Assessment of niacinamide content in commercial skin care products

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Introduction: Niacinamide is frequently used in cosmetic products and has numerous positive effects on human skin such as anti-inflammatory, antimicrobial, photoprotective etc. Cosmetic products in the EU are governed by Regulation EC 1223/2009. However, regulation that applies to cosmetic products does not include control of the active substances. There are only recommendations and no restrictions regarding the concentration of niacinamide in cosmeceuticals. On the other hand, higher concentrations in the preparations without ensuring the stability of this vitamin can cause redness or irritation after applying these products.

Purpose: The purpose of this study was to assess niacinamide content in some cosmetic products available on the market.

Method: Four different cosmetic products for skin care, marked as serum, face cream, face mask and anti-dark circle eye mask were tested. Sample preparation included liquid-liquid extraction of niacinamide by using water, methanol or their mixture. Analysis was performed using HPLC method on Zorbax Eclipse XDB C18 column at 35°C. Phosphate buffer pH=4.0 (25mM) mixed with methanol in volume ratio 90:10 was used as mobile phase. The flow rate was 0.5 ml/min. Chromatographic peak of vitamin was detected at 260 nm.

Results: The average content of niacinamide was found to be 14.0±0.11% in serum, 9.5±0.14% in face cream, 5.0±0.15% in face mask and 7.4±0.12% in anti-dark circle eye mask. The niacinamide concentration found in the cream and face mask was in line with the declared values, while in the serum and eye mask it was significantly higher than declared.

Conclusion: The presence of niacinamide was confirmed in all analyzed cosmetic products, however its content varied depending on type of formulation and its purpose. The determined concentrations of niacinamide in the examined products ranged between 5.0% and 14.0% (w/w). Usually recommended concentrations in cosmeceuticals are 3.5-5.0%. It can be noted that the content of niacinamide in some cosmetic products is significantly higher than recommended values.

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Challenges of performing clinical trials

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Introduction: Trials performed in small communities pose challenges due to number of participants and facilities. The aim was to investigate the impact of new regulations, brought into effect in January 2022, for clinical trials in Malta and create a template for clinical trial planning, to outline the steps involved in setting up clinical trials. The new EU guidelines from 2022 outlines the new regulations to be followed when setting up clinical trials, including the use of CITS which is a system that must be used to upload all documentation needed for a clinical trial.

Method: A questionnaire for healthcare professionals was developed to identify experiences and perceptions about challenges in clinical trial participation and this was disseminated in March 2024. Qualitative interviews were held with the national economic development agency to discuss national strategies to attract and support investment and operations in the area of clinical trials, with private pharmaceutical companies and private clinics to establish interest in participating in clinical trials and with medical specialists with experience in clinical trials. Subsequently a template to guide professionals through procedures was developed intended to address challenges identified.

Results: Forty-five questionnaires were completed by 43 specialist doctors and 2 pharmacists who reported time constraints, lack of funding and infrastructure as the main hurdles. Five private pharmaceutical companies were contacted but these did not show an interest in being involved in any clinical trials. The 3 private clinics contacted showed an interest and are willing to offer all their facilities for such trials. The national economic investment agency highlighted the lack of a Contract Research Organisation (CRO) in Malta as a challenge whilst an interest in strategic measures to attract CROs. Three specialist doctors from Mater Dei Hospital, involved in 3 different types of trials, were interviewed and their main concerns identified. The template developed highlights practical approach to application for approval, setting up a team of health professionals, finding premises and laboratory services, and recruiting volunteers in the context of small healthcare and pharmaceutical ecosystems.

Conclusion: This research identified challenges and opportunities at the level of the national economic development agency and in healthcare systems. The template developed addresses these challenges and serves to

support healthcare professionals embarking on participating in clinical trials by serving as a resource that identifies stakeholders which are able to offer funding, facilities like medical clinics, and services like laboratory services. The rationale for aspects in the new EU legislation regulating clinical trials intended to ensure patient safety are highlighted so that healthcare professionals are empowered to navigate the process through proper management and good governance.

Regulation of food supplements

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Introduction: Food supplements, which deliver essential nutrients like vitamins, minerals, and probiotics, face inconsistent global regulation. Jurisdictions classify them differently—some as pharmaceuticals (requiring rigorous safety evaluations) and others as food products (with laxer standards). These disparities in definitions, labeling, analytical methods, and oversight create challenges for market access, consumer trust, and safety. Harmonizing regulations is critical to address these gaps and ensure efficacy, safety, and transparency.

This study evaluates global regulatory frameworks for food supplements to identify inconsistencies and propose strategies for harmonization. It addresses the lack of a universal definition and examines how divergent approaches (e.g. pharmaceutical-grade standards vs. flexible food regulations) impact safety assessments, labeling accuracy, and consumer confidence.

Method: A systematic review followed the PRISMA framework, analysing peer-reviewed literature, policy documents, and industry reports from PubMed and Google Scholar (2013-2023). Inclusion criteria focused on studies addressing regulations, safety, or harmonization. Thematic analysis identified trends in regional regulatory approaches.

Results: Key findings illustrate clear divides across jurisdictions EU and Canada prioritize safety via precautionary principles, enforcing strict manufacturing controls and pre-market approvals. US and Asia favour market accessibility, permitting supplements with minimal oversight if labeled correctly. While medicines and medical devices are regulated by established statutory bodies such as the European Medicines Agency in Europe, food supplements are regulated haphazardly. The Food Drug Agency in the US takes a more pragmatic approach. Community pharmacists are in a position to guide patients in rationale and appropriate informed selection of food supplements.

Conclusion: Global regulatory misalignment in food supplement oversight undermines equity. This study advocates for harmonized standards to balance precautionary safeguards with market flexibility. Collaboration among policymakers, industry leaders, and health authorities is critical to establish unified definitions, testing protocols, and labeling requirements. Such alignment would enhance consumer protection, reduce disparities, and support sustainable market growth. While challenges like jurisdictional resistance persist, cohesive international efforts can bridge gaps, ensuring supplements meet consistent safety benchmarks without stifling accessibility or innovation.

Extended stability evaluation of dexrazoxane solutions: implications for prolonged clinical administration

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Introduction: Dexrazoxane, a cardioprotective adjunct in oncology, is clinically employed to mitigate anthracycline-induced cardiotoxicity. Currently, five manufacturers have obtained regulatory approval for dexrazoxane injections in China. However, stringent usage window (≤4-hour, diluted in sodium lactate Ringer's solution or 0.9% NaCl) imposes significant operational constraints. This limitation persists despite centralized preparation through Pharmacy Intravenous Admixture Services (PIVAS), necessitating evidence-based protocol revisions. This study combines physicochemical properties with pharmacokinetic parameters to systematically evaluate the stability of dexrazoxane solution, and establish scientific rationale for extending clinical usage windows.

Methods: Dexrazoxane solutions were prepared according to manufacturer guidelines and stored in infusion bags under two conditions: ambient temperature (25 ±2 °C) and refrigeration (4 ±2 °C) for 24 hours. Throughout the observation period, solutions were monitored for changes in appearance, pH, particulate matter, and concentration using visual inspection, a pH meter, a particle analyzer, and high-performance liquid chromatography at various intervals. Triplicate samples were analyzed to ensure statistical robustness. A liquid chromatography-tandem mass spectrometry method was established to quantify dexrazoxane and doxorubicin in plasma. Pharmacokinetic parameters were compared in Sprague-Dawley rats (n=6) administered fresh versus 12-hour refrigerated dexrazoxane solutions, combined with doxorubicin at clinically translatable doses.