THE POLYVINYLPYRROLIDONE CONTENT CONTROL IN DRUGS AND BIOLIQUIDS

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SUMMARY

The spectrophotometric method of determination of polyvinylpyrrolidone (PVP) with using of organic dyes brilliant yellow (BY) and bromophenol blue (BPB) is elaborated for the content control of PVP in medicinal object. The method has been tasted for determination of PVP in Haemodesum - N and also in urine. The error of determination is less than 4%.

KEY WORDS: polyvinylpyrrolidone, Haemodesum-N, spectrophotometry

INTRODUCTION

The water-soluble polymers take significant role in medical chemistry. Polyvinylpyrrolidone presents special interest. PVP is used as a component of preparations with desintoxicational and prolongational actions and also as a pellet extender and in other forms for per-oral application and therefore it necessity to elaborate the method of its determination in medical samples [1]. For quantitatively determination of PVP in clinic practice there are following methods: by precipitation of trichlorine acetic acid with following determination of nitrogen in sediment [2,3]; by spectrophotometry with formation of brown-red complex with iodine [4,5] or with a kongo red dye [6]. The methods mentioned above give certain results in those cases when solutions in which polymer is determined do not contain a protein. The results of analysis of PVP in an urine or a blood plasma are distorted. In these cases before analysis a protein needs precipitating. This operation leads to lowered results because protein is eliminated with some PVP.

MATERIALS AND METHODS

The initial 4,0 10⁻⁴ moll/l solutions of brilliant yellow and bromophenol blue dyes used were of analytical grade. The initial concentration of the PVP water solution constituted 1,0 10⁻² moll/l (M_{tPVP}=8,0·10³). The using solutions were prepared by diluting initial ones. The chloroform was spectroscopic grade. The necessary acid of environment was prepared by NaOH and H₂SO₄ solutions. The other reagents were of analytical

grade. The spectra were recorded by using spectrophotometer SF-16 and Specord M-40, pH was controlling by a glass electrod ESL-6307 on ionometr EB-74.

RESULTS AND DESCUSSION

Adding of PVP into dye-soluble system influence on the spectrum characteristics. This influence depends upon both a concentration and molecular mass of PVP. The interaction of PVP with bromophenol blue in a slight polar solvents, where the dye is in a sulfon form, leads to coloring of solution, which is familiar to HR form of reagent and this allowed to elaborate of method for determination of a polymer in bioliquids. PVP previously extracted from the urine with using of water solution of chloroform shaking with adding (NH₄)₂ SO₄ during 20 minutes for quantity transfering PVP in organic faze. Then an organic faze is being separated the dye prepared in chloroform is being added and an optical density of solution is being measured for 420 nm with respect of blank solution.

Rightness of determination was controlled by the way of adding of polymer into the urine. Given method of determination of polymer do not require separating of protein that allows to determine quantitatively content of polymer in bioliquid.

A method has been elaborated for PVP determination by using of brilliant yellow (BY) dye. The chemical - analytical characteristics of brilliant yellow and its adduct (BY+PVP) are given in the Table 1.

Table 1
The chemical-analytical characteristics of brilliant yellow and its adduct with polyvinylpyrrolidone

Reagent's form	$\lambda_{ ext{mass}}$	$\lambda_{ m add}$	рK	pH _{1/2}	Δλ	$\Delta pH_{1/2}$	composi- tion BY:PVP
$(\mathbf{H_2}^{T}\mathbf{R}^{T})_2$	400	420	0,89	-0,15	20	1,04	4:1
(HR ⁻) ₂	485	520	8,93	8,25	35	0,68	-

The optimal conditions for adduct formation are: pH10,0 -12,0 brilliant yellow concentration $2 \cdot 10^{-5}$ moll/l. The Beer's law is abided when

polyvinylpyrrolidone is in interval of (8-88)mkg/ml molar absorbtivity is equal to 8,4·10⁴ for $M_{PVP}=8.10^{\circ}$.

Adding of PVP to BY solution causes absorption maximums shifting into long-wave region. pH_{1/2} of adduct formation is also shifted in more acid range in comparison with reagent's pK. PVP concentration influence on $pH_{1/2}$ of adduct formation has been investigated.

Polyvinylpyrrolidone determination in "Haemodesum - N" (n=4, p=0,95)

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mg/l	x±Δx	$\mathbf{S_r}$
11.0	10.6 ± 0.7	0.04
14.0	13.6 ± 0.7	0.03
20.5	19.8 ± 1.3	0.04

34.6 ± 1.4 35.4

The adduct polyvinylpyrrolidone - brilliant vellow formed in the alkali region is used for spectrophotometric determination of PVP.

The elaborated method for polyvinylpyrrolidetermination has been tested in "Haemodesum - N" (Table 2).

CONCLUSION

The elaborating method for determination of PVP with using of a bromophenol blue in a chloroform allows to determine a true contain of polymer in bioliquid without preliminary separation of protein. The using of PVP - BPB complex give possibility to increase a sensibility of determination and to decrease the limit of revealing of polymer. A relative standard deflection for determination of PVP in Haemodesum - N and bioliquid is less than 0,04.

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КОНТРОЛЬ ВМІСТУ ПОЛІВІНІЛПІРРОЛІДОНУ В ЛІКАРСЬКИХ ПРЕПАРАТАХ ТА БІОЛОГІЧНИХ РІДИНАХ

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РЕЗЮМЕ

Для використання в медицині розроблено спектрофотометрична методика визначення вмісту полівінілпірролідону (ПВП) із застосуванням органічного барвника діамантового жовтого (ДЖ) або бромфенолового синього (БФС). Метод випробуваний при визначенні вмісту ПВП в Гмодезі-Н та сечі. Помилка методики склала менше 4%.

КЛЮЧОВІ СЛОВА: полівінілпірролідон, Гемодез-Н, спектрофотометрія

СОДЕРЖАНИЯ ПОЛИВИНИЛПИРРОЛИДОНА КОНТРОЛЬ **ЛЕКАРСТВЕННЫХ** ПРЕПАРАТАХ И БИОЛОГИЧЕСКИХ ЖИДКОСТЯХ

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РЕЗЮМЕ

Для применения в медицине разработан спектрофотометрическая методика определения поливинилпирролидона (ПВП) с применением органического красителя бриллиантового желтого (БЖ) или бромфенолового синего (БФС). Метод апробирован при $\,$ определении содержания ПВП в Гемодезе-H и моче. Ошибка методики составила менее $\,$ 4%.

КЛЮЧЕВЫЕ СЛОВА: поливинилпирролидон, гемодез-Н, спектрофотометрия