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Study of The Structural–Mechanical Parameters and Technological Properties of Coenzyme Q10 Substance

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Abstract

To The comprehensive evaluation of the physicochemical, structural–mechanical, and technological properties of active pharmaceutical ingredients (APIs) is a crucial stage in the development of solid dosage forms. Particle size, particle morphology, flowability, compressibility, and frictional properties directly affect the stability of the manufacturing process and the quality of the final pharmaceutical product. Therefore, the determination of these characteristics provides a scientific basis for selecting the type and quantity of pharmaceutical excipients, optimizing the granulation process, and improving technological parameters. Consequently, these evaluations ensure dose uniformity, adequate mechanical strength, appropriate disintegration and dissolution characteristics, and ultimately contribute to the development of high-quality and stable pharmaceutical formulations [1].

Keywords: Coenzyme Q10, particle size, particle morphology, technological properties, flowability, compressibility.

1. Introduction

Coenzyme Q10 (CoQ10, ubiquinone, ubiquinol) is a lipid-soluble, vitamin-like endogenous biologically active compound that serves as an essential component of the mitochondrial electron transport chain in human cells. It plays a critical role in cellular energy metabolism by participating in the synthesis of adenosine triphosphate (ATP) and exhibits potent



antioxidant activity. By scavenging free radicals, Coenzyme Q10 protects cellular membranes and biomolecules from oxidative stress-induced damage [5].

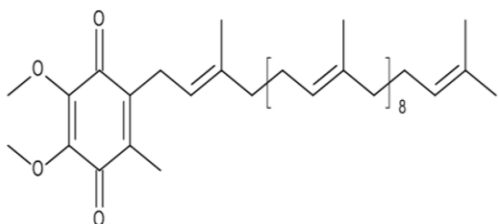
Coenzyme Q10 possesses antioxidant, cardioprotective, antihypoxic, and membrane-stabilizing properties. It enhances myocardial energy metabolism, reduces oxidative stress, supports endothelial function, and is widely used as part of combination therapy for cardiovascular diseases. Furthermore, it is administered to partially compensate for the reduction in endogenous Coenzyme Q10 levels associated with statin therapy [7].

Contemporary pharmacotherapy increasingly adopts a multitarget approach, which is based on the use of combination drug products capable of simultaneously affecting multiple pathogenic mechanisms of disease. From this perspective, the combination of valsartan with Coenzyme Q10 (ubiquinone) represents a pathogenetically justified therapeutic strategy aimed not only at inhibiting the renin–angiotensin–aldosterone system (RAAS) but also at alleviating mitochondrial dysfunction and oxidative stress associated with arterial hypertension [5].

Objective of the study. To investigate the physicochemical, structural–mechanical, and technological properties of the Coenzyme Q10 pharmaceutical substance.

2. Methods

The study was performed using Coenzyme Q10 ($C_{59}H_{90}O_4$) ((2E,6E,10E,14E,18E,22E,26E,30E,34E)-2-[(all-trans)-3,7,11,15,19,23,27,31,35,39-decamethyltetracont-2,6,10,14,18,22,26,30,34,38-decaenyl]-5,6-dimethoxy-3-methylcyclohexa-2,5-diene-1,4-dione). The substance is a yellow crystalline powder with a characteristic odor. It is practically insoluble in water but readily soluble in lipids and oils [2,9].



Furthermore, Coenzyme Q10 is readily soluble in organic solvents, including chloroform, diethyl ether and acetone. Its molecular weight is 863,34 g/mol [3].

The organoleptic properties of the Coenzyme Q10 substance were assessed by visual inspection, whereas its solubility was evaluated in accordance with the requirements and analytical procedures specified in the State Pharmacopoeia of the Republic of Uzbekistan (First Edition) [8].

According to clinical studies, the addition of Coenzyme Q10 to antihypertensive therapy improves its clinical efficacy. Coenzyme Q10 is an endogenous lipophilic antioxidant involved in the mitochondrial biosynthesis of adenosine triphosphate (ATP). It has been reported to exert beneficial effects by reducing arterial blood pressure, attenuating oxidative stress, and improving endothelial function [1,2].

Furthermore, Coenzyme Q10 has demonstrated cardioprotective and antioxidant effects in patients with cardiovascular diseases, diabetes mellitus, and acute coronary syndrome. These beneficial effects are attributed to the modulation of angiotensin-converting enzyme (ACE) activity, reduction of oxidative stress, and improvement of endothelial function [3,10].

The structural–mechanical properties of the Coenzyme Q10 substance were investigated using a Motich BA-210 (A123) trinocular microscope equipped with a Canon digital camera. Selected micrographs were digitally processed using Adobe Photoshop CS5 to enhance image quality. The microscope, with a magnification range of 26× to 900×, enabled a detailed evaluation of particle morphology, shape, and size. Linear particle dimensions were measured using an ocular micrometer, and for each substance, 30 replicate measurements were performed. The results were expressed in micrometers (μm). Statistical analysis of the experimental data was carried out using variation statistics according to the method of Zaitsev (1991) with Microsoft Excel software [10].

The technological properties of the Coenzyme Q10 substance were determined in accordance with the pharmacopoeial procedures described in the State Pharmacopoeia of the Republic of Uzbekistan, First Edition, Volume I, Part I [8].

All experiments were performed in triplicate, and the results are presented as arithmetic mean values.

3. Results and Discussion

The results of the study demonstrated that Coenzyme Q10 is a yellow crystalline powder with a characteristic odor and exhibits slight dusting properties. The substance is practically insoluble in water but readily soluble in lipids and organic solvents, including chloroform, diethyl ether, and acetone. The

poor aqueous solubility of Coenzyme Q10 is primarily attributed to its highly lipophilic nature [3,10].

To evaluate the morphological characteristics of the Coenzyme Q10 particles, microscopic images were obtained and are presented in Figure 1.1.

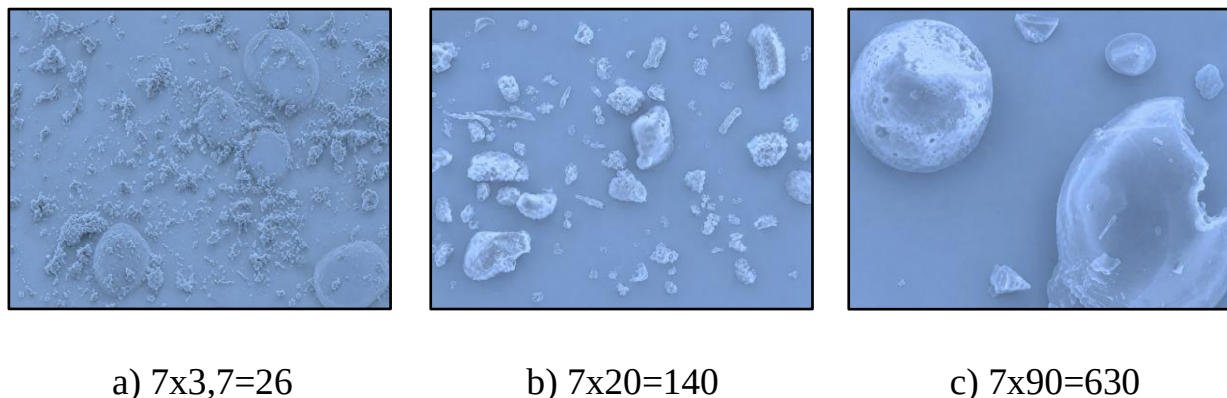


Figure 1.1. Micrographs of coenzyme Q10 substance particles obtained at various magnifications

The micrographs presented in Figure 1.1 show the Coenzyme Q10 particles at magnifications of 26 $\times$, 140 $\times$, and 630 $\times$. Microscopic examination revealed that the substance consists predominantly of plate-like and oval-shaped crystalline particles. The particle surfaces were relatively smooth, with well-defined edges, and both individual crystals and small aggregates of various sizes were observed [6,7].

The linear dimensions of the particles were determined using an ocular micrometer based on 30 replicate measurements. The obtained results indicated that the Coenzyme Q10 particles exhibited relatively uniform morphological characteristics. Such morphological features are expected to contribute positively to the flowability of the powder, its homogeneous distribution

within the formulation, and the efficiency of technological processes, including granulation and capsule filling [10].

In the subsequent stage of the study, the technological properties of the Coenzyme Q10 substance (European Pharmacopoeia, 11th Edition, Supplement 11.4, EDQM, 2023) were evaluated. Initially, its particle size distribution (granulometric composition) was determined by sieve analysis. The analysis was performed using an Endecotts Octagon 200 electronic sieve shaker (Erweka, Germany) available at the Department of Industrial Technology of Medicines, Tashkent Pharmaceutical Institute. The distribution of particles according to size fractions and the granulometric composition of the substance were evaluated. The results are presented in Figure 1.2.

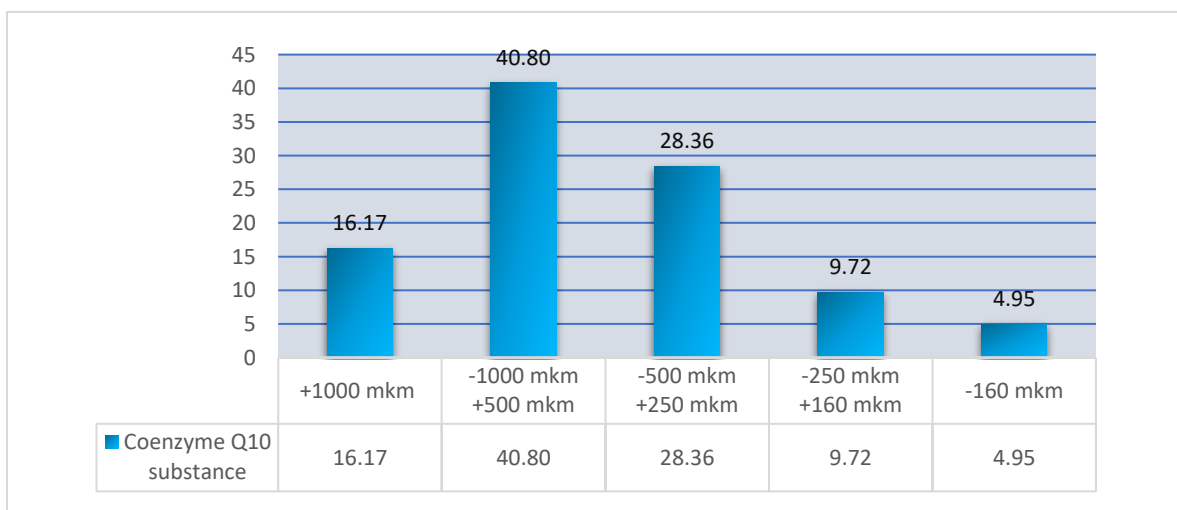


Figure 1.2. Results of determining the fractional composition of the coenzyme Q10 substance.



Based on the results obtained, it was established that the coenzyme Q10 substance particles are unevenly distributed across various fractions. The main share belongs to the $-1000+500\ \mu\text{m}$ fraction, which is 40.80%. The $-500+250\ \mu\text{m}$ fraction occupies the next place (28.36%). 16.17% in the $+1000\ \mu\text{m}$ fraction, 9.72% in the $-250+160\ \mu\text{m}$ fraction, and the lowest amount was observed in the $-160\ \mu\text{m}$ fraction, amounting to

4.95%. The results obtained showed that the majority of coenzyme Q10 substance particles are concentrated in the 250–1000 μm size range [5,10].

The results of determining the main technological parameters of the Coenzyme Q10 substance are presented in Table 1.1.

Table 1.1.

Results of determining the technological and physico-mechanical properties of the Coenzyme Q10 substance

№	Studied indicators	Unit of measurement	Substances
			Coenzyme Q10
1	Scattering with vibration	$10^{-3}\ \text{kg/s}$	$0,938\pm 0,018$
2	Non-vibratory dispersion	$10^{-3}\ \text{kg/s}$	$0,92\pm 0,08$
3	Pre-compaction dispersion density	g/sm^3	$176,12\pm 19,6$
4	Tapped density	g/sm^3	$188,16\pm 22,4$
5	Angle of repose	degree	$48,11\pm 3$
6	Compressibility	N	78,0
7	Compaction coefficient		$4,38\pm 0,08$
8	Residual moisture content 70°C	%	2,44
Physico-mechanical indicators			
1	Hausner ratio		1,06
2	Carr's Compressibility Index		6,39

The results demonstrated that the technological properties of the Coenzyme Q10 substance were characteristic of a cohesive powder. The flowability of the substance was determined using a GTL Powder Tester (ERWEKA, Germany). Under vibration-assisted conditions, the flow rate was $0.938 \pm 0.018 \times 10^{-3}\ \text{kg/s}$, whereas under non-vibrational conditions it was $0.920 \pm 0.080 \times 10^{-3}\ \text{kg/s}$ [1,10].

These values indicate that the Coenzyme Q10 substance exhibits poor intrinsic flowability, which may adversely affect the stability of powder flow during dosing and capsule filling. Therefore, appropriate technological measures are required to ensure a consistent manufacturing process.

The bulk density of the substance was evaluated using a BHY-100 TAP Density Volumeter (China). The bulk density before tapping was $176.12 \pm 19.6\ \text{kg/m}^3$, while the tapped density after compaction reached $188.16 \pm 22.4\ \text{kg/m}^3$. These results suggest that the powder particles undergo a certain degree of rearrangement and consolidation under mechanical stress [10].

The angle of repose of the Coenzyme Q10 substance was $48.11 \pm 3^{\circ}$, indicating unsatisfactory powder flow characteristics. It is well established that powders with an angle of repose exceeding 40° generally exhibit poor flowability during pharmaceutical processing. Consequently, such materials often require granulation or the incorporation of flow-enhancing excipients to improve processing performance [4,5].

The compressibility of the substance was 78.0 N, demonstrating its ability to undergo densification under externally applied pressure. The compaction coefficient was 4.38 ± 0.08 , reflecting the consolidation behavior of the powder under mechanical compression.

Analysis of the physicomachanical properties showed a Hausner ratio of 1.06 and a Carr's Compressibility Index of 6.39%. In pharmaceutical technology, a Hausner ratio below 1.25 and a Carr's Index below 10% are generally considered indicative of good packing and compressibility characteristics. Thus, although the Coenzyme Q10 substance exhibited limited free-flowing properties, its compaction behavior was satisfactory,



making it suitable for the development of capsule dosage forms [4,10].

The residual moisture content was determined at 70°C using a moisture analyzer manufactured by Kett (Japan). The residual moisture content of the Coenzyme Q10 substance was 2.44%. This value was considered appropriate for maintaining the physicochemical stability of the substance, minimizing degradation processes, and preserving its quality characteristics during storage [6,10].

4. Conclusion

Overall, the obtained results indicate that the technological characteristics of the Coenzyme Q10 substance, particularly its poor flowability, necessitate the application of additional technological approaches during the development of solid dosage forms. Nevertheless, the substance demonstrated satisfactory compaction behavior and favorable physicomachanical properties, confirming its suitability for the formulation of capsule dosage forms. Based on these findings, the application of wet granulation, together with the selection of appropriate pharmaceutical excipients, is recommended in subsequent stages of formulation development to improve powder flowability, ensure uniform particle distribution, and enhance the robustness and reproducibility of the manufacturing process.

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