

FORCED DEGRADATION STUDY OF EXPIRED AND MARKETED TABLETS OF AMLODIPINE BY RP-HPLC

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Abstract

The stability of pharmaceutical products plays an important role from the economical point of view. There are not many studies that report about the stability of drugs past their expiration dates. The objective of the current study was to determine tablet content and perform dissolution test of expired tablets and tablets where expiry date has not exceeded of Amlodipine besylate and to develop simple, accurate, sensitive and stability indicating RP-HPLC method for the determination of per cent drug remained of Amlodipine besylate in the presence of its degradation products in bulk drug, expired tablets and tablets whose expiry date has not been exceeded. Drug was subjected to different stress conditions No discrepancies between the results of determination and the declared values range for all the analysed tablets were observed. The results of performed study might suggest that storage of analysed batches of tablets over time period exceeding the expiry date given by the manufacturer did not influence their contents.

Materials and Method

Instrumentation:

Perkin Elmer HPLC system consisted of a Perkin Elmer Pump, Perkin Elmer autosampler, a UV Visible detector.

Chromatographic conditions:

Stability indicating HPLC assay method was developed on Perkin Elmer C18, 220 x 4.6 mm, 5 μ m column, using a mobile phase containing Phosphate buffer (50mM) pH 3.5:Methanol:Acetonitrile (30:60:10, v/v/v) at room temperature. The flow rate was maintained 1.5 ml/ min throughout analysis. The analytical wavelength was set at 240 nm.

Method validation:

Validation of developed analytical method was performed as per ICH guideline Q2 B, over the linearity, accuracy, precision, specificity, limit of detection, limit of quantitation and robustness.

Forced degradation studies (stress testing)

1. Drug solution in 0.1 N HCl for 8 hr
2. Solution of drug in 0.1 N NaOH for 8 hr
3. Oxidative study 3% H₂O₂ at ambient conditions for 7 days
4. Photostability test was performed as solid state photostability study.
5. Thermal degradation study

Results and Discussion

Sr.	Condition	Results
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The developed method was extended to marketed and expired tablets of Amlodipine and it was observed that there is almost similar degradation pattern found in case of both and they are less prone to force degradation studies as compared to bulk drug, only exception found in case of humidity study.

There is no considerable change found in % drug remained under various condition of stress studies performed on expired formulation with marketed formulation. This shows that even after 1 year expiry of Amlodipine tablet it's effective and potent too as its per cent estimation under normal condition is 95.97% by UV Spectrophotometry and 97.42% by RP-HPLC method which is within the limit i.e. 90-110% for Amlodipine tablets as per IP.

CONCLUSION:

Based on study, per cent drug remained under stress studies of marketed and 1 year expiry tablet of Amlodipine it can be concluded that if drugs stored under reasonable conditions it can retain 90% of their potency for at least few years after the expiration date on the label, and sometimes much longer. The results of this study, including both: tablet content analysis and estimation of dissolution profiles, might suggest that the storage of analysed batches of tablets containing Amlodipine besylate (Corvadiol® 5mg) over time period exceeding the expiry date given by the manufacturer did not influence their contents.

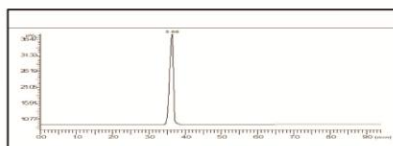


Figure 1: Chromatogram of Pure sample

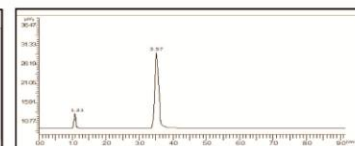


Figure 2: Acid hydrolysis

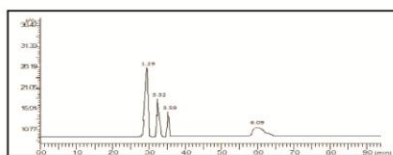


Figure 3: Alkaline hydrolysis

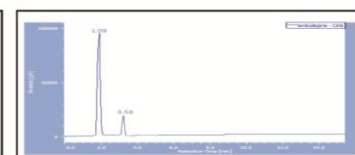


Figure 4: Oxidation of Expired (7 days)

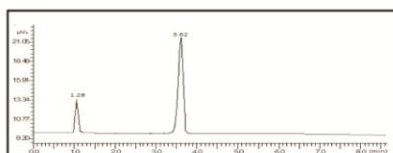


Figure 5: Photostability of Expired (15 days)

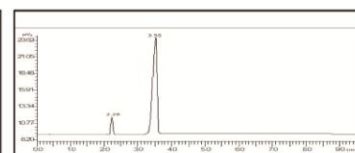


Figure 6: Thermal stability of Expired (90 days)

REFERENCES

1. Kurczewska U. Stability studies of expired tablets of Metoprolol Tartrate and Propranolol hydrochloride. Acta Poloniae Pharmaceutica- Drug Research. 2009;66(6):697-707.
2. Swaroop A P, Varun D. A glimpse on expiry date of