

## CHAPTER 9: STABILITY STUDY

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### 9.0 STABILITY STUDY

The purpose of stability testing is to provide evidence on how the quality of drug formulation varies with the influence of a variety of environmental conditions like temperature and humidity. It is also useful to establish re-test period and shelf life for the drug formulation and recommended storage conditions. The stability study was conducted in two conditions mentioned in table 9.1.

**TABLE 9.1: Stability study conditions**

Sr. No.	Stability study condition	Temperature	Relative Humidity
01	Long term stability study condition (LT)	25° C ± 2° C	65% ± 5% RH
02	Accelerated stability study condition (ACC)	45° C ± 2° C	75% ± 5% RH

### 9.1 PROCEDURE

The stability of optimized CFE loaded hydrogel sheet and collagen film was evaluated during storage for 6 months at Long term stability study condition (25°C±2° C, 60%RH±5% RH) and Accelerated stability study condition (40°C±2° C, 75%RH±5% RH) as per ICH guidelines (1). Samples were withdrawn after 1, 2, 3 and 6 month storage from stability chamber. Withdrawn samples of hydrogel sheets were evaluated for following parameters:

- 1) Physical appearance,
- 2) pH
- 3) %GF,
- 4) %Hardness,
- 5) %Water absorption,
- 6) Assay with respect to the total phenolic content and total flavonoid content
- 7) Sterility

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Collagen film Samples were withdrawn after 1, 2, 3 and 6 month and evaluated for following parameters:

- 1) Physical appearance
- 2) % wound fluid absorption capacity,
- 3) folding endurance,
- 4) pepsin digestion time,
- 5) % LOD,
- 6) Assay y with respect to the total polyphenolic content and total flavonoid content
- 7) Sterility

### 9.2 RESULTS AND DISCUSSION

- Results of stability study of CFE loaded hydrogel sheet are shown in table 9.2. Hydrogel sheet samples drawn during 6 month stability study condition did not shown major change in parameters tested from initial values, so the developed formulation is considered to be stable at both this conditions for six months.
- Results of stability study of CFE loaded collagen film are shown in table 9.3. CFE loaded collagen film samples drawn during 6 month did not shown major change in parameters tested from initial values, so the developed formulation is considered to be stable at both this conditions for six months.

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TABLE 9.2: LT and ACC stability study of CFE loaded hydrogel sheet

Quality parameter Parameters	Initial	LT stability study			ACC stability study			
		After 1 Month	After 3 month	After 6 Month	After 1 Month	After 2 month	After 3 Month	After 6 Month
Physical appearance	Transparent, flexible sheet	No change	No change	No change	No change	No change	No change	No change
%Water Absorptivity	73.8 ± 2.1%	74.1 ± 1.9%	70.5 ± 2.5%	76.8 ± 1.1%	70.8 ± 3.1%	71.1 ± 4.1%	72.4 ± 1.7%	68.2 ± 1.4%
Hardness (g)	13 ± 1	12 ± 2	14 ± 1	12 ± 1	12 ± 2	14 ± 1	12 ± 1	12 ± 2
%GF	68.4 ± 3.8 %	70.1 ± 1.4	69.5 ± 2.7	70.3 ± 2.3	68.6 ± 2.9	67.5 ± 2.7	69.1 ± 1.9	70.3 ± 3.3
Total polyphenolic content (mg GAE/g extract)	4.1430 ± 0.334	4.098 ± 0.531	4.11 ± 0.197	4.086 ± 0.262	4.21 ± 0.37	4.137 ± 0.172	4.083 ± 0.139	4.075 ± 0.135
Total flavonoid content (mg QUE/g extract)	0.4218 ± 0.11	0.4163 ± 0.091mg	0.4061 ± 0.083mg	0.4018 ± 0.071mg	0.4036 ± 0.094mg	0.4069 ± 0.073mg	0.4043 ± 0.068mg	0.4023 ± 0.087
pH	6.5 ± 0.1	6.4 ± 0.2	6.3 ± 0.2	6.4 ± 0.1	6.5 ± 0.2	6.7 ± 0.1	6.2 ± 0.3	6.4 ± 0.2
Sterility	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile

\*±SD, n=3

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TABLE 9.31: Result of stability study of CFE loaded collagen film

Quality parameter Parameters	Initial	LT stability study			ACC stability study			
		After 1 Month	After 3 month	After 6 Month	After 1 Month	After 2 month	After 3 Month	After 6 Month
Physical appearance	Transparent, flexible light brown colored film	No change	No change	No change	No change	No change	No change	No change
% Wound fluid absorption capacity (g/g)*	9.79 ± 0.90	10.21 ± 0.24	9.95 ± 0.30	9.88 ± 0.64	10.4 ± 0.29	10.10 ± 0.61	9.61 ± 0.85	9.82 ± 0.94
Folding endurance	>200 times	>200 times	>200 times	>200 times	>200 times	>200 times	>200 times	>200 times
Pepsin digestion time	About 4 hr	About 4 hr	About 4 hr	About 4 hr	About 4 hr	About 4 hr	About 4 hr	About 4 hr
%LOD*	10.44 ± 0.5%	10.38 ± 0.9%	10.72 ± 0.45%	10.29 ± 0.57%	10.07 ± 0.37%	10.00 ± 0.42%	10.61 ± 0.2%	10.37 ± 0.61%
Total phenolic content (mg GAE/100 ml extract)*	5.351 ± 0.273	5.281 ± 0.137	5.254 ± 0.371	5.128 ± 0.194	5.195 ± 0.186	5.248 ± 0.243	5.162 ± 0.373	5.075 ± 0.20
Total flavanoid content (mg QUE/100 ml extract)*	0.514 ± 0.092	0.498 ± 0.051	0.522 ± 0.034	0.494 ± 0.073	0.497 ± 0.064	0.490 ± 0.035	0.492 ± 0.069	0.4884 ± 0.042
Sterility	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile	Sterile

\*±SD, n=3

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### 9.3 CONCLUSION

The samples did not show any significant difference from the initial values in any parameters during 6 month ACC and LT stability study indicating the long term stability of developed hydrogel sheet loaded CFE and CFE loaded collagen film.

### 9.4 REFERENCES

1. ICH guidelines - [www.ich.org](http://www.ich.org).