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Study of Amlodipine Besylate on Acid, Base, Temperature and U.V. Light

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Abstract - The present paper deals the stability of Amlodipine besylate in acidic and basic pH, heat and under UV light. It also plays many important physiological and metabolic roles and has antioxidant properties. Amlodipine besylate 10mg tablets and by making its dilution 25ug/ml we exposed it to acidic and basic condition, heat and u.v light and noted their absorbance at wavelength 237nm. It is found that Amlodipine absorbance decreases in all the above mentioned stress conditions. It is concluded that stability of Amlodipine besylate decreases in acidic and medium. Stability also decreases in heat and u.v sensitive. The spectrophotometric assay of the degraded solutions of ascorbic acid has revealed that heat degrades ascorbic acid more as compared to UV light and alkaline medium.
Keywords - Amlodipine besylate, acid, base, temperature, u.v light

I. INTRODUCTION

Amlodipine besylate (AML), (4R, S)-3-ethyl-5-methyl 2-(2-amino-ethoxy-methyl)-4-(2-chlorophenyl)-1,4-dihydro-6-methyl pyridine-3,5-dicarboxylate mono benzene, sulphonate and it is a potent long-acting Ca channel blocking agent (Figure 1). (Reynolds, 1996) Amlodipine, a charged dihydropyridine-type (DHP) calcium channel blocker (CCB), has been widely used to treat angina and hypertension HT.

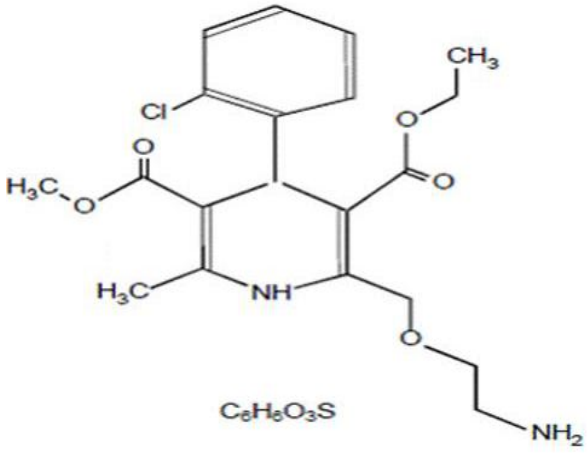

Figure 1: Amlodipine besylate

It is used as an antihypertensive agent and very successfully for treatment of cardiovascular diseases and hypertension (Wang, 2009). Other members of the class include nimodipine, nifedipine, furnidipine, and nitrendipine. Amlodipine and its class members are photosensitive and also labile for degradation in acidic and basic medium as well. These drugs also greatly degraded under thermal stress and hence there therapeutic efficacy declines. (O'Neil, 2001, Abdoh, *et al.* 2004 & Gul, 2015). Literature survey reveals that various analytical methods have been established for the analysis of Amlodipine and many stability indicating methods have also been developed for Amlodipine alone as well as in combination including spectrophotometric (O'Neil, 2001, Khan and Jain, 2006 and Sridar, *et al.* 1997), HPLC, RP-HPLC, HPTLC, GC, HPLC by mass detection, fluorescence detection, amperometric detection and chemometric protocols (O'Neil, 2001, Wankhede, *et al.* 2010; Sahu and Patel, 2007; Beresfor, *et al.* 1987; Feng, *et al.* 2002; Shivkumar, *et al.* 2007; Li Xiaolu, *et al.* 2008; Kishore kumarhotha, *et al.* 2013). Stability studies have also been conducted using different parameters on neat solutions (Mason, *et al.* 1999), pharmaceutical preparations alone and in combination (O'Neil, 2001). Research has been conducted on different drugs which are prone to degrade by different parameters like heat light, acid and base (Shah, *et al.* 2008). Aim of present work to expose Amlodipine to various stress conditions like acid at pH 3.0, base pH 8.5, heat (80°C, on water bath) and U.V light to study the degradation and stability in such force conditions (Jing Jiang, 2015 and Safila

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Naveed, *et al.* 2014; Wajhia and Fatima, 2015 and Wajiha, *et al.* 2015).

II. MATERIALS AND METHODS

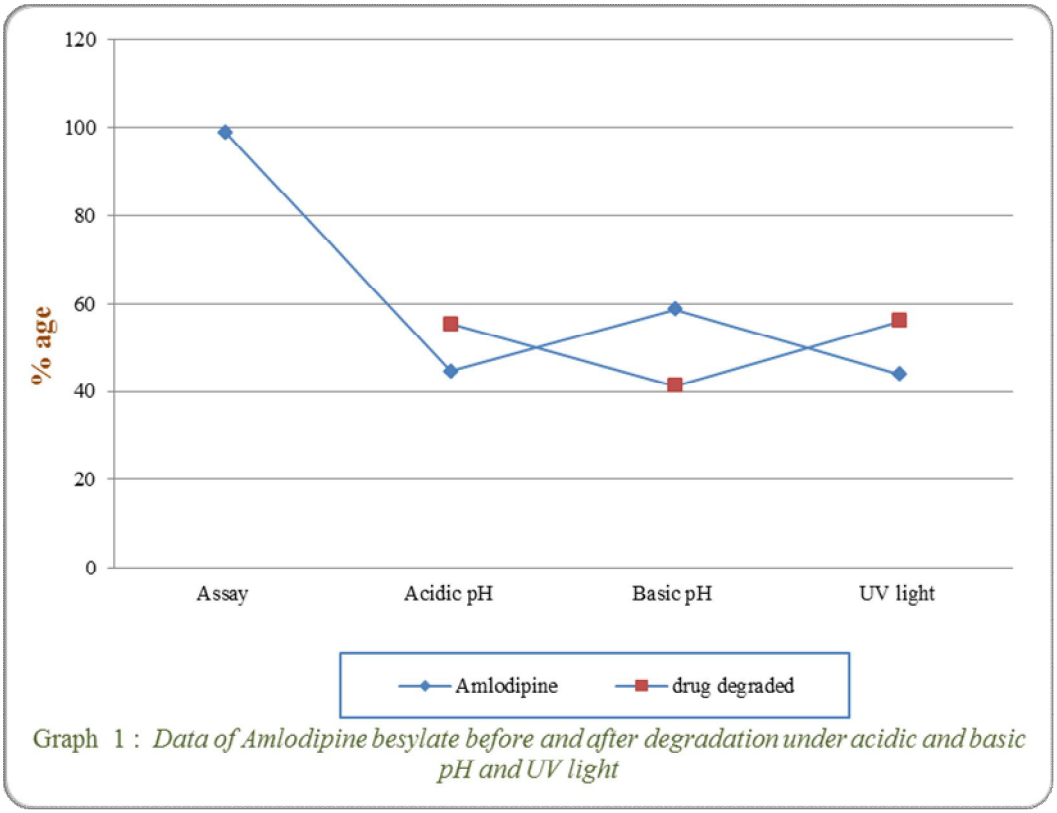
The solution was scanned in the 200-400 nm UV region and the wavelength maxima was observed at 237 nm and that wavelength was adopted for absorbance measurement. 0.1 N HCl and 0.1 N NaOH were prepared in freshly prepared distilled water. To 10 ml of the final solution 0.1 N HCl was added to achieve the pH of 3. Similarly to 10 ml of the final solution enough solution of 0.1 N NaOH was added so as to get the pH of 8.5. to determine the effect of UV light, the solution was placed in the UV light for around 30 mins. Solution was also placed in water bath at 85°C for 60 mins to study the effect of heat on the drug. The absorbance was noted at every 15 mins interval. Absorbances of the neat sample as well as of those exposed to stress conditions were taken on Uv-1600 shimadzu spectrophotometer at 237 wavelength using methanol as a blank.

III. RESULTS AND DISCUSSION

Amlodipine besylate is a potent Ca channel blocker. It is also very effective cholesterol reducing agent. Literature survey showed that various analytical methods have been developed for the analysis of Amlodipine and several stability indicating methods established. It was found that most of the stability related work was regarding method development. Therefore we aimed to observe the effects of different conditions on Amlodipine. Studies have shown that amlodipine besylate can be degraded by the factors like acidic and basic pH, heat and UV light.

Table1. Data of Amlodipine besylate before and after degradation under acidic and basic pH and UV light

Parameters	Amlodipine besylate		% Amlodipine	% drug degraded
	Standard	Sample		
Assay	0.426	0.421	98.82	
Acidic pH	-	0.190	44.60	55.35
Basic pH	-	0.250	58.68	41.33
UV light	-	0.187	43.89	56.14



Graph 1 : *Data of Amlodipine besylate before and after degradation under acidic and basic pH and UV light*

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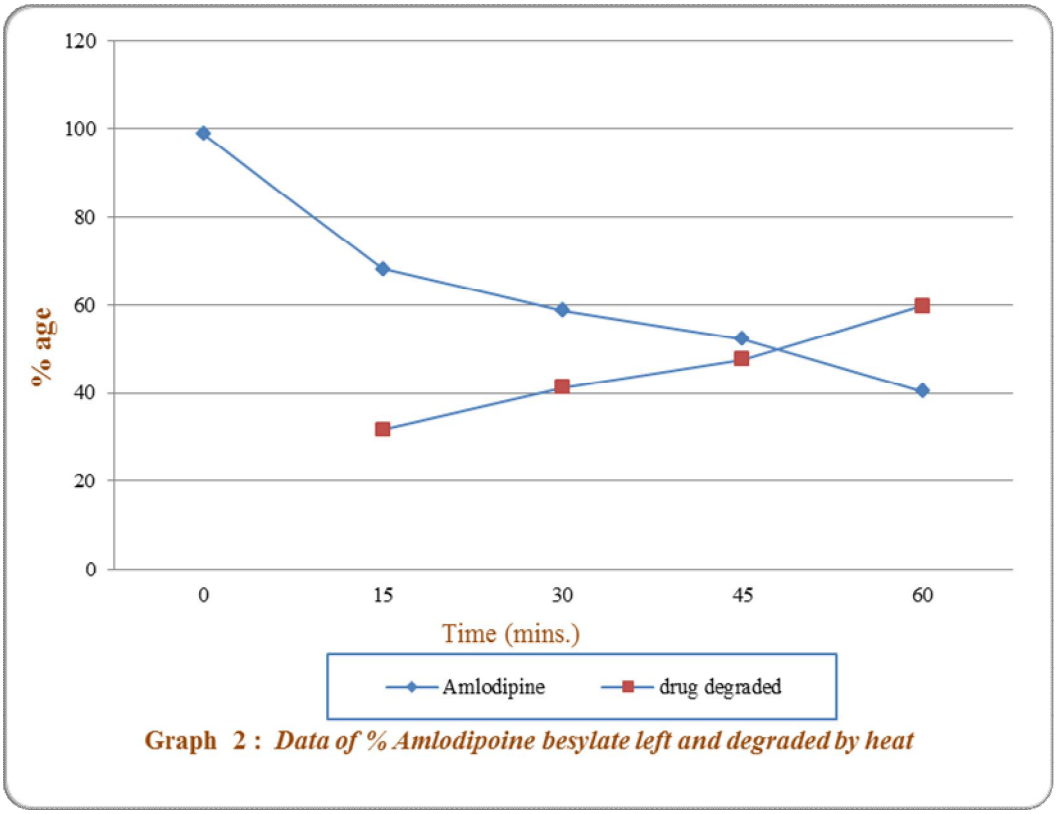
Table 2: Data of % Amlodipoine besylate left and degraded by heat

Time (mins.)	Absorbance	% amlodipine	% drug degraded
0	0.421	98.81	
15	0.290	68.08	31.90
30	0.250	58.67	41.30
45	0.223	52.36	47.63
60	0.172	40.35	59.64



Graph 2 : *Data of % Amlodipoine besylate left and degraded by heat*

The parameters chosen for the degradation of the drug were acidic condition (pH 3), basic condition (pH 8.5), U.V light and heat (water bath, 80°C). The absorbance was found to be decreases of the conditioned samples (Tables 1 & 2 and Graphs 1 & 2). It has been found that acidic pH and UV light degrade amlodipine besylate more and almost equally as compared to the basic pH. The %age of drug degraded by acid and UV light was 55.35 and 56.14 respectively while only 41.33% was degraded by the basic conditions. In case of heat it was observed that the drug is gradually destroyed on continuous exposure to heat. 4 readings were noted after the interval of every 15 mins and the last reading i.e. after 60 mins the percentage of the degraded drug was 59.64%.

IV. CONCLUSION

It was used to study the stress degradation studies as per ICH guidelines. Amlodipine was found to be degraded in almost all types of stress conditions and was found to be less stable. Thus above results clearly shows that Amlodipine is greatly affected by all above conditions and it is degraded, therefore its absorbance decreases which support the fact that Amlodipine degraded in all the above stress conditions.

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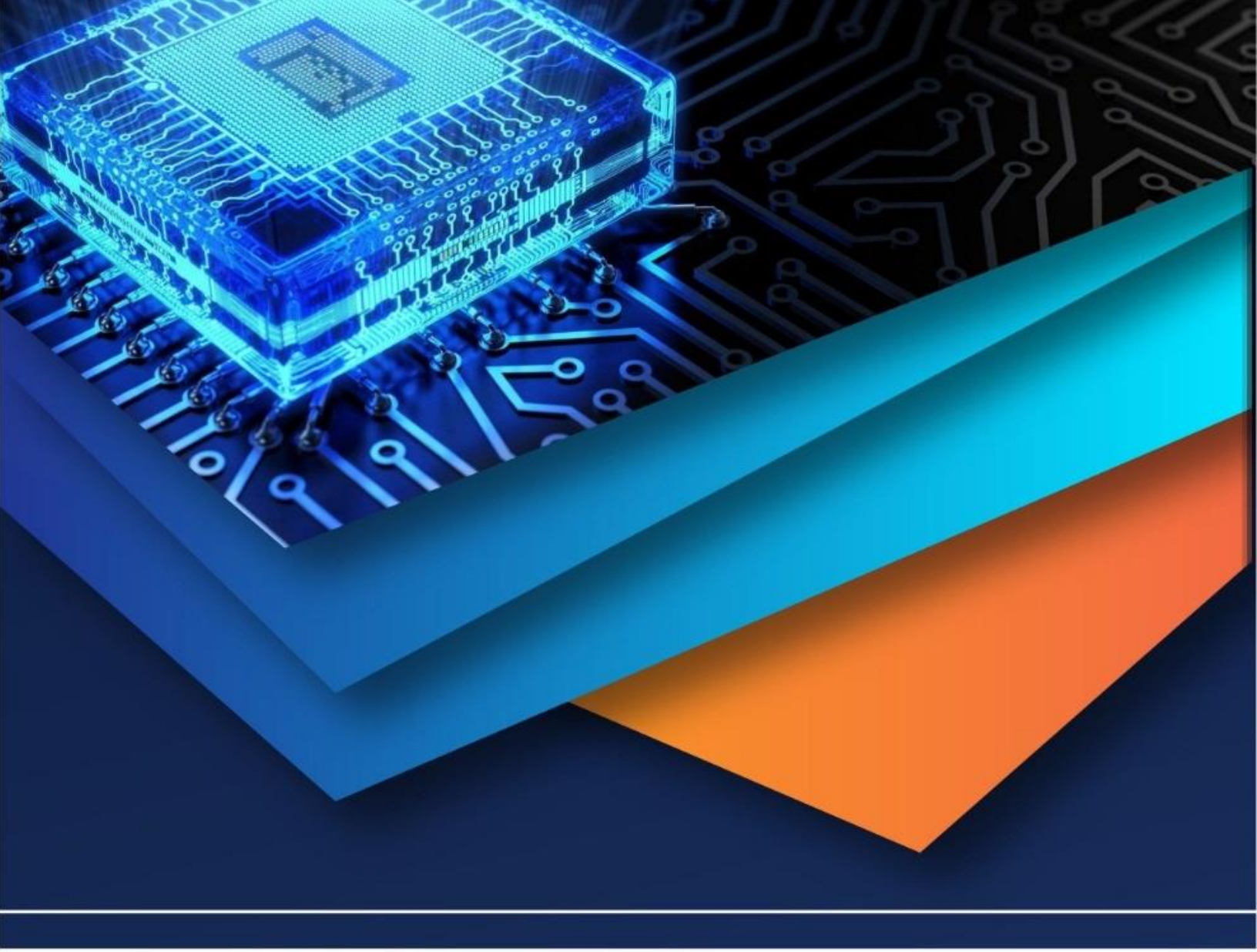

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