COMPOUNDING PREPARATION SYRUPS AND THEIR STANDARDISATION

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Compounding pharmacists around the world are faced with the demand for a novel pediatric preparation. The manufactured market of medicines in Ukraine for pediatric patients is smaller than market for adults. Most of the medicines for treatment of children have not been clinically studied in the pediatric population. In this case, extemporaneously prepared medicines with new effective active ingredients can help to meet the unique needs of the pediatric patient. Infants and children prefer sweet tastes and do not want to take the bitter preparations. Extemporaneously prepared syrups are promising dosage forms for use in pediatrics.

Syrups are thick, clear liquid, containing one or more active substances dissolved in water, usually sugars or sweeteners. Syrups are used for dissolving, suspending or emulsifying of the active pharmaceutical ingredients, appropriate medicinal forms formation, for easy use and dosage to give a pleasant taste and aroma. Usually, sucrose, glucose, fructose, aspartame, saccharin etc. are used for preparation of syrups bases. For preparation of complex syrups bases other agents are used as dextrose, sorbitol, mannitol, xylose.

There are no official flavored/sweetened vehicles for compounding preparations in the State Pharmacopoeia of Ukraine, but list of them are given in USP/NF. For example: sorbitol solution is a water solution containing D-sorbitol; suspension structured vehicle contains potassium sorbate, xanthan gum, anhydrous citric acid, sucrose, and purified water; sugar-free suspension structured vehicle contains xanthan gum, saccharin sodium, potassium sorbate, citric acid, sorbitol, mannitol, glycerin, and purified water; simple syrup contains sucrose and purified water and others. The main questions for compounding pharmacies are standardization and proving of stability of vehicles which prepared for stock and after preparation of the dosage form. Presumably all of these vehicles are generally self-preserving as long as the sugars concentration is maintained at a sufficiently high level. But in spite of this, pharmacists need with documented stability studies to prove the terms and conditions of storage for the possibility of syrups stock preparation and further use when compounding. The evaluation should include appearance, clarity for solutions, color, odor, assay, degradation products, pH, viscosity, preservative content, and microbial limits.