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## DOC-GUIDE-1027-THCStabilityReport

**Introduction:** Cannabis and its derivatives have gained widespread popularity in recent years, primarily due to their medicinal and recreational properties. Among these derivatives, tetrahydrocannabinol (THC) is the main psychoactive component responsible for the plant's effects on the human body. However, THC is a highly reactive molecule and is susceptible to degradation when exposed to various environmental factors, including heat, light, and humidity. Therefore, it is essential to study the stability of THC to ensure its potency over time, especially in storage conditions where it may be subjected to these factors.

**Objective:** In this THC stability study, we aimed to investigate the effect of storage conditions on the stability of high purity THC samples. The samples were kept in three different storage conditions, namely cool, dry, and room temperature, to mimic real-world storage conditions. To evaluate the stability of THC, we used the official certificate of analysis dates and results for the samples as the benchmark. The certificate of analysis provided information on the potency, and composition of the samples at the time of manufacture.

By analyzing the samples at regular intervals, we can track changes in the potency of THC over time and assess the impact of storage conditions on the stability of the samples. This study is crucial in determining the optimal storage conditions for THC to maintain its potency, which is essential for its efficacy in medicinal and recreational applications. The results of this study will provide valuable insights into the stability of THC and help guide storage recommendations for its safe and effective use.

To calculate potency loss over a specific time frame, you would need to know the initial concentration of the substance and the concentration at the end of the time frame. The formula used to calculate potency loss is:

Potency Loss (%) = [(Initial Concentration - Final Concentration) / Initial Concentration] x 100 Potency Loss (%) (PL) can be calculated using the formula: PL (%) = <u>(IC-FC)</u> X 100 Where IC = Initial Concentration, FC= Final Concentration IC



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This formula expresses potency loss as a percentage of the initial concentration.

**Conclusion:** The acceptable loss for an active pharmaceutical ingredient (API) over a given time frame will depend on various factors, such as the nature of the API, its intended use, and the requirements of regulatory authorities in the applicable jurisdictions.

In general, the acceptable loss for an API will be determined through stability testing, which involves subjecting the API to various environmental conditions over time and monitoring its degradation. The results of the stability testing will be used to establish a shelf-life for the API, which represents the time period during which the API is expected to remain within acceptable quality limits under specified storage conditions. Significant change, for a drug product is defined as: A 5% change in assay from its initial value; or failure to meet the acceptance criteria for potency when using biological or immunological procedures;

Protonify high potency Delta 9 THC manufactured in a controlled environment and stored in cool / dry conditions has a **retest date** of **12 months.** 

CONDITIONS	
Humidity:	60% (+- 5%)
Temperature:	20-25C (+- 2%)
Lighting:	Dark / protected from light
Airflow:	Continuous flow and refresh of air
SAMPLE #1	
LOT ID:	Immediate Container - Luer Lock Syringe (18 Months)
8BK-001-F1-AC-DCB	

#### Summary Data



	Initial	Final			
Dates	07/08/2021	04/10/2023			
D9 THC %	93.651%	89.614%			
Potency Loss (%)	4.037%				
Summary	Less than 5% degradation of D9 THC after 18 months				
SAMPLE 2					
LOT ID:	Immediate Container - Luer Lock Syringe (12 Months)				
FL-220228-01-01-DCB					
	Start	End			
Dates	03/22/2022 04/10/2023				
D9 THC %	96.319%	92.997%			
Summary	Less than 5% (3.322%) degradation of D9 THC after 12 months				
LOT ID:	Immediate Container - Amber Glass (12 Months)				
PR-0016-03232022					
	Start	End			
Dates	03/24/2022	04/10/2023			
D9 THC %	94.239%	90.546%			
Summary	Less than 5% (3.639%) degradation of D9 THC after 12 months				

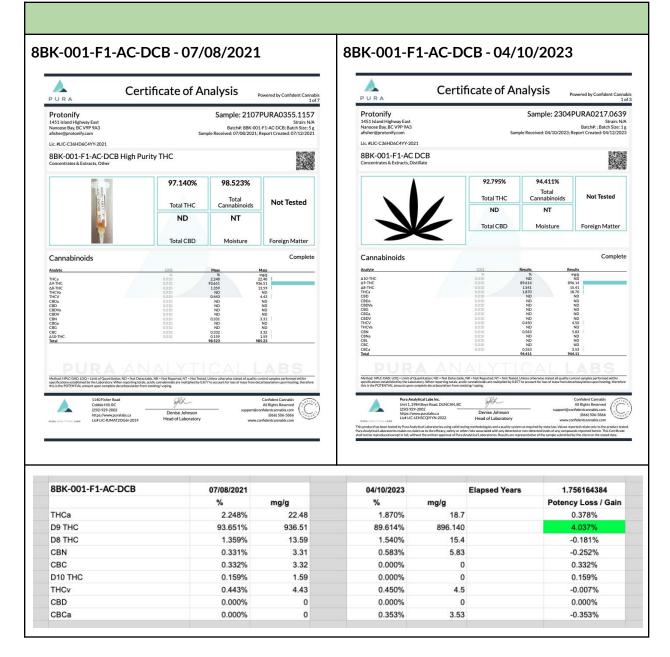


LOT ID:	Immediate Container - Amber Glass (12 Months)			
PR-0017-03232022				
	Start	End		
Dates	03/22/2022	04/10/2023		
D9 THC %	89.452%	88.256%		
Summary	Less than 5% (1.196%) degradation of D9 THC after 12 months			

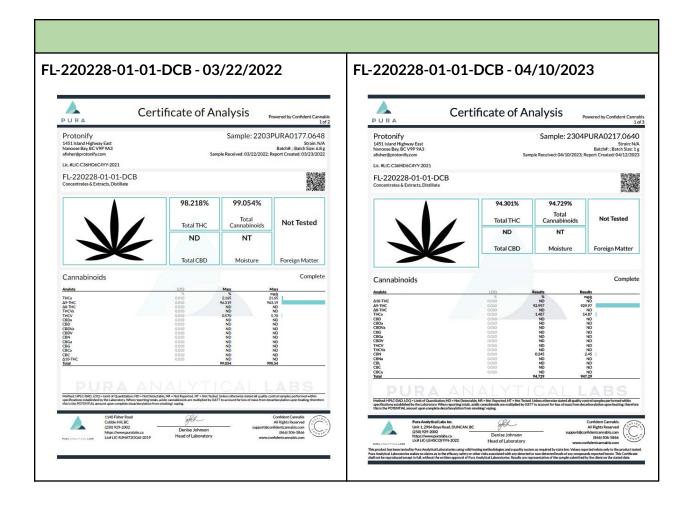


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#### **Appendix A - Detailed Analysis**



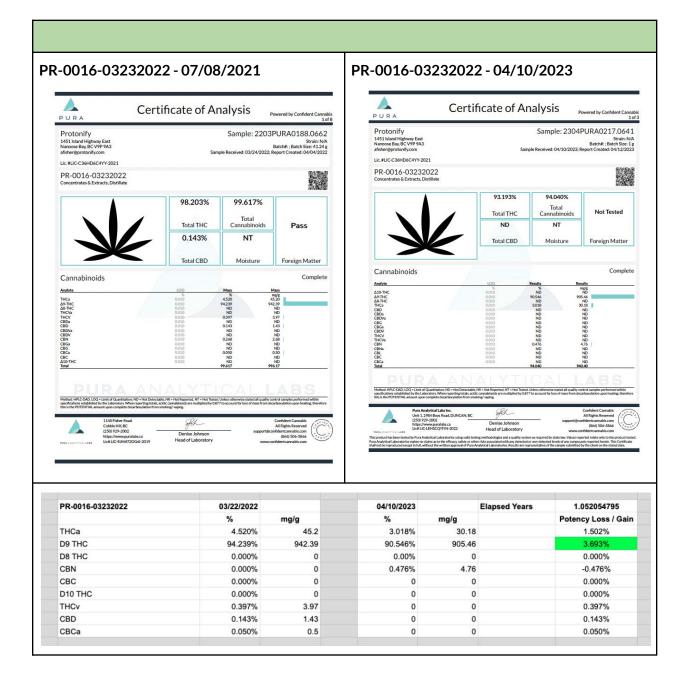




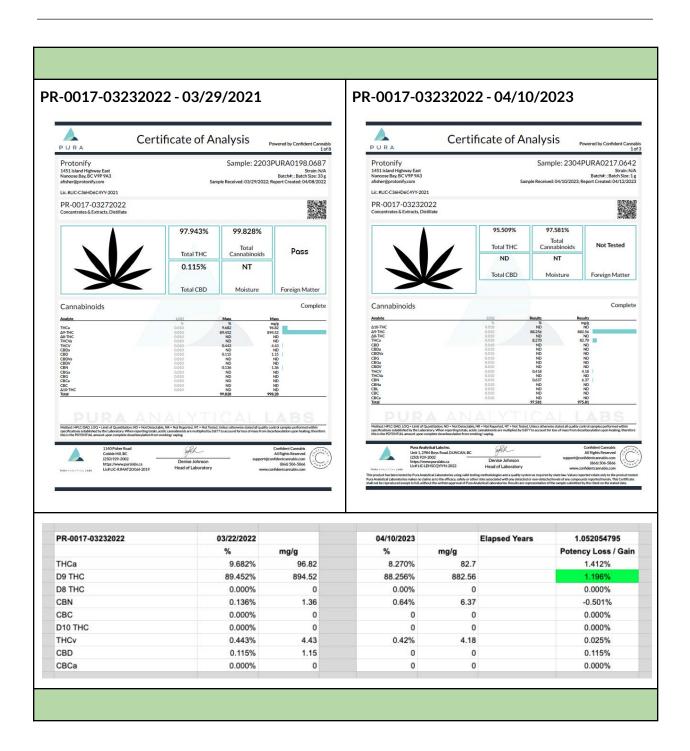


FL-220228-01-01-DCB	03/22/2022		04/10/2023		Elapsed Years	1.052054795
	%	mg/g	%	mg/g		Potency Loss / Gain
THCa	2.165%	21.65	1.487%	14.87		0.678%
D9 THC	96.319%	963.19	92.997%	929.97		3.322%
D8 THC	0.000%	0	1.49%	14.87		-1.487%
CBN	0.268%	2.68	0.25%	2.45		0.023%
CBC	0.000%	0	0	0		0.000%
D10 THC	0.000%	0	0	0		0.000%
THCv	0.570%	5.7	0	0		0.570%
CBD	0.000%	0	0	0		0.000%
CBCa	0.000%	0	0	0		0.000%











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## **About Protonify**

Protonify Corporation is a privately-held Canadian licensed global B2B manufacturer of highest-purity, CPG-grade cannabinoid isolates. Protonify's botanically-sourced cannabinoids are non-synthetic with purity approaching 100%. Available in several formats, including dry powder and nano-encapsulated, they fit seamlessly into traditional CPG formulation recipes, industrial scale production lines and supply chains and are the perfect foundation to enable cannabis product formulators and manufacturers to safely and reliably build brand affinity for consumer packaged goods containing THC and THCa. Manufacturing of Protonify ingredients follow Good Manufacturing Practices (GMP) for extracted products, aligning with existing GMP / ISO / HACCP standards and are the foundation for the next generation of Cannabis 3.0 high purity products including Infused pre-rolls, beverages, vapes, edibles, sublingual strips and tablets.

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