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ANALYSIS OF THE MAIN TECHNICAL REQUIREMENTS FOR TEST EQUIPMENT AND THEIR IMPACT ON THE PARAMETERS OF THE FINAL PRODUCT AND ITS VARIANTS

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Abstract

This document presents a comprehensive analysis of the technical requirements, calibration procedures, and experimental testing conducted for the development of an autonomous sensor capsule intended for pH measurement in complex biological and chemical environments. The study evaluates the capsule's structural materials, protective coatings, sensor design, and operational parameters, including acidity measurement ranges, temperature stability, signal penetration depth, and the influence of various additives and biological substances. Particular attention is given to the performance of planar solenoid technology, long-term durability of system components, and repeatability of measurement results.

Keywords: *Composite technical solutions in smart pharmaceutical manufacturing and their equivalents; Implementation of new technologies in pharmaceutical production; The main tool of technological integration in smart pharmaceutical manufacturing; Principles and criteria of industrial design; Integrative inventions in the pharmaceutical field; Reliability of new pharmaceutical products; Techniques and methods for developing a composite style in the creation of innovative solutions*

LIFETIME – more than 10 years (power consumption) – Durability of the system and provision of the required energy level

SIZE of the capsule – actual dimensions of the sensor capsule

According to the technical specifications, the required dimensions of the sensor capsule are as follows:

- Diameter: 30 mm;
- Length: 100 mm.

After modeling and conducting tests, the researchers concluded that, if necessary, the external dimensions of the capsule could be reduced to:

- Diameter: up to 25 mm;
- Length: up to 80 mm.

A particularly important factor in achieving this reduction is the use of a planar solenoid as the sensor element, implemented in the form of a flat coil on a single-layer printed circuit board.

The dimensions of this board – 16 mm in diameter and 1.5 mm in thickness – allow for significant optimization of space within the internal volume of the sensor capsule.

Measurement pH range (3–10) – measurement of acidity levels across an extended range.

The **range of calibration tests** was expanded – calibration was carried out on samples with acidity levels ranging from **pH 2 to pH 10**.

In principle, there are no limitations regarding the acidity values that can be measured using the new technology.

Experimental verification confirmed the possibility of measuring acidity levels as low as **pH 1** (hydrochloric acid used in sample preparation) and as high as **pH 14** (various household alkaline solutions).

The specified measurement range is therefore fully feasible for implementation.

Operational temperature range – 20 to +45 °C

According to the technical requirements, tests were conducted to evaluate the measurement accuracy at sample temperatures of **10 °C, 25 °C, and 40 °C**, at an acidity level of **pH 6**.

Additionally, pH parameters were measured on samples with acidity levels of **3, 4, 5, 6, and 7** at temperatures of **23 °C** and **39 °C**.

The measurement results demonstrated sufficient **sensitivity of the prototype** under all temperature variations and for all acidity levels of the tested samples.

Measurement resolution (pH): 0.01

During the setup of the test equipment, a program was used that allows the regulation of signal **frequency and amplitude** with a precision of up to **0.001 MHz** and **1 mV**.

Due to this factor, the **critical parameter** of the measurement system is the amount of energy available for signal generation.

Battery modeling and operational parameter simulations will be conducted in the following stages of the project; however, the fundamental feasibility of achieving the required high measurement precision has already been confirmed.

Accuracy of pH measurement: ±0.1

The required measurement accuracy was achieved during the calibration tests of the system.

Since the calibration was carried out using samples with precisely defined acidity levels, while simultaneously monitoring real-time temperature and calorimetric content, the transition to measuring glucose concentration levels provided an equivalent degree of accuracy.

Content (particles)

Influence of the Presence of Coarse Wheat Flour in the Sample

The effect of coarse wheat flour added to the sample in concentrations specified in the technical specification – 100 g, 200 g, and 400 g per 1 liter – was analyzed.

(The penetration depth of the signal from the pulse generator into the liquid sample, when using a flat coil made as a single-layer printed circuit board, is 1–1.5 mm.)

Since the flour particles in the sample tend to settle, their presence has virtually no effect on the measurement results.

Additional experiments were also carried out by introducing orange pulp into a sample of gastric juice with an acidity level of pH 6, in a concentration of 10 grams per 100 milliliters of the sample. In this case, the readings of the gastric juice sample with pH 6 and the sample containing orange pulp showed almost identical measurement results.

Feed Content

According to the technical specification, it was necessary to assess the influence of various substances introduced into the sample composition on the measurement results. Since the samples were prepared using simulated gastric juice, hydrochloric acid, and tap water containing salts and hardness compounds at a concentration of 400 mg per liter, the effect of additives was found to be nonlinear.

- Additives in concentrations of 10 and 60 mg/L had no measurable effect on the results;
- Additives in concentrations of 0.6 g/L also showed no significant influence;
- Additives in concentrations of 1.2 g/L produced varying results at different signal frequencies; however, at a measurement frequency of 25 MHz, the readings were identical to those of the reference samples with pH 6 and no additives;

- Additives in concentrations of 6 g/L similarly showed some variation depending on signal frequency, but again, at 25 MHz, the measurement results were equivalent to the baseline samples with pH 6.

Modeling of the Capsule Position in Space

Modeling of the capsule's spatial orientation, including the contact between the sensor plane and the patient's body, was carried out to evaluate the stability and reliability of the signal under different operating conditions.

Influence of a Beef Plate on Measurement Accuracy

A beef plate with a thickness of **5 mm** was placed in the sample at a distance of **2 mm** from the flat sensor coil (the penetration depth of the signal from the pulse generator into the sample liquid, when using a single-layer printed circuit coil, is **1–1.5 mm**).

The presence of the beef plate positioned 2 mm away from the coil end **has no effect** on measurement quality or accuracy.

When the beef plate is **directly attached** to the flat sensor coil (full contact), the penetration depth of the pulse generator signal remains the same (**1–1.5 mm**).

To **compensate for full contact**, it is necessary to mount the flat sensor coil at a **depth of 1.5 mm** within the capsule design.

Repeatability of Measurement Results

The test procedure was as follows:

More than **1 gallon of distilled water** and **1 gallon of tap water** were prepared.

The sample containers were hermetically sealed.

The tests were conducted under the following signal parameters:

- **Frequency:** 26.25 MHz;
- **Amplitude:** 9850 mV (distilled water); 9590 mV (tap water).

The same comparative test was performed **five times** at **three-day intervals** using the **same water samples**.

The measurement results for samples with identical chemical compositions were **absolutely consistent**, confirming the high repeatability of the system.

Technical Requirements Analysis – Preliminary Calibration of Test Equipment

During calibration, the following aspects were evaluated:

- Analysis of the feasibility and performance of the technical requirements for the project;
- Duration of the operational life of the device;
- Main dimensional characteristics;
- Measurement limits for acidity (pH) levels;
- Operating and environmental temperature ranges;
- Measurement accuracy for acidity levels;
- Ranges and scales for pH measurement of gastric fluid using the device;
- Influence of food particles or other substances on the skin surface at the measurement site
- Influence of the concentration of various components in the measurement area on the results

All parameters demonstrated **full readiness** of the equipment, materials, and instruments for testing in accordance with the **first-stage testing program**.

Results of Equipment Preparation and Impact on Autonomous Capsule Design

The results of the calibration and experimental tests influenced the design principles of the **autonomous sensor capsule**, confirming its suitability for accurate acidity level identification and other target parameter evaluations.

The preparatory work included:

- Selection and experimental verification of **structural materials;**
- Selection and testing of **protective coatings;**
- Selection and comparative analysis of **sensor design variants;**
- Selection and verification of the **testing setup;**
- Preparation of **liquid samples** for testing;
- Measurement of acidity levels **before and after testing;**
- Evaluation of the **temperature effect** on acidity level;
- Evaluation of **time-dependent stability** of acidity;

- Analysis of the **chemical composition** influence on pH;
- Influence of **organic materials** or **fruit juices** on acidity;
- Influence of **coarse wheat flour** in concentrations of **100, 200, and 400 g/L** (signal penetration depth 1–1.5 mm).

Further Calibration and Experimental Testing Considerations

For subsequent calibration and testing phases, the following factor must be taken into account:

- The influence of a **5 mm-thick beef plate** placed **2 mm** from the sensor coil (signal penetration depth **1–1.5 mm**) – this configuration **should not affect** measurement accuracy or quality;
- If the **beef plate is in full contact** with the sensor coil, the flat coil must be **structurally positioned at a depth of 1.5 mm** to ensure accurate signal compensation and reliable readings.

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