

ABSTRACT BOOK

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Contemporary Pharmacy: Issues, Challenges and Expectations 2024

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Contemporary Pharmacy: Issues, Challenges and Expectations 2024

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Synthesis of Xylometazoline Suitable for Lipophilic Dosage Forms

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Background. Xylometazoline hydrochloride has been used in the EU in the treatment of nasal congestion caused by rhinitis/sinusitis since 1959 (1). One of its side effects is dryness of the nasal mucosa. However, it can be used in combination with essential oils to eliminate nasal dryness.

Xylometazoline hydrochloride is hydrophilic and practically insoluble in non-polar solvents. However, xylometazoline base is a lipophilic molecule, which makes it possible to create a formulation with essential oils.

Aim: method of obtaining xylometazoline base for further development of formulations in combination with essential oils.

Methods: xylometazoline hydrochloride, which is commercially available, and aqueous sodium hydroxide solution were used to prepare xylometazoline base.

Results: xylometazoline base was obtained with a yield of about 89% of the theoretical yield. The chlorides content was less than 200 ppm, which indicates the completion of the neutralization reaction. The solubility of the obtained base in water was studied. The analysis showed that the obtained product is practically insoluble in water, which indicates the formation of a lipophilic xylometazoline form after removal of the chloride ion. The optimal time mode for drying the free base was selected, which does not lead to degradation of the product and the formation of impurities. The drying temperature was 25–30 °C. Analysis of the substance by liquid chromatography showed the absence of related substances at the limit of detection (less than 0.005%).

Thus, a method for obtaining a lipophilic form of xylometazoline, suitable for use in formulations in combination with essential oils, was developed.

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