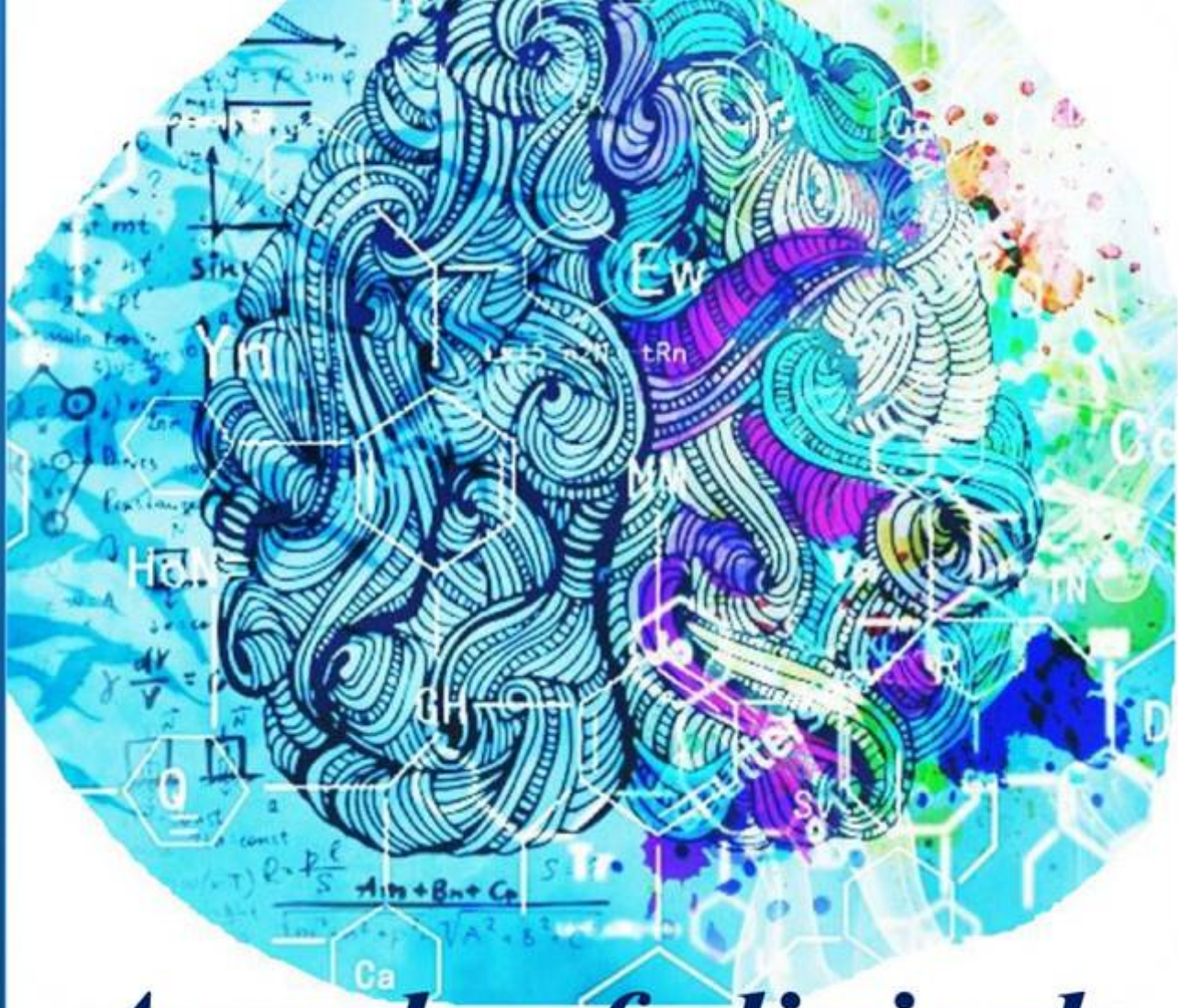
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Адрес редакции: Республика Узбекистан, 200114, г. Бухара, ул. Гиждуван, 23
Телефон: +998(65)2230050
Сайт: https://tadqiqot.uz/index.php/spjacd
e-mail: abumkur14@gmail.com

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Jalilova F.S.
Bukhara State Medical Institute, Bukhara, Uzbekistan

SAFETY EVALUATION OF A BIOLOGICALLY ACTIVE SUPPLEMENT FORMULATED FROM MOMORDICA CHARANTIA CULTIVATED IN BUKHARA

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ANNOTATION

This study focuses on evaluating the acute toxicity of a biologically active food supplement developed from Momordica charantia (bitter melon) cultivated in the Bukhara region of Uzbekistan. Known for its antioxidant, antidiabetic, and immune-enhancing properties, this plant holds significant potential in the development of functional food products. During the experiment, white rats were administered single doses of the supplement ranging from 2000 to 5000 mg/kg via oral gavage. Over a 21-day observation period, no signs of toxicity or mortality were recorded. The LD_{50} was determined to exceed 5000 mg/kg, indicating the non-toxic nature of the product. These findings confirm the toxicological safety of the supplement and support its potential application as a nutraceutical.

Keywords: Momordica charantia, toxicological evaluation, LD50, food supplement, Bukhara, safety, nutraceutical.

Джалилова Ф.С.
Бухарский государственный медицинский институт, Бухара, Узбекистан

ОЦЕНКА БЕЗОПАСНОСТИ БИОЛОГИЧЕСКИ АКТИВНОЙ ДОБАВКИ, СОЗДАННОЙ ИЗ MOMORDICA CHARANTIA, ВЫРАЩИВАЕМОЙ В БУХАРЕ

АННОТАЦИЯ

В этом исследовании основное внимание уделено оценке острой токсичности биологически активной пищевой добавки, разработанной из Momordica charantia (горькая дыня), выращиваемой в Бухарской области Узбекистана. Известное своими антиоксидантными, противодиабетическими и иммуностимулирующими свойствами, это растение обладает значительным потенциалом в разработке функциональных пищевых продуктов. В ходе

эксперимента белым крысам вводили однократные дозы добавки в диапазоне от 2000 до 5000 мг/кг через пероральный зонд. В течение 21-дневного периода наблюдения не было зафиксировано никаких признаков токсичности или смертности. Было установлено, что LD_{50} превышает 5000 мг/кг, что указывает на нетоксичность продукта. Эти результаты подтверждают токсикологическую безопасность добавки и поддерживают ее потенциальное применение в качестве нутрицевтика.

Ключевые слова: Momordica charantia, токсикологическая оценка, LD50, пищевая добавка, Бухара, безопасность, нутрицевтик.

Jalilova F.S.
Buxoro davlat tibbiyot instituti Buxoro, O'zbekiston

BUXORODA EKIB YETISHTIRILGAN MOMORDICA CHARANTIADAN TUZILGAN BIOLOGIK FAOL QO'SHIMCHALARNING XAVFSIZLIGINI BAHOLASH

ANNOTATSIYA

Ushbu tadqiqot O'zbekistonning Buxoro viloyatida yetishtiriladigan Momordica charantia (achchiq qovun) dan ishlab chiqarilgan biologik faol oziq-ovqat qo'shimchasining o'tkir toksikligini baholashga qaratilgan. Antioksidant, diabetga qarshi va immunitetni mustahkamlovchi xususiyatlari bilan mashhur bo'lgan bu o'simlik funktsional oziq-ovqat mahsulotlarini ishlab chiqarishda muhim salohiyatga ega. Tajriba davomida oq kalamushlarga 2000 dan 5000 mg/kg gacha bo'lgan qo'shimchaning bir martalik dozalari og'iz orqali yuborilgan. 21 kunlik kuzatuv davrida toksiklik yoki o'lim belgilari qayd etilmagan. LD_{50} 5000 mg/kg dan oshib ketgani aniqlandi, bu mahsulotning toksik bo'lmaganligini ko'rsatadi. Ushbu topilmalar qo'shimchaning toksikologik xavfsizligini tasdiqlaydi va uning ozuqaviy vosita sifatida qo'llanilishini qo'llab-quvvatlaydi.

Kalit so'zlar: Momordica charantia, toksikologik baholash, LD_{50}, oziq-ovqat qo'shimchasi, Buxoro, xavfsizlik, ozuqaviy.

Introduction. In recent decades, the global scientific community has increasingly turned its attention toward the exploration of plant-derived biologically active compounds due to their promising therapeutic potential and relative safety compared to synthetic pharmaceuticals. Phytochemicals-naturally occurring chemical compounds in plants-have been extensively studied for their ability to modulate biological processes and contribute to human health. These compounds, which include flavonoids, alkaloids, terpenoids, phenolics, and glycosides, are recognized for their antioxidant, anti-inflammatory, anticancer, and immunomodulatory effects. As the demand for natural health products continues to rise, there is growing interest in identifying and evaluating lesser-known medicinal plants that may contribute to the development of safe and effective nutraceuticals and functional foods [1,2].

One such plant that has attracted significant attention is Momordica charantia, commonly referred to as bitter melon or bitter gourd. Belonging to the Cucurbitaceae family, M. charantia is widely distributed in tropical and subtropical regions and has

a long history of traditional use in Ayurvedic, Traditional Chinese, and African medicine systems. Traditionally, it has been employed to manage a variety of ailments, including diabetes mellitus, gastrointestinal disturbances, infections, and inflammatory conditions. Recent pharmacological studies have validated many of these traditional uses, attributing them to the presence of diverse bioactive compounds, such as saponins, flavonoids, alkaloids, polysaccharides, vitamin C, and polyphenols [18].

The pharmacodynamic effects of M. charantia are attributed to its multifaceted mechanisms of action. For example, its antidiabetic effect is thought to result from insulin-mimetic activity, stimulation of pancreatic β-cells, and inhibition of intestinal glucose absorption. Moreover, the antioxidant properties of its constituents help to neutralize free radicals, thereby reducing oxidative stress—a key contributor to the pathogenesis of chronic diseases such as cancer, cardiovascular disease, and neurodegenerative disorders. Additionally, some studies have suggested that extracts of M. charantia may exhibit antimicrobial, hepatoprotective, and lipid-lowering effects, further expanding its potential applications in complementary medicine [7,16].

The cultivation of M. charantia is not confined to its native regions, and its agricultural adaptation in various parts of the world has been explored to meet growing demands. In Uzbekistan, particularly in the Bukhara region, the agro-climatic conditions are highly favorable for the cultivation of this species. Recent agricultural developments have led to the successful introduction and large-scale cultivation of M. charantia, with the aim of utilizing its phytochemical wealth for the production of high-value biologically active food supplements. Such initiatives not only promote agricultural diversification but also offer new opportunities for the development of plant-based therapeutic agents within the country [17].

Despite the recognized therapeutic potential of M. charantia, it is imperative to ensure the safety and efficacy of any health product derived from this plant, especially when introduced into the human diet. Toxicological evaluation, particularly acute toxicity studies, plays a critical role in determining the appropriate dosage range, identifying possible adverse effects, and ensuring consumer safety. Acute toxicity testing provides foundational data that inform regulatory guidelines, risk assessments, and subsequent long-term safety studies.

Research purpose. Therefore, the present study was designed to evaluate the acute toxicological profile of a biologically active food supplement derived from M. charantia cultivated in the Bukhara region of Uzbekistan. The findings of this investigation will contribute to the growing body of evidence supporting the safe use of M. charantia-based products in health and nutrition. Furthermore, this study aligns with the broader objectives of promoting evidence-based use of traditional medicinal plants and developing safe, locally sourced nutraceuticals that can enhance public health outcomes.

Materials and Methods. Plant Material and Supplement Preparation.

The plant material used in this study consisted of mature fruits of Momordica charantia L., which were cultivated under field conditions in the Jondor district of the Bukhara region, Republic of Uzbekistan. The region’s dry, warm climate and fertile

soil are conducive to the successful growth of this tropical and subtropical species. The selection of plant material was carried out during the peak fruiting season to ensure maximum phytochemical content. Fruits were harvested manually, carefully sorted, and washed to remove any dirt or foreign particles [3,10,11].

Post-harvest, the fruits underwent a standardized processing protocol designed to preserve their bioactive compounds. This included slicing, drying under controlled temperature and humidity conditions, and pulverization into fine powder. The dried powder was then subjected to further processing using a proprietary method developed by a local biotechnology facility. This method involved cold extraction and encapsulation to produce a stable, concentrated biologically active food supplement rich in saponins, polyphenols, flavonoids, and vitamin C. The final product was stored in airtight containers under dark and dry conditions to prevent degradation prior to toxicological testing.

Toxicological analysis. The acute toxicity study was conducted in accordance with the Organization for Economic Co-operation and Development (OECD) guidelines for testing of chemicals (OECD Guideline 423: Acute Oral Toxicity – Acute Toxic Class Method). The toxicological evaluation was carried out at a certified pharmacological laboratory in Tashkent, authorized to perform preclinical safety studies of nutraceuticals and herbal preparations [4,5,9]

For the study, healthy adult albino rats (Rattus norvegicus), weighing between 170 and 190 grams, were obtained from a licensed animal breeding facility. The animals were acclimatized to laboratory conditions for seven days prior to the initiation of the experiment. They were housed in standard polypropylene cages under controlled environmental conditions (temperature 22 ± 2°C, relative humidity 50–60%, and 12-hour light/dark cycle) and were provided with a standard pellet diet and water ad libitum.

The animals were randomly divided into five groups (n = 6 per group), consisting of one control group and four experimental groups. The control group received distilled water only, whereas the experimental groups were administered the M. charantia supplement orally in single doses of 2000 mg/kg, 3000 mg/kg, 4000 mg/kg, and 5000 mg/kg body weight, respectively. The administration was performed using a sterile stainless-steel gastric gavage needle to ensure accurate delivery of the supplement into the stomach.

Following administration, the animals were closely monitored for 4 hours on the first day for immediate toxic effects, including signs of distress, behavioral abnormalities, tremors, convulsions, salivation, lethargy, or coma. Daily observations continued for 21 consecutive days to evaluate sub-acute outcomes such as changes in food and water intake, body weight, grooming behavior, posture, and overall activity. Mortality, if any, was recorded, and the median lethal dose (LD_{50}) was estimated based on the number of deaths observed in each dose group.

At the end of the observation period, all surviving animals were subjected to a detailed physical examination. In addition, necropsy was performed on both deceased and euthanized rats to assess any gross pathological changes in major organs, including the liver, kidneys, lungs, heart, and gastrointestinal tract. The organ

samples were preserved in 10% formalin for potential histopathological evaluation if required.

This methodological approach enabled the comprehensive assessment of the acute oral toxicity profile of the biologically active food supplement derived from M. charantia, ensuring compliance with international ethical and scientific standards for laboratory animal research [6,15,12].

Results and discussion. The acute oral toxicity assessment of the biologically active supplement derived from Momordica charantia revealed no evidence of toxicity or adverse effects in any of the test groups throughout the 21-day observation period. Even at the highest administered dose of 5000 mg/kg body weight, all experimental animals remained alive and exhibited normal physiological and behavioral responses, indicating that the supplement was well tolerated.

Following administration, all rats were monitored continuously for signs of acute toxicity, including but not limited to changes in locomotor activity, body posture, reflexes, skin and fur condition, eye and mucous membrane appearance, and autonomic responses such as salivation and urination. No deviations from normal behavior or appearance were noted at any dose level, including the highest dose. The animals remained alert, exhibited normal grooming behavior, maintained stable food and water intake, and showed no indications of distress or discomfort.

Observation records specifically for the group receiving the 5000 mg/kg dose—the maximum dosage tested—are summarized in Table 1. The data clearly show that none of the animals experienced mortality or any overt toxic symptoms during the study period.

Table 1.

Mortality Outcomes Following Oral Administration of 5000 mg/kg of the Supplement (n = 6)

Dose (mg/kg)	Day 1	Day 2	Day 3	Day 4	Day 5	Day 6	Day 14	Day 21
5000	6/0	6/0	6/0	6/0	6/0	6/0	6/0	6/0

Note: Data presented as number of surviving animals/number of deaths.

As shown in Table 1, all six animals survived throughout the 21-day experimental period without any signs of morbidity. The total number of deceased animals across all dose groups, including the 5000 mg/kg group, was zero. On the basis of these observations, the approximate median lethal dose (LD_{50}) of the supplement can be estimated to exceed 5000 mg/kg. According to the classification standards defined under GOST 12.1.007-76, substances with an LD_{50} greater than 5000 mg/kg fall into Class IV, which denotes "low-hazard" substances.

These results are in agreement with previously published studies that suggest the high safety margin of M. charantia-based preparations. For instance, several animal studies have demonstrated the absence of significant toxicological effects following short-term or single-dose administration of M. charantia extracts, particularly when used in moderate to high doses. The present study further substantiates these findings by confirming the non-toxic nature of the supplement formulated from M. charantia grown in Uzbekistan’s Bukhara region.

Furthermore, the absence of physiological abnormalities or behavioral deviations suggests that the formulation does not interfere with essential metabolic or neurological functions. This is especially important when considering the potential application of the supplement in human populations, where safety and tolerability are critical prerequisites for regulatory approval and public health utilization.

In addition to the toxicological evaluation, macroscopic examinations of the animals at the end of the study revealed no visible pathological changes in major internal organs. Although histopathological analysis was not the primary objective of this acute study, the gross anatomical integrity of organs such as the liver, kidneys, heart, and intestines supported the conclusion that the supplement did not induce organ-specific toxicity within the observation period [8,13,14].

Overall, the findings indicate that the biologically active food supplement derived from Momordica charantia exhibits a high safety threshold, with no acute toxic effects observed even at relatively high oral doses. These results serve as a foundational step for future subchronic and chronic toxicity studies, and provide scientific justification for the continued development of this supplement as a safe, plant-based nutraceutical product for potential human consumption.

Conclusion. The findings of this study indicate that the biologically active food supplement prepared from Momordica charantia cultivated in Bukhara does not exhibit acute toxic effects. Animal testing confirmed its toxicological safety.

The bioactive compounds in M. charantia, including saponins, flavonoids, vitamin C, and polyphenols, provide significant therapeutic potential. Such supplements may enhance antioxidant activity in the body and could help prevent chronic diseases such as diabetes and cardiovascular disorders.

Integrating this supplement into nutritional systems could be especially beneficial for populations with weakened immunity or those living in environmentally stressed regions. Further clinical trials and the development of technological standards are recommended.

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