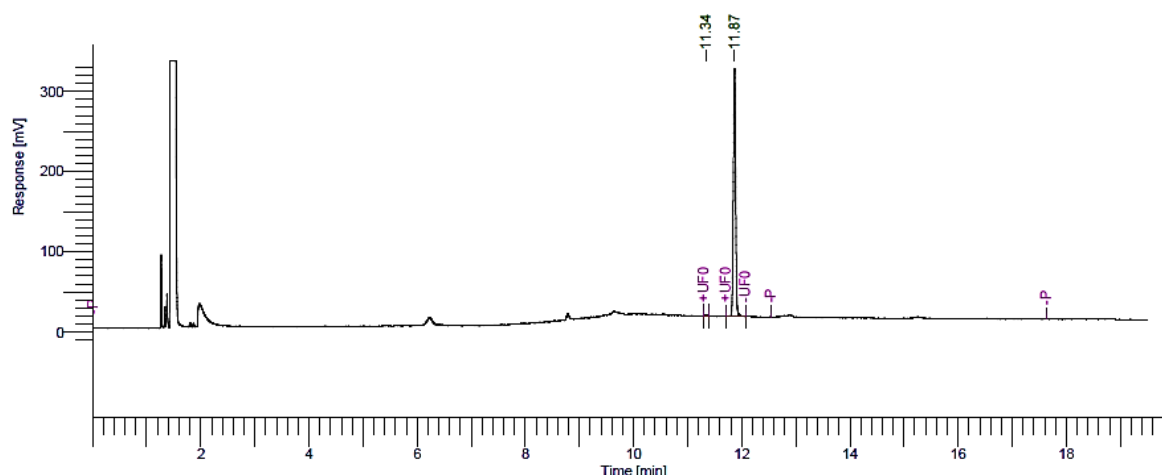
**Column:** Agilent Technologies DB-FFAP 30mx 0.530mm, 1.0micron

**Instrument:** PerkinElmer, GC 2014,

**Detector:** FID, **Carrier gas:** Nitrogen

**Temp programming:** Initial 50°C hold for 1min, 5° C Ramp/ min., 100 °C hold for 1 min., 25°C Ramp up to 250°C hold for 2 min., Run time 20 min.

Software Version	: 6.3.4.0700	Date	: 08-04-2024 18:29:51
Operator	: manager	Sample Name	: Cetylpyridinium chloride-monohydrate
Sample Number	: 001		
AutoSampler	: BUILT-IN	Study	:
Instrument Name	: Clarus 690	Rack/Vial	: 0/30
Instrument Serial #	: None	Channel	: A
Delay Time	: 0.00 min	A/D mV Range	: 1000
Sampling Rate	: 12.5000 pts/s	End Time	: 25.00 min
Sample Volume	: 1.000000 ul		
Sample Amount	: 1.0000		
Data Acquisition Time	: 08-04-2024 17:12:46	Area Reject	: 0.000000
		Dilution Factor	: 1.00
		Cycle	: 1



## GC Reports

Peak #	Component Name	Time [min]	Area [uV*sec]	Height [uV]	Area [%]
1		11.340	2802.17	996.32	0.31
2		11.865	897300.48	309000.01	99.69
			900102.65	309996.33	100.00

Warning -- Signal level out-of-range in peak

Missing Component Report

Component Expected Retention (Calibration File)

All components were found

**Purity by GC-FID: 99.69 %**

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## IDENTIFICATION TESTS

### GC-MS Spectrum:

#### METHOD: GC-MS conditions:

**Column:** Agilent Technologies, Elite -5MS, 30 m X 0.25 mm, 1.0micron

**Instrument:** Perkin Elmer, **Carrier gas:** Helium

**Source Temp.:** 230°C, Transfer line: 250°C

**Inlet Temp.:** 180°C, **Diluent:** Methanol

**Source energy:** 70eV

#### Mass by GC-MS:

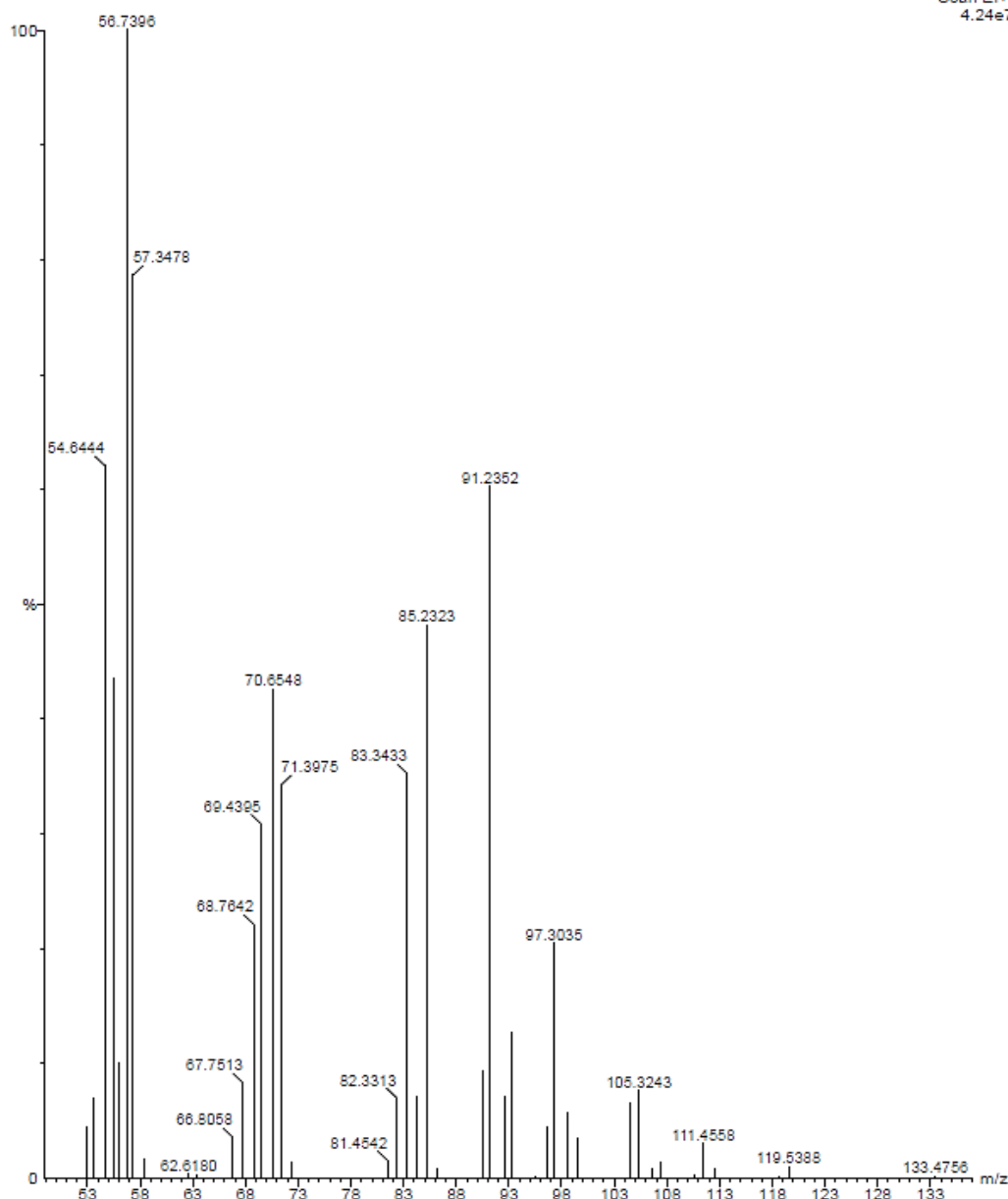
**Product Name:** Cetylpyridinium chloride monohydrate

**Product Code:** PSR37855

**CETYLPIRIDINIUM CHLORIDE MONOHYDRATE**

, 08-Apr-2024 + 14:11:42

Scan EI+  
4.24e7



Identification by GC-MS: Conforms to molecular mass

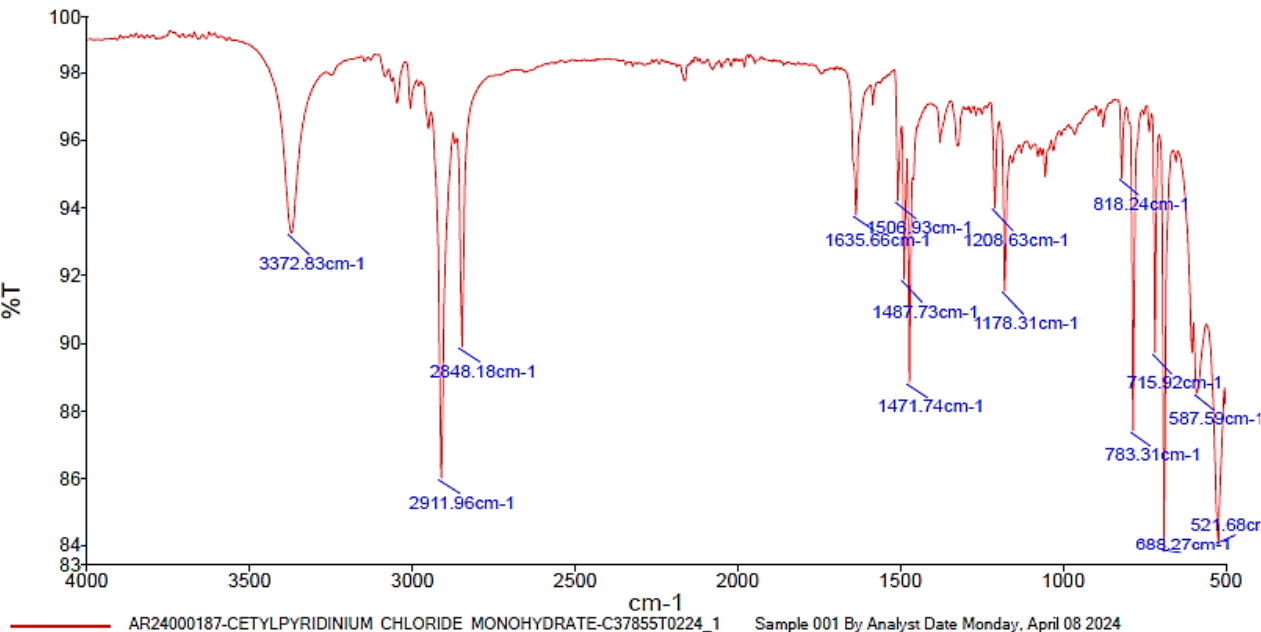
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Infrared spectrum:

Product Name: Cetylpyridinium chloride monohydrate  
Product Code: PSR37855

Analyst  
Date



Source Spectra Results		
Spectrum Name		Number Of Peaks
AR24000187-CETYLPIRIDINIUM CHLORIDE MONOHYDRATE-C37855T0224_1		15
List of Peak Area/Height		
Peak Number	X (cm-1)	Y (%T)
1	3372.83	93.27
2	2911.96	86.02
3	2848.18	89.90
4	1635.66	93.79
5	1506.93	94.22
6	1487.73	91.91
7	1471.74	88.84
8	1208.63	94.02
9	1178.31	91.56
10	818.24	94.89
11	783.31	87.42
12	715.92	89.73
13	688.27	83.84
14	587.59	88.53
15	521.68	84.05

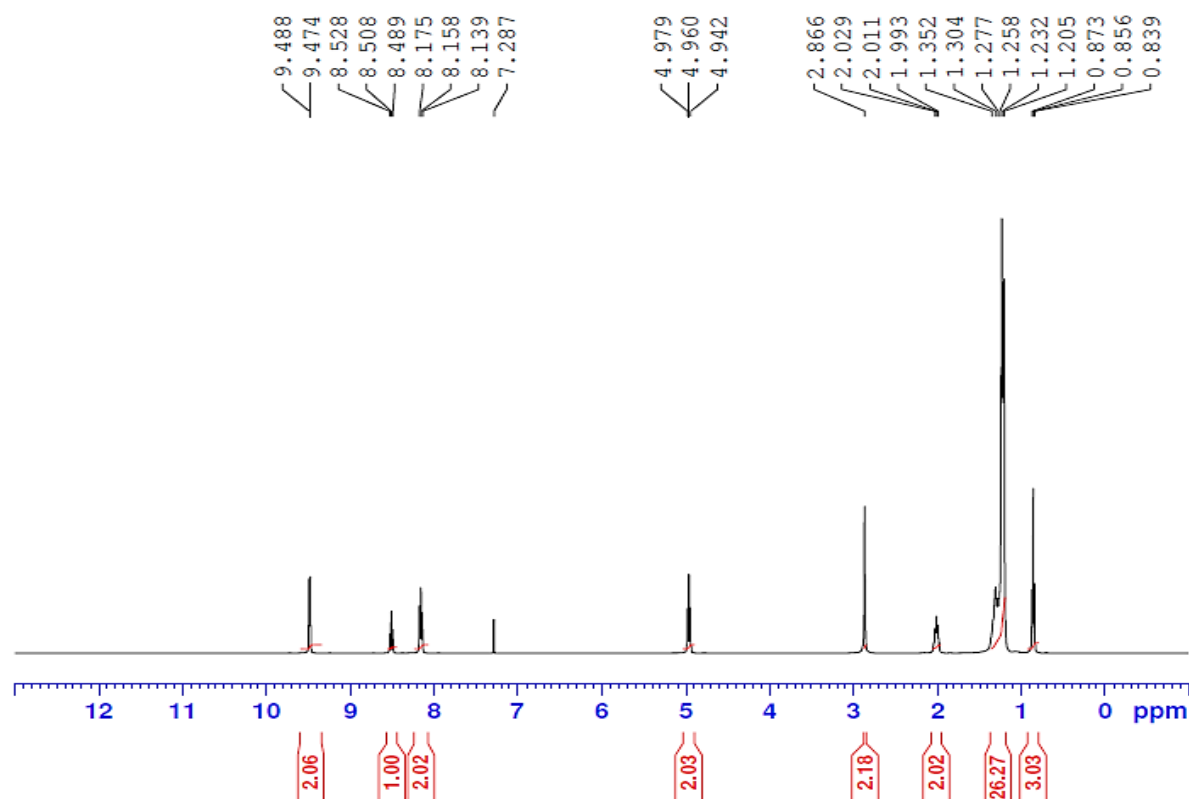
Identification by IR: Conforms to structure

# **<sup>1</sup>H NMR Spectrum:**

**Product Name:** Cetylpyridinium chloride monohydrate

**Product Code:** PSR37855

Cetylpyridinium chloride monohydrate  
B.No: C37855T0224  
<sup>1</sup>H-NMR in CDCl<sub>3</sub>



Identification by <sup>1</sup>H NMR: Conforms to structure

## **Maximum limits of impurities**

### **WATER DETERMINATION**

Method: Karl Fisher titration

Water Content (PSR37855) = **0.127 %**

Approved By  
Head - Technical

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