

STUDY OF STABILITY OF TWO LIQUID FORMULATIONS OF OMEPRAZOLE ELABORATED IN THE PHARMACEUTICAL SERVICE

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BACKGROUND: As many medicines are not available for paediatric use they have to be elaborated in the pharmacy service. Generally there are different formulations described in the bibliography.

PURPOSE: To compare two liquid formulations of omeprazole elaborated in the pharmacy service of a tertiary hospital evaluating physicochemical stability and organoleptic characteristics (OC) with the aim of defining what the most ideal formulation is.

MATERIAL AND METHODS: A bibliographic check of the different formulations of omeprazole carried out and two liquid magistral preparation were elaborated in triplicate.

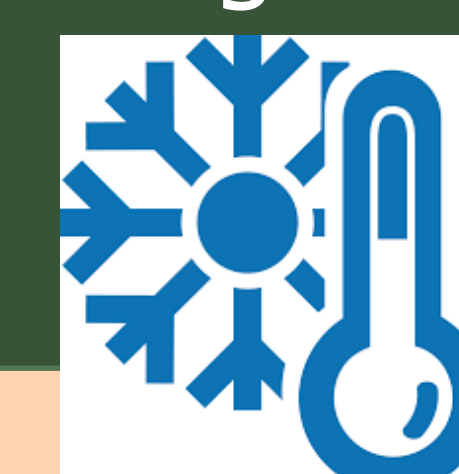
FORMULATION 1

omeprazole monohydrate salt, using as excipients: simple syrup, mixture conservans and purified water

FORMULATION 2

omeprazole capsules using bicarbonate 1M as excipient

Conditions of refrigeration and of light protection were established.



As an indicator of physicochemical stability the pH was selected. For its determination a pH measurer, Mettler Toledo SevenMulti™ was used.

The data was analyzed using an Excel® 2010 spreadsheet.

The results were expressed as average ± standart deviation. Also OC (colour, smell and taste) were evaluated, as well as homogeneity of the formulations.

30 days was established as a period of study. The determinations were carried out the days 0, 10, 17, 24 and 30 post elaboration.

RESULT:

The pH was stable with barely any oscillations during the period of study.



The homogeneity of the formulations remained stable. The OC fluctuated significantly during the period of study.

PH	SAMPLE 1	SAMPLE 2	SAMPLE 3
FORMULATION 1	8.476 ± 0.012	8.544 ± 0.01	8.547 ± 0.018
FORMULATION 2	6.777 ± 0.026	6.373 ± 0.005	6.382 ± 0.003

Formulation 1

- The colour of evolved from amber and opaque to dark brown
- The smell evolved from sweet to metallic
- The taste (bitter-sweet) remained stable

Formulation 2

- Opaque white colour and the disagreeable metallic smell remained unchanged
- The taste changed, going from very bitter to salty

CONCLUSION: In both formulations the pH remained stable.

The formulation based on raw material presents significant changes OC mainly in colour. With regard to the formulation whose elaboration is made from capsules, the OC remain more stable.

As a result of this, it was decided to establish formulation 2 as a preferential formula in spite of its more disagreeable taste.



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