Concurrent Validation and Statistical Analysis of Novel Bi-Layer Floating Tablet of Sucralfate and Metoprolol Succinate

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ABSTRACT

The research work is based on validation and statistical analysis of Bilayer Floating Tablet containing bilayer floating tablet of Sucralfate and Metoprolol Succinate. First the initially formulated and evaluated Bi layer floating tablet of Sucralfate and Metoprololsuccinate (DSFMS). We performed the stability study as per the ICH guideline. Then evaluation of the tablets according to Concurrent validation process. Then final resultant value compared with the initial resultant values and checked the equivalency with the acceptance criteria of Bilayer Floating Tablet. Then statistical analysis were done by calculating mean deviation and standard aviation. Then compared statistical parameters a over limit or under limit.

After stability study and Concurrent validation of (DSFMS) it is confirmed that the formulation fulfill all the acceptance criteria of Bilayer floating tablet. It is confirmed that the formulation (DSFMS) satisfying all acceptance criteria of Bilayer floating tablet. The statistical parameters are under limit.

Keyword: Ulcer protective, Sucralfate, Antihypertensive, Metoprolol Succinate, Bilayer floating tablet

Introduction During pregnancy antacid is a common problem. Hypertension [2] causes complications in pregnancy.

Ulcer protective Sucralfate [4] is used in treatment both Duodenal and Gastric ulcer. Metoprolol Succinate[5] is used in treatment of hypertension. Between Sucralfate and MetoprololSuccinate having minor drug interaction. [6.] Concurrent validation is defined as the process of detecting the steps of manufacturing. [10] Statistical analysis [11]is the collection and interpretation of data in order to uncover patterns and trends. The present study focusing on Concurrent validation and statistical analysis of of the Bilayer floating tablet.

MATERIAL AND METHODS

Selection of the initially prepared Bi Layer Floating Tablet of formulation (DSFMS)

Table-1: Composition of the selected formulation of Sucralfate and Metoprolol Succinate. (DSFMS)

SL NO	INGREDIENTS	QUANTITY PER TABLET (MG)	INGREDIENTS	QUANTITY PER TABLET (MG)
		100mg	**METOPROLOL**	50mg

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1	SUCRALFATE		**SUCCINATE**	
2	CROSS POVIDONE	7mg	HPMC K 100	25mg
3	AEROSIL	1mg	SODIUMBICARBONATE	15mg
4	LACTOSE MFL	31.250mg	AEROSIL	3mg
5	MCC PH101	43.5750mg	EUDRAGIT-RSPO	20mg
6	SODIUM BICARBONATE	15mg	EUDRAGIT-RLPO	7.50mg
7	POLYSORBATE 80	7mg	EUDRAGIT-RS100	5mg
8	HPC-1	5mg	NA CMC	17.50mg
9	MAGNESIUMSTEARATE	3.750mg	SODIUM ALGINATE	15mg
10	(SUNSETYELLOW(0.25%)	0.31250mg	HPC	12.50mg
11	PURIFIED WATER	qs	ETHYL CELLULOSE	10mg
	TOTAL WEIGHT	214mg	PVPK -90	2.5mg
12		TALC	3	
13		IPA	Quantity sufficient	
14		PURIFIED WATER	Quantity sufficient	
15		TOTAL WEIGHT	186mg	

Stability Study [12]

Stability study is method of determining existence of the drug product at particular temperature and humidity condition as per the ICH guideline.

Comparison Study

The present resultant values of stability studies compared with compared the initial resultant values the specification of acceptance criteria.

Determination of floating lag time

Single tablet is taken from the prepared formulation (DSFMS). It is put into the 200 ml beaker containingPh 1.2. solution. The time required to start floating of the tablet is determined.

Determination of total floating time

A single tablet is taken from the prepared formulation. (DSFMS). It is put into the 200ml beaker containingsolution of Ph 1.2. Then the time of existence of the tablet is observed.

Statistical analysis

10 tablets the formulation (DSFMS) are taken.Floating lag time is tested of each tablet.

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Then the time is noted.

Statistical analysis.

10 tablets of the formulation **(**DSFMS) are taken.Total Floating Time is tested of each tablet.

Then the time is noted and the mean deviation and standard deviations are calculated.

RESULT:

Stability study:

Table-2: Evaluated parameters.

1	Average weight (mg)	402	403	390-410
2	Friability.	0.20	0.191	less than 1
3	Hardness.	3.10	3.61	4-6kg/cm^2
4	Drug content (%)			
	Sucralfate	91.960	100.05	94%-102%
	Metoprolol Succinate	98.760	96.90	91%-102%

Statistical analysis

Table-03: Statistical parameters of of Bilayer Floating tablet (DSFMS)

Sl No	(Floating Lag Time) in Second	(x-μ)
1	26	-1.8
2	28	0.2
3	29	1.2
4	27	-0.8
5	28	0.2
6	29	1.2
7	27	-0.2
8	28	0.2
9	27	-0.2
10	29	1.2
n=10	∑x= 278	∑(x-μ) =1.2

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Calculation of Mean deviation and standard deviation of Floating Lag Time

- $\mu = \sum x/n = 278/10 = 27.8$
- $\sum(x-\mu) = 1.2$
- Mean Deviation = $\sum(x-\mu)/\mu$
- Mean Deviation = 1.2/27.8=0.043 =less than 1
- Standard deviation= $\sigma = \sqrt{\frac{\sum(X-\mu)^2}{n}}$

- $(x-\mu)^2 = 1.44$
- Standard Deviation = $\sqrt{1.44/10} = \sqrt{0.144} = 0.379$
- less than 1

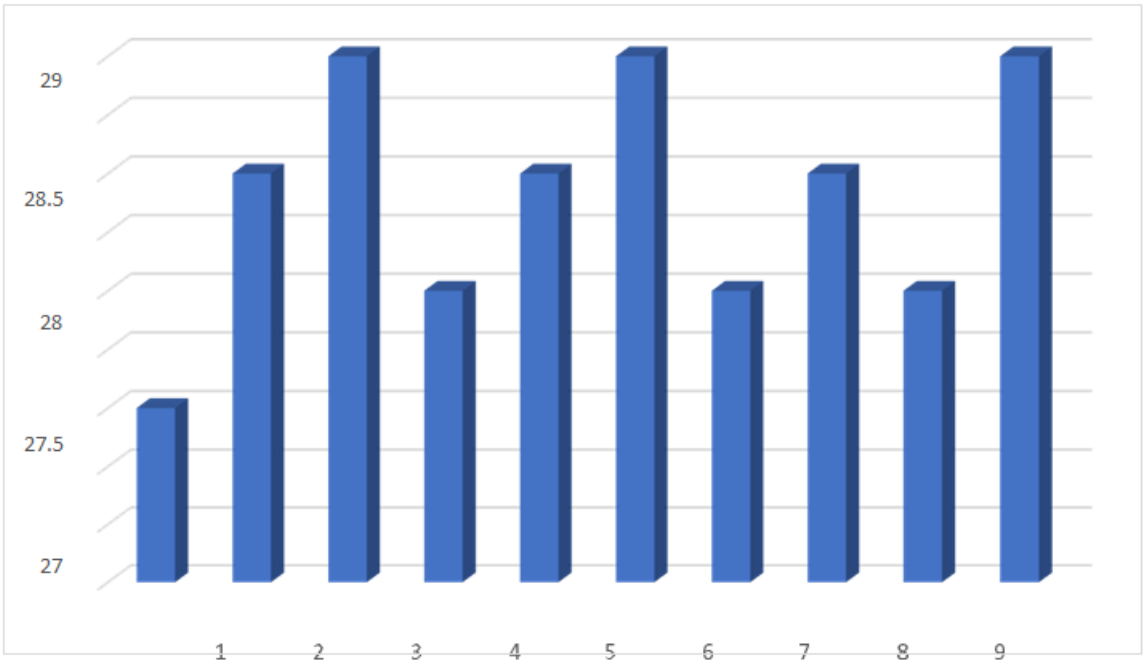

Figure-1: Statistical graph of (FLT) of (DSFMS).

Table-4: Statistical parameters of (F.L.T) of (DSFMS)

SL No	x (Floating Lag Time) in hours	(x-μ)
1	18.13	0.005
2	18.15	0.015
3	18.13	0.005
4	18.15	0.015

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5	18.13	0.005
6	18.10	-0.029
7	18.15	0.015
8	18.13	0.005
9	18.15	0.015
10	18.13	0.005
n=10	∑x= 181.35	∑(x-μ)=0.056

- μ=∑x/n =181.35/10=18.135
- ∑(x-μ)=0.056
- Mean Deviation = $\sum(x-\mu)/\mu$
- Mean Deviation = 0.056/18.135= 0.003= less than 1
- Standard deviation= $\sigma = \sqrt{\frac{\sum(X-\mu)^2}{n}}$
- $(x-\mu)^2$ =0.003136
- Standard Deviation= √ 0.003136/10 = √0.003136 = 0.017
- less than 1

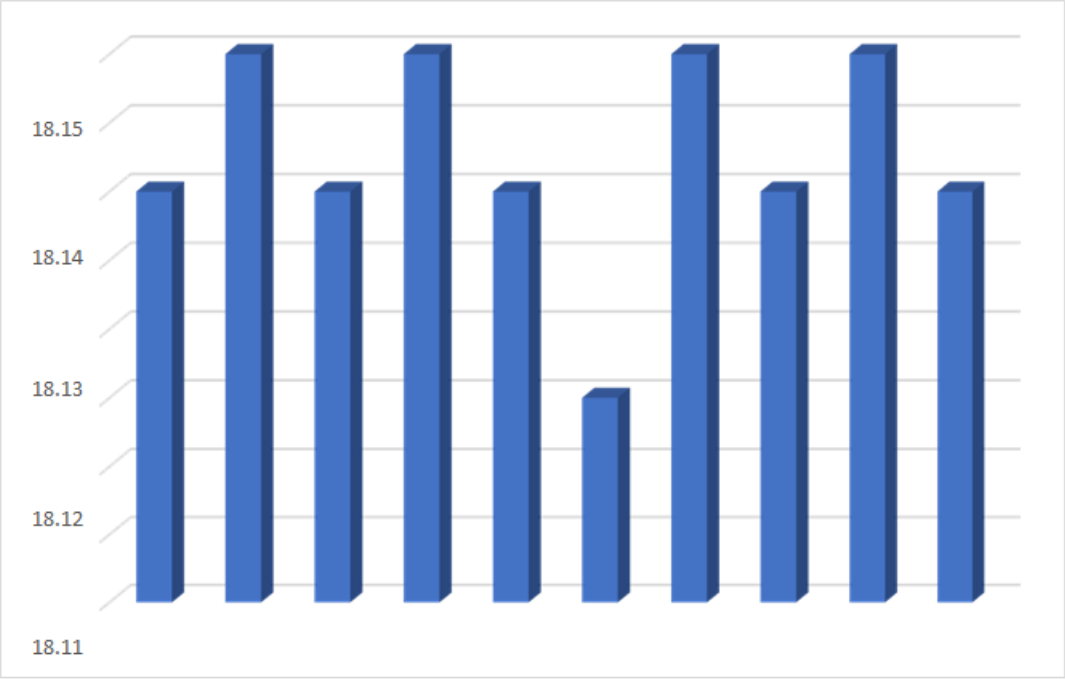

Fig:2-Statitical graph of (TFT) of 10 tablets of (DSFMS)

CONCLUSION

The comparison between present resultant values of stability studies and the initial resultant values showsbetter equivalency and it fulfill all the acceptance criteria of Bilayer floating tablet.

The Floating lag time (FLT) is produced as 25 second and total Floating Time TFT is more than 18 hours after 90 daysof stability study.

The analytical deviation of all parameters remains less than 1. The statistical values are under limit.

The drug content of Sucralfate is 99.23% and Metoprolol Succinate is 100.06%.

So the Bi layered Floating Tablet (DSFMS) can be determined as an acceptable formulation as Gastro Retentive Drug Delivery System.

Conflict of Interest

The author declares that there is no conflict of interest regarding the publication of the paper.

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