



Stability of magistral prepared pantoprazole syrups as appropriate pharmaceutical dosage forms for use in the pediatric population

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There are no authorized pantoprazole formulations suitable for all pediatric populations on the drug market of the Republic of Serbia. The solution in such situations is magistral preparation of medicines, which need to be constantly improved and stability studies carried out.

The aim of this work is to make pantoprazole syrups in different vehicles and to examine their stability during 28 days, under different storage conditions.

Formulation vehicles were selected based on data from the USP Pharmacopoeia and the German Drug Codex (DAC). A commercially available syrup base was also used. The content was determined by high performance liquid chromatography (HPLC). Additionally, changes in organoleptic properties and pH values were noticed. The syrups were stored at room temperature and in the refrigerator.

Components	F1 (USP)*				F2 (DAC)**				F3 (Syrspend)
	pH 8,4		pH 4,5		pH 8,4		pH 6,5		
Pantoprazole	200 mg	200 mg	200 mg	200 mg	200 mg	200 mg	200 mg	200 mg	200 mg
Xanthan gum	0,05g	0,05g	0,05g	0,05g					
Glycerol	10 ml	10 ml	10 ml	10 ml					
Sorbitol solution 70%	25 ml	25 ml	25 ml	25 ml					
Saccharine	2 tbl	2 tbl	2 tbl	2 tbl					
HEC					0,5g	0,5g	0,5g	0,5g	
Glucose					11,0g	11,0g	11,0g	11,0g	
K-sorbate				0,1g				0,14g	
Methyl paraben		0,1g		0,1g		0,1g			
Citric acid			1,5g	1,5g			0,07g	0,07g	
Na-citrate			2,0g	2,0g					
Na-bicarbonate	8,4g	8,4g			8,4g	8,4g			
Syrspend® syrup base									100 ml
Purified water	ad 100 ml	ad 100 ml	ad 100 ml	ad 100 ml	ad 100 g	ad 100 g	ad 100 g	ad 100 g	



The chemical stability of magistral prepared syrups is in direct correlation with the pH value of the preparation. At low pH values, the greatest change occurs over time, both in terms of organoleptic properties and in terms of content. The presence of carbonate in the formulation leads to less degradation of pantoprazole. Additionally, storage at refrigerator temperature leads to less degradation of the active substance. The use of preservatives is associated with a smaller change in the color of the preparation, but at the same time with a greater reduction in content.

Of all the magistral prepared pantoprazole syrups tested, the best properties of chemical stability were shown by the formulation that had in composition: bicarbonates for adjusting the pH value, xanthan gum and hydroxyethyl cellulose to improve viscosity and did not contain a preservative. The preferred storage temperature is 2-8 °C.