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Stability Study for Captopril 25mg Tablets

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Abstract:

This study was to investigate the physicochemical and microbiological stability of Captopril 25mg tablets, chemical stability and physical parameters as appearance, hardness, friability, water content, dissolution and disintegration time was studied according to the United States Pharmacopeia USP 37 and BP 2015 using fresh samples. The Captopril tablets was chemically, physically and microbiologically stable for not less than 36 months at (30 ± 2)℃.

Key words: Captopril, hardness, friability, dissolution, disintegration, pharmacopeia

INTRODUCTION

Captopril tablet is a specific competitive inhibitor of angiotensin I-converting enzyme (ACE), the enzyme responsible for the conversion of angiotensin I to angiotensin II.

Captopril is a white to off-white crystalline powder that may have a slight sulfurous odor; it is soluble in water (approx.

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160 mg/mL), methanol, and ethanol and sparingly soluble in chloroform and ethyl acetate [1,2].

Captopril is available in potencies of 12.5 mg, 25 mg, 50 mg, and 100 mg as scored tablets for oral administration. The chemical formula of Captopril is $C_9H_{15}NO_3S$ (Figure 1) [1,3].

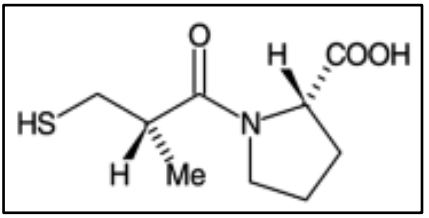

Figure 1. Chemical formula of Captopril ($C_9H_{15}NO_3S$)

MATERIALS AND METHODS

In this study the trade name (Captaman 25mg tablets) was used to investigate for the determination of expiration date. The below apparatus and equipment are used in this study:

1. Electronic balance.
2. Drying oven.
3. Friability tester.
4. Disintegration time tester.
5. Hardness tester.
6. HPLC (High Performance Liquid Chromatography).

The preparation and analysis of Captopril are investigated according to the United States Pharmacopeia USP 37 [4]. The following parameters were studied for the stability of Captopril tablets:

1. Assay of Captopril.
2. Appearance.
3. Hardness.
4. Friability.
5. Water content.
6. Dissolution.
7. Disintegration time.

8. Microbiology.

RESULTS AND DISCUSSION

Assay of Captopril

The data in table (1) express the long term testing at (30 ± 2)°C and (40 ± 2)°C and showed no significant changes and the assay after 36 months from its initial value which was less than 5% of change.

Table 1 Captopril Assay long term testing at (30 ± 2)°C and (40 ± 2)°C

Time (months)	Captopril at 30 °C (%)	Captopril at 40 °C (%)
0	102.3	102.3
3	102.0	101.8
6	101.5	101.3
9	101.1	100.9
12	100.6	100.4
15	100.2	99.9
18	99.7	99.3
21	99.2	98.8
24	98.8	98.5
30	98.3	98.0
36	97.9	97.2
% loss in 36 months	**4.3 %**	**4.9 %**

Appearance

The data in table (2) of the long term testing at (30 ± 2)°C and (40 ± 2)°C showed no chanced in appearance of Captopril tablets during and after 36 months.

Table 2 Appearance test of Captopril tablets for long term testing at (30 ± 2)°C and (40 ± 2)°C

Time (months)	White uncoated tablets (at 30 °C)	White uncoated tablets (at 40 °C)
0	No change	No change
3	No change	No change
6	No change	No change
9	No change	No change
12	No change	No change
15	No change	No change

18	No change	No change
21	No change	No change
24	No change	No change
30	No change	No change
36	No change	No change

Hardness

The hardness test results of uncoated tablets was comply with the test for hardness of tablets and capsules as per BP 2015 (Table 3).

Table 3 Hardness test of Captopril tablets for long term testing at (30 ± 2)°C and (40 ± 2)°C

Time (months)	Uncoated tablets hardness (at 30 °C)	Uncoated tablets hardness (at 40 °C)
0	4.9	4.9
3	4.9	4.9
6	4.9	4.9
9	4.9	4.9
12	4.9	4.9
15	4.9	4.9
18	4.9	4.9
21	4.9	4.9
24	4.9	4.9
30	4.9	5.0
36	5.0	5.0

Friability

The friability test results in table (4) of the long term testing at (30 ± 2)°C and (40 ± 2)°C showed no significant changes in the friability of Captopril tablets.

Table 4 Friability test of Captopril tablets for long term testing at (30 ± 2)°C and (40 ± 2)°C

Time (months)	Friability at 30 °C (%)	Friability at 40 °C (%)
0	0.6	0.6
3	0.6	0.6
6	0.6	0.6
9	0.6	0.6
12	0.6	0.6

15	0.6	0.6
18	0.6	0.6
21	0.6	0.6
24	0.6	0.5
30	0.5	0.5
36	0.5	0.5

Water content

The water content test results in table (5) of the long term testing at (30 ± 2)°C and (40 ± 2)°C showed no significant changes in tests results.

Table 5 Water content test of Captopril tablets for long term testing at (30 ± 2)°C and (40 ± 2)°C

Time (months)	Water content at 30 °C (%)	Water content at 40 °C (%)
0	2.9	2.9
3	2.9	2.9
6	2.9	2.9
9	2.9	2.9
12	2.9	2.9
15	2.9	2.9
18	2.9	2.8
21	2.8	2.8
24	2.8	2.7
30	2.8	2.7
36	2.7	2.7

Dissolution

The dissolution test results in table (6) of the long term testing at (30 ± 2)°C and (40 ± 2)°C showed no significant changes within the 36 months of testing period.

Table 6 Dissolution test of Captopril tablets for long term testing at (30 ± 2)°C and (40 ± 2)°C

Time (months)	Dissolution at 30 °C (%)	Dissolution at 40 °C (%)
0	89	89
3	88	88
6	88	88
9	88	88
12	88	87

15	87	86
18	86	85
21	86	85
24	85	84
30	85	84
36	85	84

According to USP 37 requirements of Captopril tablets not less than 80% of the labeled amount of ($C_9H_{15}NO_3S$) is dissolved in 20 minutes.

Disintegration time

The disintegration time test results in table (7) of the long term testing at (30 ± 2)°C and (40 ± 2)°C express the stability of tablets within the 36 months of testing period.

Table 7 Disintegration time test of Captopril tablets for long term testing at (30 ± 2)°C and (40 ± 2)°C

Time (months)	Disintegration time at 30 °C (min)	Disintegration time at 40 °C (min)
0	11.0	11.0
3	11.0	11.0
6	11.0	11.0
9	11.5	11.5
12	11.5	11.5
15	11.5	11.5
18	11.5	11.5
21	11.5	11.5
24	12.0	12.0
30	12.0	12.0
36	12.0	12.5

Microbial limit test

The data of multiple tube method in table (8) and (9) for aerobic count plate method for molds and yeasts showed comply with USP 37 microbiology tests for tablets.

Table 8 Microbial limit test of Captopril tablets for long term testing at (30 ± 2)°C

Time (months)	Pathogenic	Nonpathogenic (Molds and Yeasts/ml)	Nonpathogenic (Aerobic count/ml)
1	Nil	less than 10	44
3	Nil	less than 10	44
6	Nil	less than 10	44
12	Nil	less than 10	44
18	Nil	less than 10	44
24	Nil	less than 10	44
30	Nil	less than 10	44
36	Nil	less than 10	45

Table 9 Microbial limit test of Captopril tablets for long term testing at (40 ± 2)°C

Time (months)	Pathogenic	Nonpathogenic (Molds and Yeasts/ml)	Nonpathogenic (Aerobic count/ml)
1	Nil	less than 10	44
3	Nil	less than 10	44
6	Nil	less than 10	44
12	Nil	less than 10	44
18	Nil	less than 10	44
24	Nil	less than 10	44
30	Nil	less than 10	44
36	Nil	less than 10	44

All the data of physicochemical and microbiological tests of Captopril 25mg tablets investigated in this study showed comply with USP 37 and BP 2015 at (30 ± 2)°C within the 36 months of tests.

CONCLUSION

The result of this study suggest an expiration date of not less than 36 months (3 years) for Captopril 25mg tablets at (30 ± 2)°C.

REFERENCES

[1] BP (2015) British Pharmacopoeia. https://www.pharmacopoeia.com/BP2015
[2] RxList (2016) http://www.rxlist.com/capoten-drug.htm
[3] Reynolds JEF (1996). Martindale the extra pharmacopoeia 31stad, pp. 27-28, pharmaceutical press, London.
[4] USP 37 (2014) The United States Pharmacopeia (USP) and the National Formulary (NF). United States Pharmacopoeial Convention, Rockfield, MD, USA.