

FORMULATION AND STABILITY EVALUATION OF ATENOLOL GEL IN TWO DIFFERENT BASES

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ABSTRACT

The aim of the research about atenolol gel is to formulate and evaluate its stability in HPMC and Aqupec HV-505 gel base. The stability testing included organoleptic examination, pH, viscosity, consistency, bleeding, qualitative analysis by Thin-Layer Chromatography (TLC) and quantitative analysis by UV-Visible Spectrophotometry during 56 days of storage. The result showed that the best formula was the one with 1% Aqupec HV-505 base (F_{A2}). Further investigation were conducted by varying Atenolol concentration to know it's influence into gel stability. It included organoleptic examination, pH, viscosity, consistency, bleeding, microbiology, qualitative and quantitative stability testing using Thin-Layer Chromatography (TLC) and UV-Visible Spectrophotometry during 56 days of storage. The result showed that the best gel formula was the one using 1% Aqupec HV-505 with 0,5% Atenolol (F_{A22}). The patch test showed that all atenolol gels were safe to be used.

Key word : Gel, Atenolol, HPMC, Aqupec HV 505.

INTRODUCTION

Atenolol is one of a β - selective adrenergic blocking agent in the treatment of angina pectoris. However, it is reported to be subjected to extensive hepatic first pass effect following oral administration (Ghosh, *et al*, 1994; Aqil,*et.al*, 2006).

Conventional therapy such as orally, may result higher fluctuations in plasma concentration of the drug and unwanted side effect (Bhaskaran S. And Shree, 2000). Hence, the development of transdermal therapeutic system that provides a predetermined constant drug delivery would be beneficial for effective and safe therapy. Kim and Shin (2004) has developed and study the release of Atenolol from the EVA matrix containing various plasticizers (Jin Kim and Shang-Chul Shin, 2004; Cho and Shin, 2004; Gupta and Jain, 2004). The objectives of this study was to formulate and investigate the physical stability of atenolol in two different gel bases.

EXPERIMENTALS

Materials

Atenolol (PT. Kalbe Farma), Ammonia 21%, *Aqupec HV-505* (Sumitomoseika), Aquadest, DMDM Hydantoin, Ethyl acetat, HPMC (*Hydroxypropyl methylcellulose*), Methanol, Nutrien Agar, Propylenglycol, Triethanolamine (TEA).

Atenolol concentration was determined by Spektrophotometry UV-VIS (Specord 200). The pH was measured by pH-meter 744 Methrohm while gel viscosity was measured by Viscotester Rion (VT-04 F)

Methods

Preparation of Gels

1. HPMC Gel samples

The composition of gel formulation shown in Table 1. The HPMC was dispersed with continuous stirring until uniformly dispersed and the solution was allowed to cool to 50°C. The other ingredients were added with continuous stirring. Atenolol dissolved in propylenglycol was added slowly with stirring. Other ingredients were added slowly while stirring until homogenous gel was obtained

2. *Aqupec* HV-505 Gel Samples

Aqupec HV-505 powder was dispersed in hot water while being stirred with a stirrer at 2500 rpm, the gels then were left overnight at ambient temperature. Triethanol amine was added until the clear gel was obtained. Atenolol dissolved in propylenglycol was added slowly with stirring Into solution, the other ingredients were added with continuous stirring.

Physical stability investigation

It was including organoleptic and bleeding investigation., pH and viscosity measurement.

Table 1. Formula of Atenolol Gel

INGREDIENTS	F _A			F _B		
	F _{A1}	F _{A2}	F _{A3}	F _{B1}	F _{B2}	F _{B3}
HPMC (%)	-	-	-	1,50	2,00	2,50
<i>Aqupec HV-505</i> (%)	0,50	1,00	1,50	-	-	-
Atenolol (%)	0,50	0,50	0,50	0,50	0,50	0,50
TEA (%)	1,00	1,75	2,50	1,00	1,00	1,00
Propylen Glycol (%)	25,00	25,00	25,00	25,00	25,00	25,00
Ethyl Acetat (%)	5,00	5,00	5,00	5,00	5,00	5,00
DMDM Hydantoin (%)	0,30	0,30	0,30	0,30	0,30	0,30
Aquadest ad (%)	100,00	100,00	100,00	100,00	100,00	100,00

F_A = Formula gel using *Aqupec HV-505*
 F_{A1} = Formula gel using *Aqupec HV-505* 0,5%
 F_{A2} = Formula gel using *Aqupec HV-505* 1%
 F_{A3} = Formula gel using *Aqupec HV-505* 1,5%
 F_B = Formula gel using basis HPMC
 F_{B1} = Formula gel using HPMC 1,5%
 F_{B2} = Formula gel using HPMC 2%
 F_{B3} = Formula gel using HPMC 2,5%