PP-009 -"IMPLEMENTING APPROPRIATE COMPOUNDED PEDIATRIC CHLORAL HYDRATE RECTAL DOSAGE FORM"

T. Dimitrovska Manojlovik,[1] D. Trombeva [2]

1.Clinical hospital-Bitola, Hospital pharmacy-Drug information centre, Bitola, R. Macedonia,
2.Clinical hospital-Bitola, Control and analytical laboratory at the Department for infusion solutions production, Bitola, R. Macedonia,

CLINICAL HOSPITAL BITOLA

BACKGROUND:

The demand for unlicensed medicines tends to increase, as the pharmaceutical industry does not supply drugs for all special needs and/or for small patients groups.Beside that no commercial products containing chloral hydrate are available in our country pediatricians have increased request for oral and parentheral dosage forms.Faccing that problem we approached of compounding rectal drug containing chloral hydrate for off-label, unlicensed and rutine use in pediatric procedures.

PURPOSE:

To develop appropriate and stabile chloral hydrate compounded formulation for rectal pediatric use.

METHODS:

Three batches of 10% rectal emulsion were prepared and packed in glass and plastic bottles too.Before dispensing to the pediatric ward quantitative analysis (Chemical tests and assays, USP 31.Ed) of the chloral hydrate content in each batch was performed.After the analysis, the glass-bottle packed preparatons were dispensed to the ward.The plastic-bottle packed preparations were stored in dark place of our pharmacy at the room temperature (cca. 25°C) and kept for at least 3 months.We are still keeping them for further investigation of their stability and shelf life.Stability was defined as containment of at least of 95% of initial concentration of chloral hydrate and absence of visible particles or/and colour and/or odour changes.Test samples were taken in the same time from preparations used on the wards and from those kept in our pharmacy and quantitative analysis of the chloral hydrate content were done.Ingredients used for compounding of these medicines were:Chloral hydrate (Sigma - Aldrich Chemie GmbH,Germany,Ph.Eur.BP), EMPROVE® Exp.Gummi arabicum (Merck KGaA, Germany,Ph,Eur,.BP) and Aqua sterillisata (Department for infusion solutions production in our hospital, Ph,Eur).Determination (according USP 31.Ed, Chemical tests and assays) of the chloral hydrate content as well as the testing of the physical properties-colour and odour were done at the Control and analytical laboratory at the Department for infusion solutions production in our hospital.

RESULTS:

Quantitative examinations of chloral hydrate in the series of samples on the same day of the production indicated that the average content (≥99.7 %) of the active substance was in the rank of declared concentrations.The average concentrations in all test samples after 3 months of keeping or/and using (on the wards) were higher than 95% of initial chloral hydrate concentrations that indicate no significant loss of chloral hydrate.There was no presence of visible particles nor changes of colour and/or odour in none of the test samples.

CONCLUSIONS:

In the hospital pharmacy of the Clinical hospital in Bitola we developed appropriate compounded formula and producing process for 10% Chloral hydrate rectal emulsion (for enema) that can be used at least 90 days.

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