3PC-022: DESIGN AND STABILITY STUDY OF AN ISONIAZID AND PYRIDOXINE ORAL LIQUID FORMULATION

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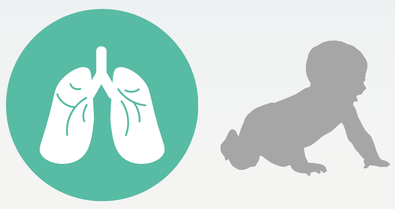
Background and importance

Infant <u>**tuberculosis treatment**</u> is a **combined therapy**, which entails two main issues:

- **Commercialized pediatric presentations scarcity**.
- **Inadequate adherence**.



Isoniazid is indicated as a front-line treatment. In order to prevent isoniazid's induced peripheral neuropathy, **pyridoxine** should be supplemented.

Aim and objectives

To develop and study the **physicochemical and microbiological stability** of a combined isoniazid+pyridoxine oral liquid formulation

Materials and Methods

<u>Literature search</u>: Pharmacopeia, The National Formulary, scientific literature and Methodological Guidelines for non-sterile products.

Physical study
- Organoleptic characters
- Clarity and degree of opalescence
- pH: pH-goal ≈ 5

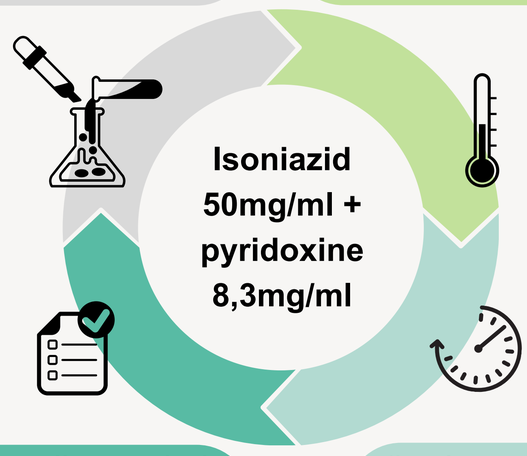
Microbiological study
- Aerobic microbial <10^3UFC/ml
- Yeasts/moulds <10^2 UFC/ml
- Absence *E.coli*/ml

Chemical study
- HPLC analysis and method validation
- Acceptable purity limit: 90-110%

Results

Aqua conservans 70%-liquid sorbitol

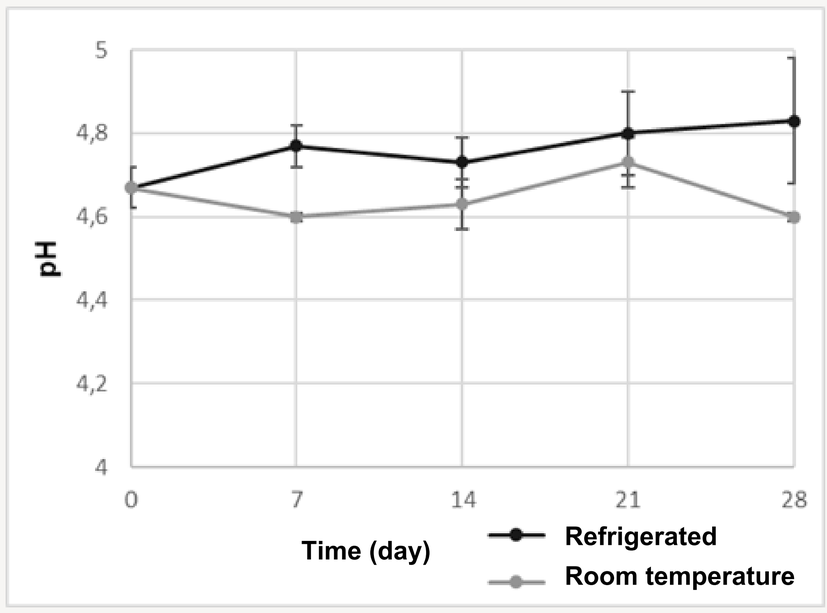
Room and refrigerated temperature



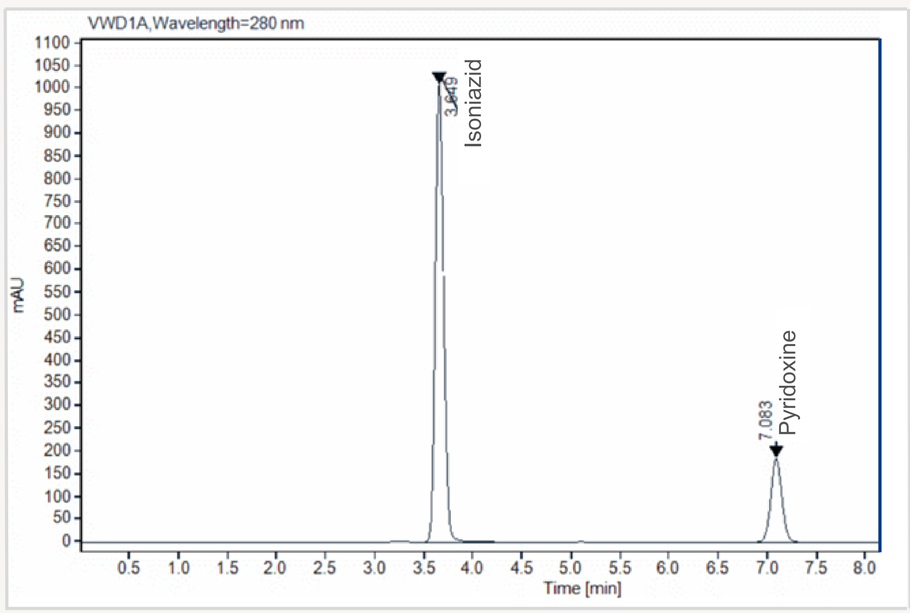
Sampling period: 0,7,14,21,28 days

Study period: 28 days

pH mean and standard deviation



HPLC chromatogram



- **Room temperature** samples got **darker, bitter and slightly acidified**.
- All samples maintained **microbiological stability**.
- The validated method was: **selective, linear, precise (CV<2%) and accurate (recovery 98-102%)**.

Conclusion and relevance

- Isoniazid and pyridoxine oral liquid formulation was <u>**physicochemical and microbiological stable stored at refrigerated conditions for 28 days**</u>.
- The proposed analytical method was viable to <u>simultaneously determine two different active ingredients</u>.
- It provides a <u>reliable solution to enhance therapeutic adherence of children.</u>

Chemical stability study of isoniazid+pyridoxine