

REVIEW

by Assoc. Prof. Velichka Jordanova Andonova, Ph.D.,

Head of the Department of Pharmaceutical Technology at the Faculty of Pharmacy of the Medical University – Varna “Prof. Dr. Paraskev Stoyanov”

Internal member of the scientific jury, appointed by Order No. P-109-380/18.09.2025 of the Rector of the Medical University – Varna

Subject: procedure for the defense of a dissertation for the educational and scientific degree “Doctor” on the topic *“Centralized Preparation of Medicinal Products for Systemic Treatment of Malignant Diseases in Hospital Pharmacies in Bulgaria – Specifics, Challenges and Prospects”* by author *Velina Grigorova, MSc. Pharm.*, in the Higher Education Area 7. “Health Care and Sports”, Professional Field 7.3. “Pharmacy”, Doctoral Program “Hospital Pharmacy”

General overview of the procedure

The presented set of documents from the doctoral candidate Velina Grigorova, MScPharm, complies with the requirements of the Regulations on Academic Staff Development at the Medical University Prof. Dr. P. Stoyanov – Varna. She was enrolled as a self-training student (Order No. P-109-340/11.08.2022) under the doctoral program “Hospital Pharmacy,” professional field 7.3. Pharmacy, in the Department of “Organization and Economics of Pharmacy” of the Faculty of Pharmacy at the Medical University – Varna (MU-Varna) with scientific supervisors Prof. Evgeni Grigorov, Ph.D., and Prof. Asena Serbezova, Ph.D., DMSc. Velina Grigorova, MSc. Pharm., has fulfilled all requirements for a self-study basis PhD, which is evident from the presented documents. She has been enrolled with the right to defense by Order No. P-109-380/18.09.2025 of the Rector of MU-Varna.

Brief biographical data about the doctoral candidate

Velina Hristova Grigorova, MSc. Pharm., holds a Master’s degree in “Biology” from Sofia University “St. Kliment Ohridski” and in “Pharmacy” from MU-Sofia, recognized professional qualification “Master of Pharmacy,” as well as two specializations for continuous professional development: “Clinical Pharmacy” and “Hospital Pharmacy.” In 2022 she was enrolled as a self-training student in the doctoral program “Hospital Pharmacy” in the Department of Organization and Economics of Pharmacy at the Faculty of Pharmacy at MU-Varna.

Velina Grigorova is an active member and participant in the development of the professional guild, holding various positions in the Bulgarian Pharmaceutical Union – member of the Management Board, Deputy Chair of the Management Board and Acting Chair of the Management Board. For 10 years she has been the Chair of the Management Board of the

Professional Organization of Hospital Pharmacists in Bulgaria; she has been a member of the Management Board and Chair of the Bulgarian Association for Oncologic Pharmacy. Since 2006 to the present, her professional path is linked to hospital healthcare facilities where treatment of malignant diseases is carried out, and since 2008 she has held the position of Hospital Pharmacy Manager consecutively at the Uni Hospital – Panagyurishte Multidisciplinary Hospital for Active Treatment, Acibadem City Clinic Mladost and currently – Acibadem Clinic Tokuda in Sofia. She is an active participant in numerous national and international professional meetings and conferences.

Structure and sections of the doctoral work

The dissertation is structured in accordance with the requirements of the “Rules for the Development of the Academic Staff of MU ‘Prof. Dr. Paraskev Stoyanov’ Varna – introduction, literature review, aim and objectives, materials and methods, results and discussion, conclusions, contribution, bibliography and appendices – total 139 pages. The formulated research tasks are exhaustively discussed and commented in separate sub-sections of the results chapter, with an overarching discussion/conclusions at the end of the separate parts. The dissertation comprises 139 pages, illustrated with 54 figures and 10 tables. Five appendices are included. The bibliography includes 139 sources in Bulgarian and English.

Relevance of the topic and appropriateness of the stated aims and objectives

The dissertation proposed for discussion and evaluation, developed by Velina Grigорова, MSc., Pharm., is titled: “CENTRALIZED PREPARATION OF MEDICINAL PRODUCTS FOR SYSTEMIC TREATMENT OF MALIGNANT DISEASES IN HOSPITAL PHARMACIES IN BULGARIA – SPECIFICS, CHALLENGES AND PROSPECTS.”

The work is entirely within the doctoral program field, highly timely, and, for the first time, provides a systematic analysis of centralized dissolution of parenteral anticancer drugs for systemic treatment in Bulgaria since its introduction in 2015. It reviews the current state, prospects, and possibilities for optimizing processes in oncology pharmacy and hospital pharmacies. The results and recommendations are presented in a way that, if implemented, could lead to more effective and safer preparation, storage, and administration of medicines for systemic cancer treatment in the country. The study, as well as the specific nature of the activity, clearly demonstrates the need to introduce specialized theoretical and practical training for pharmacists preparing solutions of anticancer drugs in hospital pharmacies.

Problem awareness

The literature review spans 48 pages, divided into five parts. It covers the classification of anticancer drugs, details the reasons for the emergence and introduction of centralized preparation of solutions of anticancer medicinal products, and the particularities of aseptic work. It presents established practices in other countries for training pharmaceutical staff who prepare parenteral solutions. It traces the historical development in Bulgaria of centralized dissolution of medicines for systemic cancer treatment. The presentation demonstrates completeness, a clear and

understandable writing style, analytical rigor, and logical coherence between the sections of the literature review.

Aim and objectives of the research

Based on the thorough literature review, the doctoral candidate formulates the aim of the present dissertation: to study and analyze the process of centralized preparation of solutions of medicinal products for the systemic treatment of malignant diseases /SMPSTMD/ in hospital pharmacies in Bulgaria, as well as the training of personnel for the performance of this specific pharmaceutical activity. A secondary aim is to present prospects for the further development of the process in our country. Six objectives are defined, whose logical sequence and achievement enable the attainment of the final goal.

Research methodology

The overall methodology follows a logical sequence aimed at solving the stated tasks in relation to the dissertation's goal. The candidate has chosen contemporary methods (historical method, documentary method, statistical method, graphical method, interview method), which she deftly applies, demonstrating deep theoretical knowledge of their essence. The large number of methods applied in the development of the dissertation highlights the broad multidisciplinary nature of the study and a comprehensive approach.

Analysis of results

The obtained results are presented clearly and concisely, organized into six points. In the first point, the regulatory framework in Bulgaria governing centralized preparation of solutions for direct administration of medicines for systemic cancer treatment is analyzed. The second point presents an analysis of the healthcare institutions where oncology and/or clinical hematology and/or pediatric clinical hematology and oncology activities are performed. The third point analyzes the unusable residues from the preparation of medicinal products for the systemic treatment of malignant diseases reported to the National Health Insurance Fund (NHIF) for the period 2020-2024. The fourth and fifth points present results from the study of the demographic and professional characteristics of pharmacists who prepare parenteral solutions of anticancer drugs and their training for this specific activity. Recommendations for improving the regulatory framework and specialized training of pharmacists are presented in the sixth point.

The reviewer is impressed by the candidate's ability to analyze results and reveal complex causal relationships, which indicates her well-developed research thinking. The presentation and discussion of results are characterized by high precision, depth, and analytical rigor, clearly reflecting excellent theoretical preparation and the ability for a critical scientific approach.

In conclusion, the conclusions (14 in total) are formulated clearly and precisely, arising from the results of each assigned task in the dissertation.

Contributions and significance of the work for science and practice

My detailed acquaintance with Velina Grigorova's dissertation shows that the identified scientific and theoretical and scientific and practical contributions are original in nature and are

genuinely supported in the presented work. I highly value the scientific and practical contributions concerning proposed legislative changes in the sector, which would improve the quality of prepared products, ensure a safe working environment for staff, optimize the use of public funds in hospital facilities, and contribute to the creation of a nationally approved and recognized training program for pharmacists who prepare solutions for systemic treatment of malignant diseases.

Assessment of publications related to the dissertation

The presented full-text publications related to the dissertation topic include one in English in a journal indexed in global databases Scopus/Web of Science with an impact factor, and four in Bulgarian peer-reviewed scientific journals. In four of these publications, the doctoral student is the first author. The publications reflect the conducted studies, results, and analyses of the dissertation to a significant extent. Participation in scientific events in Bulgaria and abroad totals 14.

Personal participation of the doctoral student in the conducted dissertation research

A very large amount of experimental work has been carried out. The obtained results have scientific and applied significance. There is no doubt about the doctoral student's personal involvement in reviewing the problem, formulating the aim and objectives, conducting the experimental studies, analyzing the results and the contributions derived, as well as in supporting the scientific supervisors. There is evident a deep understanding of the specific subject matter and a fluent command of the terminology used in the dissertation.

Author's abstract

The abstract has been prepared in accordance with the requirements. It includes the aim and objectives and a description of the materials and methods used. The presented investigations and discussion fully reflect the main results achieved in the dissertation. The obtained results are illustrated with a sufficient number of figures and tables. The conclusions coincide with those in the dissertation. The abstract includes the scientific contributions, as well as a list of publications and participation in scientific forums related to the dissertation and observed citations. Familiarizing oneself with the abstract provides a complete understanding of the problem being developed, the research conducted, and the interpretation of the results obtained.

Critical remarks and recommendations

I have no critical remarks. I strongly recommend continuing the research on the topic.

CONCLUSION

The dissertation ***presents original scientific results that constitute a contribution to science and meets all the requirements*** of the Act on Development of the Academic Staff in the Republic of Bulgaria, the Regulations on the Implementation of the Development of Academic Staff in the Republic of Bulgaria act, and the relevant Regulations on Academic Staff Development at the Medical University Prof. Dr. P. Stoyanov – Varna. The dissertation demonstrates that the

doctoral candidate ***Velina Hristova Grigorova*** possesses theoretical knowledge and professional skills in the scientific field of “Hospital Pharmacy.” She has mastered many methods, conducted a substantial volume of experimental research, and shown the ability to interpret the obtained results. This demonstrates qualities and skills for independent conducting of scientific research.

For the above reasons, I confidently provide my positive assessment of the conducted research, the reviewed above doctoral dissertation, the abstract, the achieved results and contributions, and ***I propose to the esteemed scientific jury to confer the educational and scientific degree “Doctor” on Velina Hristova Grigorova in the Doctoral Program “Hospital Pharmacy,” Professional Field 7.3. Pharmacy, for the developed dissertation on the topic “Centralized Preparation of Medicinal Products for Systemic Treatment of Malignant Diseases in Hospital Pharmacies in Bulgaria – Specifics, Challenges and Prospects.”***

13.11.2025
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Prepared by
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