

Abstract

Preparation of Nortriptyline Mouthwash and Investigation of Its Microbial Resistance for Use in Oral Mucositis Caused by Radiotherapy or Chemotherapy.

Background and objectives: Oral mucositis as a complication has posed significant challenges to the quality of life of cancer patients. Tricyclic antidepressants, including nortriptyline can control the pain caused by mucositis by inhibiting sodium channels. Since the mouthwash is designed for people with mucositis, the mouthwash must be free of bacteria and mold/yeast. The convenience of use and the correct observation of the medicinal effect by stabilizing the concentration of the drug within 28 days are among the goals of the proposed formulation, it was decided to prepare and evaluate a nortriptyline mouthwash according to the United States Pharmacopeia.

Methods: Based on the pharmacopeia, the necessary excipients in the nortriptyline mouthwash were determined, and the amount of each was specified. After validating UV spectrophotometric technique, drug interaction with the mouthwash container was investigated. In addition to measuring the aqueous activity, necessary microbiological tests were also performed.

Results: The UV spectroscopy method validation for nortriptyline was performed at the obtained maximum absorption wavelength (238 nm). The findings of the investigation of the interaction of polyethylene terephthalate container with nortriptyline indicate almost no drug adsorption into the internal part of the mouthwash container in 28 days. The results of antibacterial and antifungal/antimycotic tests were within the standard range of the United States Pharmacopeia. The mouthwash's aqueous activity was also found to be 0.81, indicating an unfavorable environment for microbial growth.

Conclusion: This study has shown that the prepared nortriptyline mouthwash meets microbiological resistance standards and there is no interaction between the active drug ingredient and the proposed container. Therefore, this formulation can be suggested as a promising candidate for clinical exploration.

Keywords: Mouthwash, Nortriptyline, Mucositis, Microbial resistance, Validation