



My Stat Report

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STABILITY

DATA ANALYSIS

Company Name ACME S.r.l.

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Brief data description: Data analysis to determine the shelf life of Prozac + Capsule 10mg



Document approval

The signatures below certify that the data and statistical analysis have been analyzed and verified by competent personnel in statistical analysis and according to the internal procedures of Agile Quality Support S. r. l.

	Name/ Signature/Date	Role
Prepared by		Quality Consultant
Approved by		CEO

Document versions

This section records the versions of the document and any updates

Revision	Update	Source	Month/Year
022022	First version	Order number XX	02/2022

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1 Stability Data Analysis and Shelf-Life Determination

1.1 Description of the study

Stability data trending according to ICH guideline Q21E, data analysis and data summary. Data integrity statement: all data were verified by author and quality approver against the data provided by the customer.

1.2 Stability Studies Information

Product Name: Prozac Capsules

Strenght: 10mg

Batch number	Time points	Conditions
AAA	0, 3, 6, 9, 12, 18, 24	25°C/60%RH
BBB	0, 3, 6, 9, 12, 18, 24	25°C/60%RH
CCC	0, 3, 6, 9, 12, 18, 24	25°C/60%RH

The data sheet is available in the "Data Summary" section

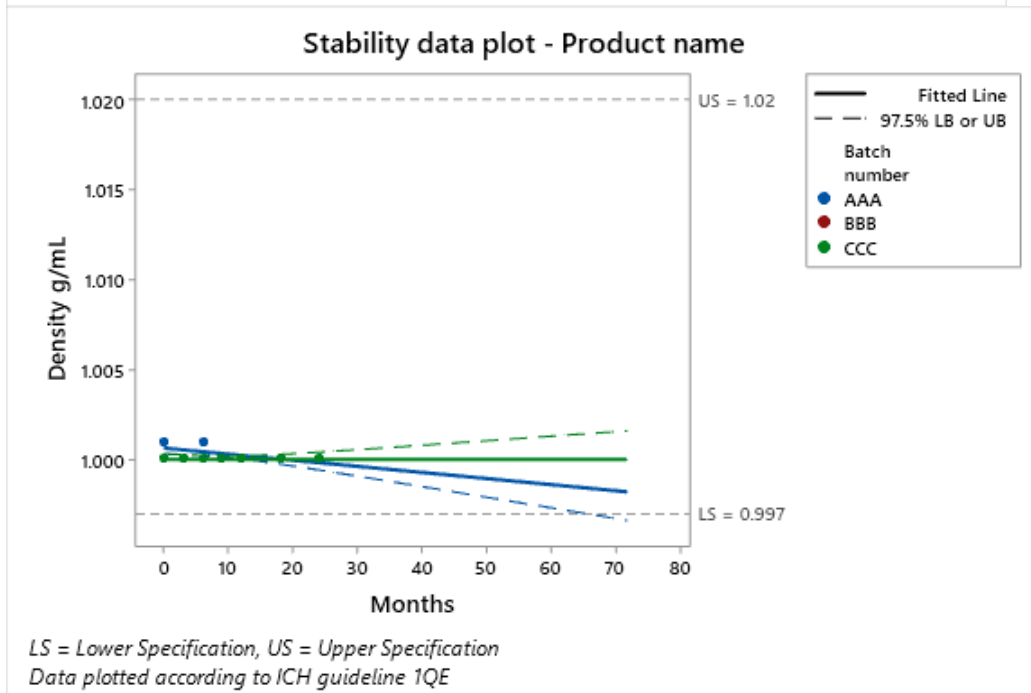
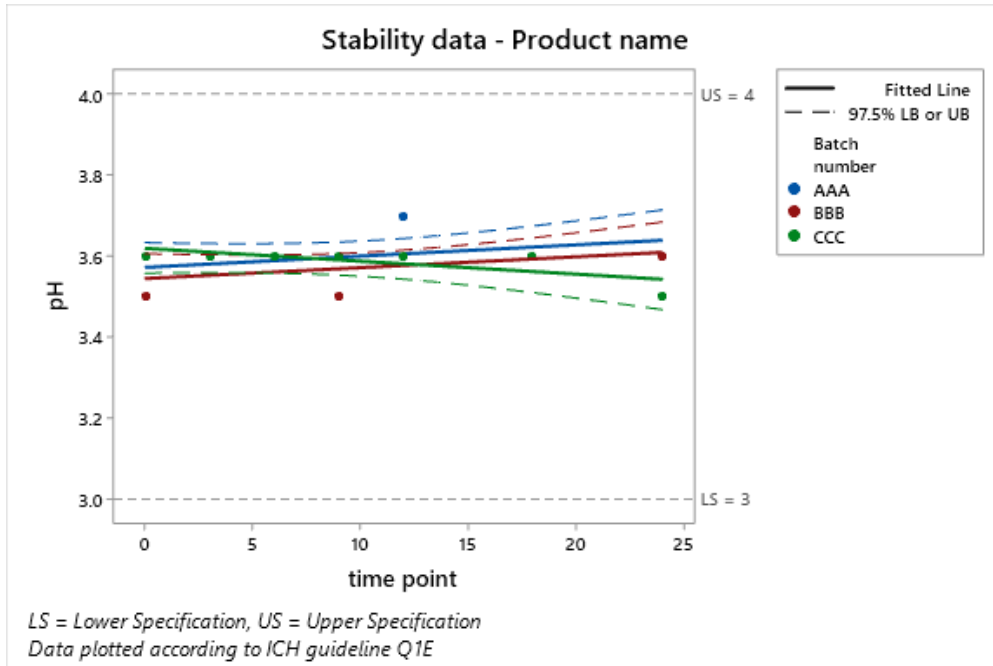
1.3 Studies Results

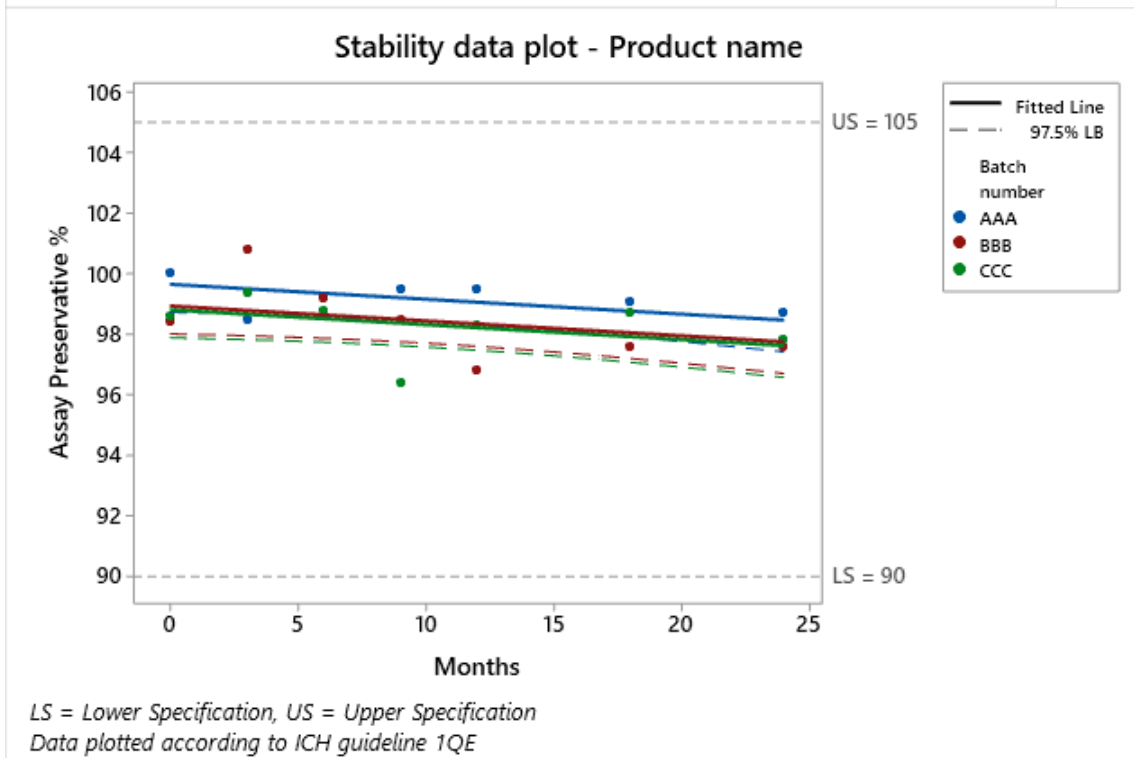
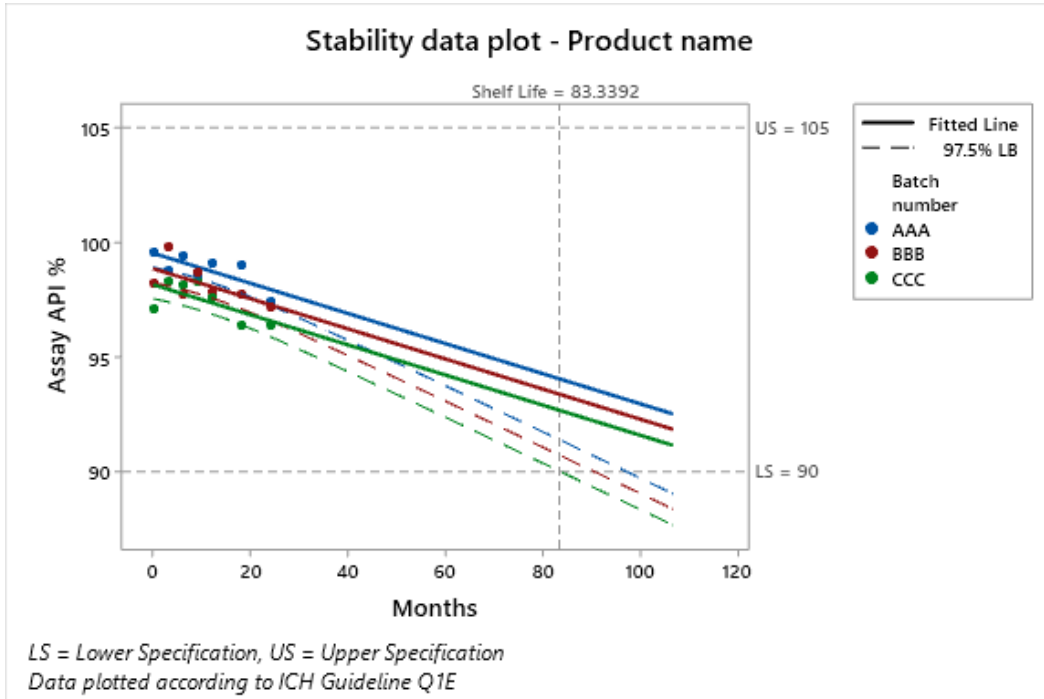
Quality Attribute	Specifications shelf life	Predicted shelf life	Trend across available time points
pH	3.0-4.0	Not predicted	Flat
Density	0.997-1.020 g/mL	Not predicted	Flat
API Assay	90.0-105.0%	83 months	Significant decrease
Preservative assay	90.0-105.0%	Not predicted	Flat
Impurity C	≤ 1.5%	29 Months	Significant Increase
Impurity D	≤ 1.5%	155 Months	Significant Increase

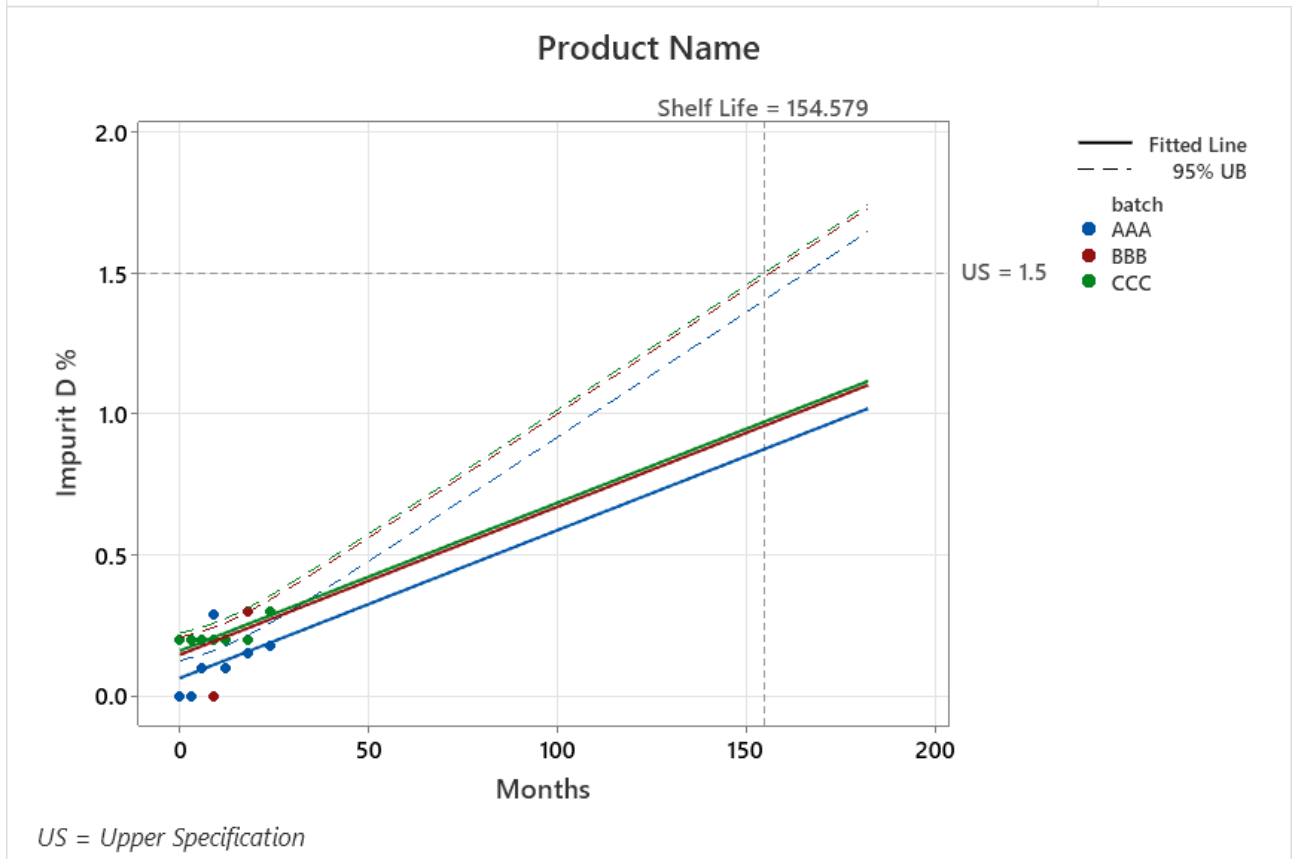
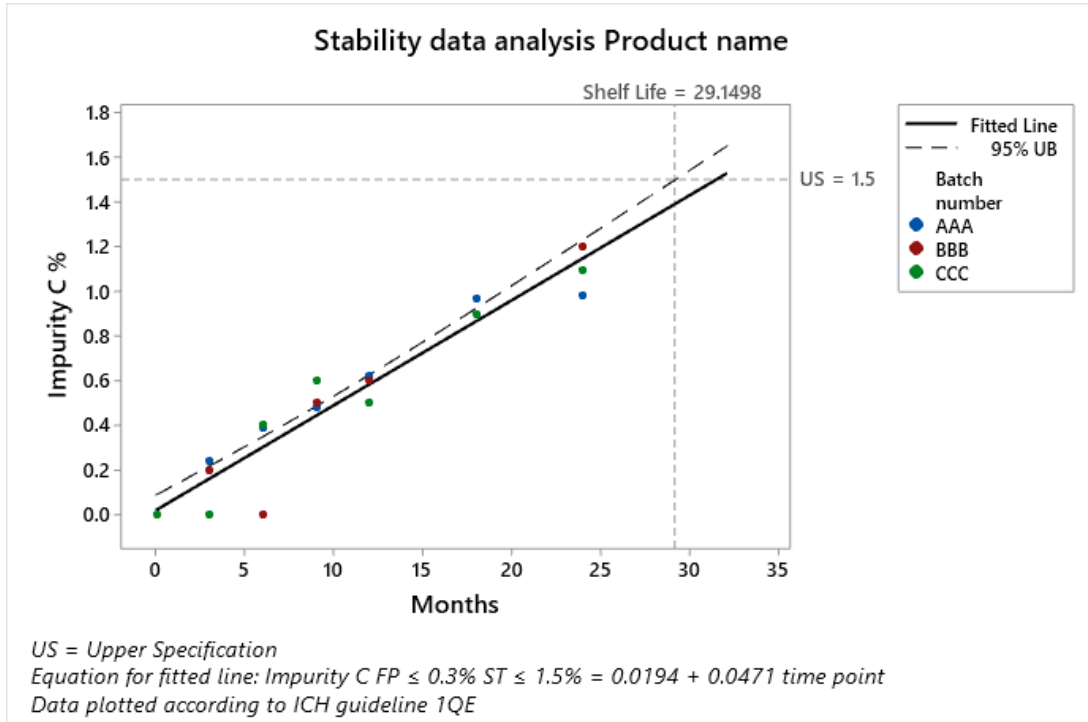
The data indicates that 29 Months is the date by which all attributes would be in the specifications provided (see table in section 1.5 for details).



1.4 Plots









1.5 Data Summary

Specifications	time point	Density	pH	Assay API	Assay: Results	Impurity C:	Impurity D:	Unspecified Degradants:	Total Known and Unknown Degradants and Impurities
		0.997 - 1.020 g/mL	3.0 - 4.0	95.0 - 105.0%	FP 95.0 - 105.0% ST 90.0 - 105.0%	FP ≤ 0.3% ST ≤ 1.5%	FP ≤ 0.3% ST ≤ 1.5%	FP ≤ 0.10% ST ≤ 0.3%	≤ 1%
Study information	0	1.001	3.5	99.6	100	ND	ND	ND	ND
BN. AAA	3	1.000	3.6	98.8	98.5	0.24	ND	ND	ND
Study n. AAA	6	1.001	3.6	99.4	98.6	0.39	0.1	ND	ND
Date started:	9	1.000	3.6	98.5	99.5	0.48	0.29	ND	ND
T 25 °C	12	1.000	3.7	99.1	99.5	0.62	0.1	ND	ND
RH 60 %	18	1.000	3.6	99	99.1	0.97	0.15	ND	ND
	24	1.000	3.6	97.4	98.7	0.98	0.18	ND	ND
Study information	0	1.000	3.5	98.2	98.4	ND	0.2	ND	ND
BN. BBB	3	1.000	3.6	99.8	100.8	0.2	0.2	ND	ND
Study n. BBB	6	1.000	3.6	97.7	99.2	ND	0.2	ND	ND
Date started:	9	1.000	3.5	98.7	98.5	0.5	ND	ND	ND
T 25 °C	12	1.000	3.6	97.8	96.8	0.6	0.2	ND	ND
RH 60 %	18	1.000	3.6	97.7	97.6	0.9	0.3	ND	ND
	24	1.000	3.6	97.2	97.6	1.2	0.3	ND	ND
Study information	0	1.000	3.6	97.1	98.6	ND	0.2	ND	ND
BN. CCC	3	1.000	3.6	98.3	99.4	ND	0.2	ND	ND
Study n. CCC	6	1.000	3.6	98.1	98.8	0.4	0.2	ND	ND
Date started:	9	1.000	3.6	98.3	96.4	0.6	0.2	ND	ND
T 25 °C	12	1.000	3.6	97.6	98.3	0.5	0.2	ND	ND
RH 60%	18	1.000	3.6	96.4	98.7	0.9	0.2	ND	ND
	24	1.000	3.5	96.4	97.8	1.1	0.3	ND	ND

T, temperature; RH relative humidity; C complies; ND Not detected; FP finished product specifications, ST, stability specifications. Not detected results were trended as 0.