

# **Bản tiêu chuẩn sản phẩm**

*Tài liệu được xác nhận bằng chữ ký số*

*Hà Nội, ngày 12 tháng 05 năm 2022*

**Người đại diện hợp pháp của cơ sở**

**Giám đốc**

**Nguyễn Thị Minh Phương**

# DIAPATH

Analytical Method: CP 001 SL

Bulk Product: CP001 SL

Finish Product: CP103 - CP204 – **CP306** - CP403

		Funzione	Data	Firma
Issued by:	Alessia Tommasini	Quality Control	21/03/2022	
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Analytical method: CP 001 SL

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Analytical method: CP 001 SL

## 1. Purpose

Execution of tests on the semi-finished product CP.001SL.

Tests performed measuring pH and alcohol content

## 2. Product code (bulk product)

CP.001SL

## 3. Reference sample

Sample to be taken according to the capacity of the sample to be measured

## 4. Appearance

Colorless appearance, free from suspended particles

## 5. Operating mode

Take an aliquot of semi-finished product in a container and visually check its characteristics

The data obtained must be reported in the data reporting file of the semi-finished product subject to analysis for the stability study and in the SAP for process controls.

## 6. Measurement of pH

Limit values of the test

pH: 5.0-6.0

## 7. Operating mode

Check that the pH meter is switched on and calibrated, check the cleanliness of the pH meter and the probe, wash with the instrument with deionized water and dry it with absorbent paper, insert the probe inside the container making sure that at least one third of the probe is immersed in the solution.

Start the measurement by clicking on the ENTER key and wait for the data to be processed, which is confirmed by the instrument's emission of a beep with consequent viewing of the result on the display.

The probe used must be rinsed and immersed in the reference solution that protects it from the outside.

The data obtained must be reported in the data reporting file of the semi-finished product subject to analysis for the stability study and in the SAP for process controls.

## 8. Measurement of the alcohol content

Limit values of the test

Alcoholic degree: 45-60%

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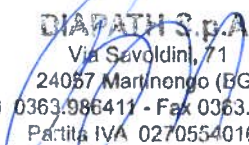
## 9. Operating mode

Check that the measuring instrument, densimeter, is calibrated, select the recipe with the code of the product you want to measure from the instrument display, take a small aliquot of the instrument twice by aspirating the semi-finished product to be analyzed from the cannula to "win" the instrument , select the parameter to be tested and wait for the result on the instrument display.

The data obtained must be reported in the data reporting file of the semi-finished product subject to analysis for the stability study and in the SAP for process controls.

## 10. Revision history

Rev.	Date	Purpose
01	21/03/2022	First issue

  
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