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FORMULATION AND STABILITY OF HEPTAMINOL SUPPOSITORIES

PART I: Comparative stability of Heptaminol base and Heptaminol hydrochloride

Ali A. Kassem, Mohamed F. El-Miligi, & Siham A. Ali
Department of Pharmaceutics, Faculty of Pharmacy, Cairo University , Cairo, Egypt.

ABSTRACT

The chemical stability of Heptaminol Base and of Heptaminol hydrochloride was determined after shelf-life storage in an aqueous solution at room temperature. Under these conditions, the Base was found about 10.54 times more stable than the hydrochloride.

INTRODUCTION

Two chemical forms of heptaminol are generally available; namely Heptaminol Base and Heptaminol Hydrochloride[1]. Both forms are water soluble; the base is only slightly so while the hydrochloride is freely soluble[1]. It was, as yet, unpublished, which of the two forms is chemically more stable. Such a property would help to choose the proper form for new formulations.

EXPERIMENTAL

Materials and Apparatus:

1- Pure samples of Heptaminol Base and of Heptaminol Hydrochloride*

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* Adequate samples were kindly supplied by SWISSPHARMA S.A.A., Cairo, Egypt, free of charge.

2- Pharmacopoeial grades of Chloroform, Sodium Hydroxide, Glacial Acetic Acid, Mercuric Acetate, and Perchloric Acid.

3- Potentiometer, PYE-Unicam, Model 290 MK.

Methods:

Heptaminol Base, 15 g., were dissolved in 100.0 ml of distilled water and the solution was filled in 2-ml. ampoules and sealed. A similar solution of Heptaminol Hydrochloride in water, 5 per cent w/v, was also prepared but filled in 5-ml. ampoules for ease of designation during this study. Sets of about 50 ampoules of each group were stored on the shelf at room temperature protected from direct sunlight . At suitable intervals, samples were removed for chemical assay by non-aqueous titration[2,3], and the results are compiled in Tables 1 and 2 .

DISCUSSION

From the present work, it is quite obvious that Heptaminol Base is by far more stable than its hydrochloride. This observation is based on examination of their aqueous solutions stored at room temperature for periods of 476 and 580 days for the Base and the Hydrochloride, respectively. However , under the present conditions, the half-life periods for the Base and its salt were calculated to be 2432.7 and 230.7 days, respectively. This means that the Base is about 10.54 times more stable than the Hydrochloride. By this finding, itis a self-explanatory suggestion to employ the Base form of Heptaminol for new formulations, unless some other properties of the Hydrochloride are seen to overweigh the stability of the medicament.

Table 1: Percentage remained of Heptaminol Base and Heptaminol Hydrochloride in Aqueous solutions kept at room temperature (20° - 35°)

Time intervals (days)	*M E D I C A M E N T*	
	Heptaminol	*Heptaminol Hydrochloride*
0	99.98	99.98
20	98.00	-
27	96.53	-
30	-	98.00
34	94.72	-
56	92.96	-
60	-	92.50
96	-	78.95
125	-	66.51
163	-	57.62
476	79.27	-
580	-	18.17

Table 2: Mathematical and Kinetic data pertinent to the stability study of Heptaminol Base and Heptaminol Hydrochloride in Aqueous solutions at room temperature (20° - 35°).

Medicament	*b(Slope) x 10^{-4}*	*a(y-Intercept)*	*K (Decomposition Coefficient) x 10^{-4}*	*$t_{1/2}$ (days)*	*t_{90} (days)*
Heptaminol	1.237	1.983	2.849	2432.774	369.930
Heptaminol HCl	13.046	2.010	30.045	230.654	35.070

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REFERENCES

1) *SWISSPHARMA S.A.A., Cairo, Egypt, personal communications.*
2) *British Pharmacopoeia, Volume 11, A 89, London (1980).*
3) *A.A.Kassem, M.F. El-Miligi and S.A.Ali; Experimental Evaluation of Heptaminol, in press.*

صياغة وثبات اقماع الهبتامينول

الجزء الاول : مقارنة ثبات قاعدة الهبتامينول وايدروكلوريد الهبتامينول

على على قاسم - محمد فريد المليجى - سهام عبد الحسين على

تم فى هذا البحث تعيين درجة الثبات الكيماوى لمادتى قاعدة الهبتامينول وايدروكلوريد الهبتامينول خلال فترة تخزين على الرف لفترة تتراوح بين خمسة عشر وتسعة عشر شهرا فى محاليل مائية عند درجة حرارة الغرفة . وقد ثبت تحت هذه الظروف ان ثبات قاعدة الهبتامينول يفوق ثبات ايدروكلوريد الهبتامينول بأكثر من عشرة اضعاف ونصف .

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