



## Design and stability study of a paediatric oral solution of methotrexate 2mg/ml

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Oral paediatric forms development by pharmaceutical industry is still insufficient. The present study was performed to propose an adapted and pleasant formulation of liquid oral formulation of MTX. The solution is composed of injectable methotrexate, water, Ora Sweet(®) and sodium bicarbonate. After 120 days storage, pH remained stable at about 8 in all formulations, insuring no risk of MTX precipitation. MTX content in solution formulation, determined by high performance liquid chromatography measurements, remained in the specifications of >90% of the initial concentration when stored at 4 and 25°C. Forced degradation of MTX by heat and acidic conditions allowed formation and detection of degradation products by the analytical method. Microbial study of the preparation shows that the solution remains in the specifications during all the storage, or after one sample each week during one month, eventually indicating the microbial properties are not affected by patient use. To conclude, we here propose a new MTX liquid formulation stable for at least 120 days.

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### Liens

- [1] [http://okina.univ-angers.fr/publications?f\[author\]=10465](http://okina.univ-angers.fr/publications?f[author]=10465)
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