

L04 - MAGISTRAL FORMULATION FOR A PATIENT WITH MULTIPLE FOOD ALLERGY

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BACKGROUND

There are 8 group of food allergies which all have to be checked on their use in medicines. **Multiple food allergy (MFA)** in severe stage is a pathology with nutritional and pharmacotherapeutic restrictions. It is a current practical challenge to substitute allergen-free medicines unsuitable complex vehicles. The patient's intolerance to marketed medicines and thus, the lack of alternatives lead us to have recur to Magistral Formulation.



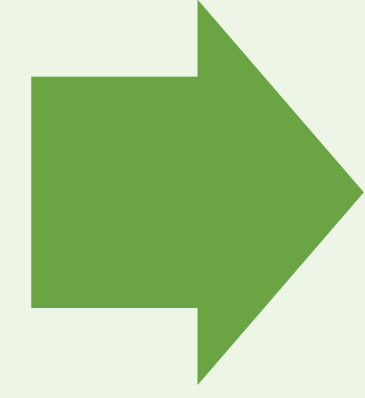
PURPOSE

To compound oral liquid formulations of iron, zinc and sirolimus by eliminating all the preservatives, antioxidants, colourings and flavourings, and evaluate their use in a paediatric patient with MFA.

MATERIAL AND METHODS

Literature review including:

- Physicochemical characteristics of the active principles.
- Compounding magistral formulations described.



Comparison between the commercialized drugs and simple syrups.



Efficacy was evaluated by clinical monitoring since patient's birth in 2017.

RESULTS



According to our bibliographic review, the three active principles were formulated with an adjuvant-free vehicle:

64% preservative-free simple syrup (PFSS).

Sirolimus 0,5mg/ml oral suspension:

Sirolimus in 1% preservative-free carboxymethylcellulose and PFSS. It was compounded using as pattern the formulation of tacrolimus suspension, based on molecular similarities.



Zinc 5mg/ml oral solution:

Zinc acetate dihydrate in sterile water 20% and diluted PFSS, based on the formulations existent. We used the best tolerated salt.

Iron 30mg/ml oral solution:

Ferrous sulfate heptahydrate in sterile water 20% and diluted PFSS. We chose the salt with the highest absorption and solubility.



A period of validity of 30 days in refrigerated amber glass was considered.



Quality controls

- Solutions showed clarity and absence of precipitates and the suspension, redispersibility and homogeneity after stirring.
- The organoleptic characteristics were not optimal for the taste.
- The results of microbiological controls were negative.

Clinical efficacy

- Zinc and iron deficiency were corrected and the blood levels of sirolimus were within the adequate range.
- Currently, the patient continues in treatment and an exhaustive follow-up is being carried out.

CONCLUSIONS

- ✓ Our oral liquid formulations was appropriate for the pathology of our patient and contribute to his growth and health.
- ✓ The comprehensive pharmaceutical care and an individualized compounding for the MFA was essential.

