



Analytical Method Validation Report for the Determination of Assay of Alpha Amylase & Papain By Microbiological Assay Method

1. Summary:

Microbiological Assay Method for the determination of Assay of Alpha Amylase & Papain in Capsules has been carried out using Microbiological Assay Method. Microbiological Assay Method for the determination of Assay of Alpha amylase & Papain has been validated. The method is found to be linear, precise, specific, accurate & rugged for the intended studies and therefore suitable for use in determining the assay of Alpha amylase & Papain in Capsules.

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1. Summary Table

The method is studied for following parameters for Papain.

Content	Observation	Acceptance Criteria
➤ Specificity	<ul style="list-style-type: none">- There is no interference of Placebo and blank with the Papain in Capsules.- %RSD of zone of SH in replicate: 0.73%- %RSD of zone of SL in replicate : 0.60%- No zone of inhibition in Test High & Test Low	<ul style="list-style-type: none">- Any other placebo and blank should not interfere with the Papain in Capsules.- %RSD of zone of SH in replicate: Not more than -1.0%- %RSD of zone of SL in replicate : Not more than -1.0%- No zone of inhibition in Test High & Test Low
➤ Precision		
- Method Precision	Result (mg)	% Assay
	101.70	101.70
	101.15	101.15
	101.90	101.90
	101.30	101.30
	100.60	100.60
	100.83	100.83
Mean	101.25	101.25
% RSD	0.49	0.49
		- Relative Standard deviation (%RSD) for Assay of six different sample preparations: Not more than - 2.0%



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Content	Observation	Acceptance Criteria	
➤ Intermediate Precision (Ruggedness)			
- Method Precision	Result (mg)	%Assay	-Relative Standard deviation (%RSD) for Assay of six different sample preparations: Not more than - 2.0%
	102.11	102.11	
	102.59	102.59	
	101.24	101.24	
	102.24	102.24	
	102.37	102.37	
	101.72	101.72	
Mean	102.05	102.05	
% RSD	0.48	0.48	
Summary for overall 12 Assay	Overall Relative Standard deviation (%RSD) of assay of Papain for Capsules with 12 determinations is 0.62%	-Relative Standard deviation (%RSD) for Assay of 12 different sample preparations: Not more than - 2.0%	
Accuracy as Recovery	Recovery for assay from the sample obtained with triplicate test preparation at each level (i.e. about 80%, 100%, 120% of specification level) is in the limit of 98-102%.	-Recovery for assay from the sample obtained with triplicate test preparation at each level (i.e. about 80%, 100%, 120 % of specification level) should be between 98 and 102 %	
Prep. No	80%	100%	120%
1	101.04	100.23	99.23
2	101.44	100.13	99.59
3	101.23	101.21	99.88
Linearity	Active Ingredient	Correlation Coefficient (R²)	- The Correlation Coefficient (R ²) should be not less than 0.99
	Papain	0.997	



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The method is studied for following parameters for Alpha amylase,

Content	Observation	Acceptance Criteria
➤ Specificity	<ul style="list-style-type: none"> - There is no interference of Placebo and blank with the Alpha amylase in Capsules. - %RSD of zone of SH in replicate: 0.50% - %RSD of zone of SL in replicate : 0.59% - No zone of inhibition in Test High & Test Low 	<ul style="list-style-type: none"> - Any other placebo and blank should not interfere with the Alpha amylase in Capsules. - %RSD of zone of SH in replicate: Not more than -1.0% - %RSD of zone of SL in replicate : Not more than -1.0% - No zone of inhibition in Test High & Test Low

Precision

Method Precision	Result (mg)	%Assay	
	101.27	101.27	- Relative Standard deviation (%RSD) for Assay of six different sample preparations: Not more than - 2.0%
	101.86	101.86	
	100.25	100.25	
	101.48	101.48	
	99.64	99.64	
	101.30	101.30	
Mean	100.97	100.97	
% RSD	0.83	0.83	

Intermediate Precision (Ruggedness)

Method Precision	Result (mg)	%Assay	
	100.31	100.31	- Relative Standard deviation (%RSD) for Assay of six different sample preparations: Not more than - 2.0%
	100.41	100.41	
	99.75	99.75	
	99.89	99.89	
	99.80	99.80	
	99.80	99.80	



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Content	Observation		Acceptance Criteria	
	99.92	99.92		
Mean	100.01	100.01		
% RSD	0.27	0.27		
Summary for overall 12 Assay	Overall Relative Standard deviation (%RSD) of assay of Alpha amylase for Capsules with 12 determinations is 0.77%		- Relative Standard deviation (%RSD) for Assay of 12 different sample preparations: Not more than - 2.0%	
Accuracy as Recovery	Recovery for assay from the sample obtained with triplicate test preparation at each level (i.e. about 80%, 100%, 120 % of specification level) is in the limit of 98 -102%.		Recovery for assay from the sample obtained with triplicate test preparation at each level (i.e. about 80%, 100% and 120 % of specification level) should be between 98 and 102 %.	
Prep. No	80%	100%	120%	
1	101.63	99.61	99.93	
2	101.25	99.76	100.07	
3	100.80	100.79	100.22	
Linearity	Active Ingredient	Correlation Coefficient (R²)	The Correlation Coefficient (R ²) should be not less than 0.99	
	Alpha Amylase	0.996		

"The analytical data of each study shows satisfactory results against acceptance criteria defined in the Protocol, hence it is concluded that method is validated for above parameters and suitable its intended use for the determination of assay in Capsules.

1. Introduction

This report describes the validation of test procedure used for the determination of assay in Capsules. The analytical methodology used for Microbiological Assay Method. The method was validated as per validation protocol.

2. Objective



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The objective of this analytical method is to demonstrate that it is suitable for its intended purpose. The overall purpose of the validation is to provide documented evidence of specificity, precision, accuracy and linearity for the method with the help of the following parameters.

- Specificity
- Precision
- Method Precision
- Intermediate precision (Ruggedness)
- Accuracy as recovery
- Linearity & Range

Detail of method, each experiment, and observations during the performance and results are reported below.

3. Working standard and sample used

Working standard

Name : Papain
Working STD :
Potency : 100 %

Working standard

Name : Alpha Amylase
Working STD :
Potency : 800 μ /g

Sample

Name : Capsule
Batch no. :

REAGENTS & PRERQUISITIES:

- 90mm Petriplates
- Disodium hydrogen phosphate
- Citric acid



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- Casein
- Sodium hydroxide
- Ortho phosphoric acid
- Hydrochloric acid
- Starch soluble
- Sodium chloride
- Agar
- Iodine
- Distilled water

4.0 EQUIPMENTS:

- Antibiotic Zone Reader
- Calibrated Weighing Balance
- Micropipette

5.0 PREPARATIONS PROCEDURE:

5.1 Macllvaine's citrate phosphate buffer pH 6.0 (single strength):

Dissolve 107.5 gm of Disodium hydrogen phosphate and 12.5 gm of citric acid in water and made up to 500 ml with water adjust the pH with 1N sodium hydroxide or phosphoric acid.

5.2 Macllvaine's citrate phosphate buffer pH 6.0 (Half strength):

Transfer 250 ml of double strength Macllvaine's buffer to 500 ml volumetric flask and make up volume with distilled water.

5.3 Casein solution:

Dissolve 4.0 gm of Hammerstein's Casein in 90 ml of water. Add 5.0ml of 1N sodium hydroxide solution drop by drop mix slowly with the help of glass rod or blender avoid frothing. Blend the casein solution at a very low speed and 1N HCl drop by drop avoid cluster formation, adjust the pH 7.0 with 1N HCl and add the volume 40 ml water prepare fresh solution every time.

5.4 Starch solution:

Dissolve 2.2 g of soluble starch (on dried basis) in 75 ml of boiled water and cool it to room temperature. Than add 1.8 gm of sodium Chloride.

5.5 Standard preparation of Papain:

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Weigh accurately and transfer about 250 mg of Papain working std in a 25 ml Volumetric flask add 15 ml of half strength Macllvaine's buffer pH 6.0 allow and shake well and make up the volume up to the mark with half strength Macllvaine's buffer. This std preparation (Stock solution A) contain about 10.00 mg/ml of Papain. Mark this solution as **S_H for Papain**. Transfer 5ml aliquot dilutions (SH) in test tube add 5ml of half strength of Macllvaine's buffer. Mark this as **S_L for Papain**

5.6 Standard preparation for Alpha amylase:

Weigh accurately and transfer about 90 mg of alpha amylase working std in a 25 ml Volumetric flask add 15 ml of half strength Macllvaine's buffer pH 6.0 allow and shake well and make up the volume up to the mark with half strength Macllvaine's buffer. This std preparation (Stock solution B) contain about 3.6 mg/ml of alpha amylase. Transfer 5ml from stock solution B in 100 ml volumetric flask and make up the volume with half strength Macllvaine's buffer. Mark this solution as **S_H for Alpha amylase** transfer 5ml aliquots of the dilution in the test tube add 5 ml of half strength of Macllvaine's buffer. Mark this solution as **S_L for Alpha amylase**.

5.7 Test preparation for Papain:

Select 20 Capsule and find the average fill and collect the powder. Weigh the capsule powder equivalent to 250 mg of papain in a 25 ml Volumetric flask add 15 ml of half strength Macllvaine's buffer pH 6.0 allow and shake well and make up the volume up to the mark with half strength Macllvaine's buffer. This test preparation (Stock solution C) contain about 10.00 mg/ml of Papain. Mark this solution as **T_H for Papain**. Transfer 5ml aliquot dilutions (SH) in test tube add 5ml of half strength of Macllvaine's buffer. Mark this as **T_L for Papain**.

5.8 Test preparation for Alpha amylase:

Weigh the capsule powder equivalent to 90 mg of alpha amylase in a 25 ml Volumetric flask add 15 ml of half strength Macllvaine's buffer pH 6.0 allow and shake well and make up the volume up to the mark with half strength Macllvaine's buffer. This test preparation (Stock solution D) contain about 3.6 mg/ml of alpha amylase.

Transfer 5ml from stock solution D in 100 ml volumetric flask and make up the volume with half strength Macllvaine's buffer. Mark this solution as **T_H for Alpha amylase** transfer 5ml aliquots of the dilution in the test tube add 5 ml of half strength of Macllvaine's buffer. Mark this solution as **T_L for Alpha amylase**.

5.9 Procedure:

Prepare a medium: Weigh the 3 gm agar powder in a 500 conical flask and add 120 ml purified water autoclave for sterilization at 121 °C for 15 minute. After sterilization remove the media from



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autoclave when media temperature is approx 85°C. add slowly – slowly, 25 ml single strength of MacIlvaine’s buffer pH 6.0, 22.5ml of casein solution and 22.5 ml of starch solution than mix gently pour the equally 25 ml portion of the molten medium while hot in seven Petri dishes kept at flat surface and allow to solidify at room temperature for 15 minute and then keep the Petri dishes in a refrigerator (8 °C) for 30 -60 minute use 2 Petri dishes for analysis of Papain and keep two for alpha amylase make four cup of 8.0 mm diameter with card borer on each plate. In each Petri dish pour 100µl each of std solution (S_H & S_L) and test solution (T_H & T_L). Keep the plate 1 hour for diffusion of solution. Transfer the plate carefully in to incubator set at 37 °C. So that there is no spill of dilution filled into each cup. Incubate Petri dishes at 37 °C for 24 hours.

Measure the diameter white zone produced by Papain after incubation and the reading flood the alpha amylase plates with 0.1 % w/v Iodine solution to estimate amylase activity of amylase by measuring the clear zone diameters on the blue background.

Calculation:

% if potency = Antilog 2 + a log I

Where, $a = \frac{(T_H + T_L) - (S_H + S_L)}{(T_H - T_L) + (S_H - S_L)}$

log I = Ratio of dilution

Papain = $\frac{\text{Antilog}}{100} \times \frac{WS_1}{25} \times \frac{25}{WT} \times \text{Potency} \times \text{Avg. fill wt.}$

Alpha amylase = $\frac{\text{Antilog}}{100} \times \frac{WS_2}{25} \times \frac{25}{WT} \times \text{Potency} \times \text{Avg. fill wt.}$

6.0 Specificity

Separately test Assay with placebo solution and spiked solution (triplicate). In the Assay result showed no significant zone of inhibition of Placebo solution of Capsule and results are shown in the Table-1.

Table –1: Specificity (Papain)

Test No.	Standard High(mm)	Standard Low(mm)	Test High(mm)	Test Low(mm)
1.	20.74	18.82	0.0	0.0
2.	20.56	18.75	0.0	0.0
3.	20.86	18.60	0.0	0.0

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Mean	20.72	18.72	0.0	0.0
STD.DEV.	0.15	0.11	0.0	0.0
RSD (%)	0.73	0.60	0.0	0.0

Table –1: Specificity (Alpha Amylase)

Test No.	Standard High (mm)	Standard Low (mm)	Test High (mm)	Test Low (mm)
1.	27.20	26.28	0.0	0.0
2.	27.35	26.16	0.0	0.0
3.	27.08	26.47	0.0	0.0
Mean	27.21	26.30	0.0	0.0
STD.DEV.	0.14	0.16	0.0	0.0
RSD (%)	0.50	0.59	0.0	0.0

Conclusion: There is no interference from placebo. Hence the method is found to be specific.

7. PRECISION**7.1 Precision (Papain):**

Precision was performed by Microbiological assay in six replicates of sample preparations of Alpha amylase in Capsules at 100 % specification level and results are shown in the Table – 2.

Table –2: Precision

Capsules (Papain)		
Sample Preparation	Result (mg)	%Assay



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1	101.70	101.70
2	101.15	101.15
3	101.90	101.90
4	101.30	101.30
5	100.60	100.60
6	100.83	100.83
Mean	101.25	101.25
Stdev	0.50	0.50
RSD (%)	0.49	0.49

Conclusion: Relative standard deviation (%RSD) for Papain in **Capsules** with six replicates sample preparation is less than 2.0%.

7.2 Precision (Alpha Amylase):

Precision was performed by Microbiological assay in six replicates of sample preparations of Alpha amylase in Capsules at 100 % specification level and results are shown in the Table – 2.

Table –2: Precision

Capsules (Alpha Amylase)		
Sample Preparation	Result (mg)	%Assay
1	101.27	101.27
2	101.86	101.86
3	100.25	100.25
4	101.48	101.48
5	99.64	99.64
6	101.30	101.30
Mean	100.97	100.97
Stdev	0.84	0.84
RSD (%)	0.83	0.83

Conclusion: Relative standard deviation (%RSD) for Alpha amylase in **Capsules** with six replicates sample preparation is less than 2.0%.

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Conclusion: The method is found to be precise.

7.3 Intermediate precision (Ruggedness):

This study shall be carried out as per method precision by a different analyst, different day by using different set of standard solution and sample solution.

Intermediate Precision of the method was demonstrated by calculating the assay with six different sample preparations prepared results found of Alpha Amylase is 0.27% & of Papain is 0.48% of 6 assays RSD results are shown in the Table – 5 & Table-7.

Table –5: Precision (Alpha Amylase)

Sample Preparation	Result (mg)	%Assay
1	100.31	100.31
2	100.41	100.41
3	99.75	99.75
4	99.89	99.89
5	99.80	99.80
6	99.92	99.92
Mean	100.01	100.01
R.S.D. (%)	0.27	0.27

% RSD of assay for 12 sample preparations between different analysts

Table 6:

Sample Preparation	Alpha Amylase Assay (%)
1	101.27
2	101.86
3	100.25
4	101.48



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5	99.64
6	101.30
7	100.31
8	100.41
9	99.75
10	99.89
11	99.80
12	99.92
Mean	100.49
R.S.D. (%)	0.77

CONCLUSION:

The % R.S.D. for the overall assay of the twelve sample preparations is within the limits

Table -7: Precision (Papain)

Sample Preparation	Result (mg)	% Assay
1	102.11	102.11
2	102.59	102.59
3	101.24	101.24
4	102.24	102.24
5	102.37	102.37
6	101.72	101.72
Mean	102.05	102.05
R.S.D. (%)	0.48	0.48

% RSD of assay for 12 sample preparations between different analysts

Table 8:

Sample Preparation	Papain Assay (%)
1	101.70



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2	101.15
3	101.90
4	101.30
5	100.60
6	100.83
7	102.11
8	102.59
9	101.24
10	102.24
11	102.37
12	101.72
Mean	101.65
R.S.D. (%)	0.62

CONCLUSION:

The % R.S.D. for the overall assay of the twelve sample preparations is within the limits

8. Accuracy as recovery

The accuracy of the method was demonstrated at three different concentration levels by calculating recovery (about 80 %, 100 %, and 120 % of specification level). The method is found to be accurate. Results are shown in table-9 & table-10

Table -9: % Recovery

% Level	Sample Preparation	(Papain)
80 %	1	101.04
	2	101.44
	3	101.23
100 %	1	100.23
	2	100.13
	3	101.21



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120 %	1	99.23
	2	99.59
	3	99.88

Table –10: % Recovery

% Level	Sample Preparation	(Alpha Amylase)
80 %	1	101.63
	2	101.25
	3	100.80
100 %	1	99.61
	2	99.76
	3	100.79
120 %	1	99.93
	2	100.07
	3	100.22

CONCLUSION:

% Recovery complies with specified acceptance criteria, hence the method is found to be accurate in the range of 80 to 120%.



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9. Linearity and Range:

The linearity of an analytical procedure is its ability (within a given range) to obtain test results which are directly proportional to the concentration (amount) of analyte in the sample.

- ◆ Established the linearity over a range of five different concentrations of the analyze from 80 %, 90%, 100%, 110% and 120% of specification level, injected each concentration in triplicate.
- ◆ Plot a graph with concentration against response (% Potency) and calculate the correlation coefficient. Results are shown in table-11& table-12

Standard Preparation:

For Papain:

- ◆ Accurately weigh about 250 mg of Papain working standard in 25 ml volumetric flask (Solution A).
- ◆ Take above solution (SH).
- ◆ Take 5ml from Solution A and add 5ml of half strength of Macllvaine's buffer (SL).

For Alpha Amylase:-

- ◆ Accurately weigh about 90 mg of Alpha Amylase and dissolve and Sonicate then make up with Distilled water to 25 ml (Solution B).
- ◆ Take 5ml from Solution B and make up the volume upto 100ml with half strength of Macllvaine's buffer (SH).
- ◆ Take 5ml from SH and add 5ml of half strength of Macllvaine's buffer (SL).

Test-1 at 80 %:-

For Papain:-

- ◆ Accurately weigh about 200 mg of Papain working standard in 25 ml volumetric flask (Solution A).
- ◆ Take above solution (TH).
- ◆ Take 5ml from Solution A and add 5ml of half strength of Macllvaine's buffer (TL).

For Alpha Amylase:

- ◆ Accurately weigh about 72 mg of Alpha Amylase and dissolve and Sonicate then make up with Distilled water to 25 ml (Solution B).



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- ◆ Take 5ml from Solution B and make up the volume upto 100 ml with half strength of Macllvaine's buffer (TH).
- ◆ Take 5ml from SH and add 5ml of half strength of Macllvaine's buffer (TL).

Test-2 at 90 %:

For Papain:-

- ◆ Accurately weigh about 225 mg of Papain working standard in 25 ml volumetric flask (Solution A).
- ◆ Take above solution (TH).
- ◆ Take 5ml from Solution A and add 5ml of half strength of Macllvaine's buffer (TL).

For Alpha Amylase:-

- ◆ Accurately weigh about 81 mg of Alpha Amylase and dissolve and Sonicate then make up with Distilled water to 25 ml (Solution B).
- ◆ Take 5ml from Solution B and make up the volume upto 100 ml with half strength of Macllvaine's buffer (TH).
- ◆ Take 5ml from SH and add 5ml of half strength of Macllvaine's buffer (TL).

Test-3 at 100 %:

For Papain:-

- ◆ Accurately weigh about 250 mg of Papain working standard in 25 ml volumetric flask (Solution A).
- ◆ Take above solution (TH).
- ◆ Take 5ml from Solution A and add 5ml of half strength of Macllvaine's buffer (TL).

For Alpha Amylase:-

- ◆ Accurately weigh about 90 mg of Alpha Amylase and dissolve and Sonicate then make up with Distilled water to 25 ml (Solution B).
- ◆ Take 5ml from Solution B and make up the volume upto 100ml with half strength of Macllvaine's buffer (TH).
- ◆ Take 5ml from SH and add 5ml of half strength of Macllvaine's buffer (TL).

Test-4 at 110 %:



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For Papain:-

- ◆ Accurately weigh about 275 mg of Papain working standard in 25 ml volumetric flask (Solution A).
- ◆ Take above solution (TH).
- ◆ Take 5ml from Solution A and add 5ml of half strength of Macllvaine's buffer (TL).

For Alpha Amylase:-

- ◆ Accurately weigh about 99 mg of Alpha Amylase and dissolve and Sonicate then make up with Distilled water to 25 ml (Solution B).
- ◆ Take 5ml from Solution B and make up the volume upto 100ml with half strength of Macllvaine's buffer (TH).
- ◆ Take 5ml from SH and add 5ml of half strength of Macllvaine's buffer (TL).

Test-5 at 120 %:

For Papain:-

- ◆ Accurately weigh about 300 mg of Papain working standard in 25 ml volumetric flask (Solution A).
- ◆ Take above solution (TH).
- ◆ Take 5ml from Solution A and add 5ml of half strength of Macllvaine's buffer(TL).

For Alpha Amylase:

- ◆ Accurately weigh about 108 mg of Alpha Amylase and dissolve and Sonicate then make up with Distilled water to 25 ml (Solution B).
- ◆ Take 5ml from Solution B and make up the volume upto 100ml with half strength of Macllvaine's buffer (TH).
- ◆ Take 5ml from SH and add 5ml of half strength of Macllvaine's buffer (TL).
- ◆ For Above all standard preparation in Linearity test, test preparation as following:

Table –11: Linearity of Papain

S.No.	Conc. %	Concentration (ppm)	Mean % Potency
1.	80.0	4000	64.75



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2.	90.0	4500	82.00
3.	100.0	5000	101.33
4.	110.0	5500	121.17
5.	120.0	6000	143.57
Correlation coefficient (R²)		0.997	

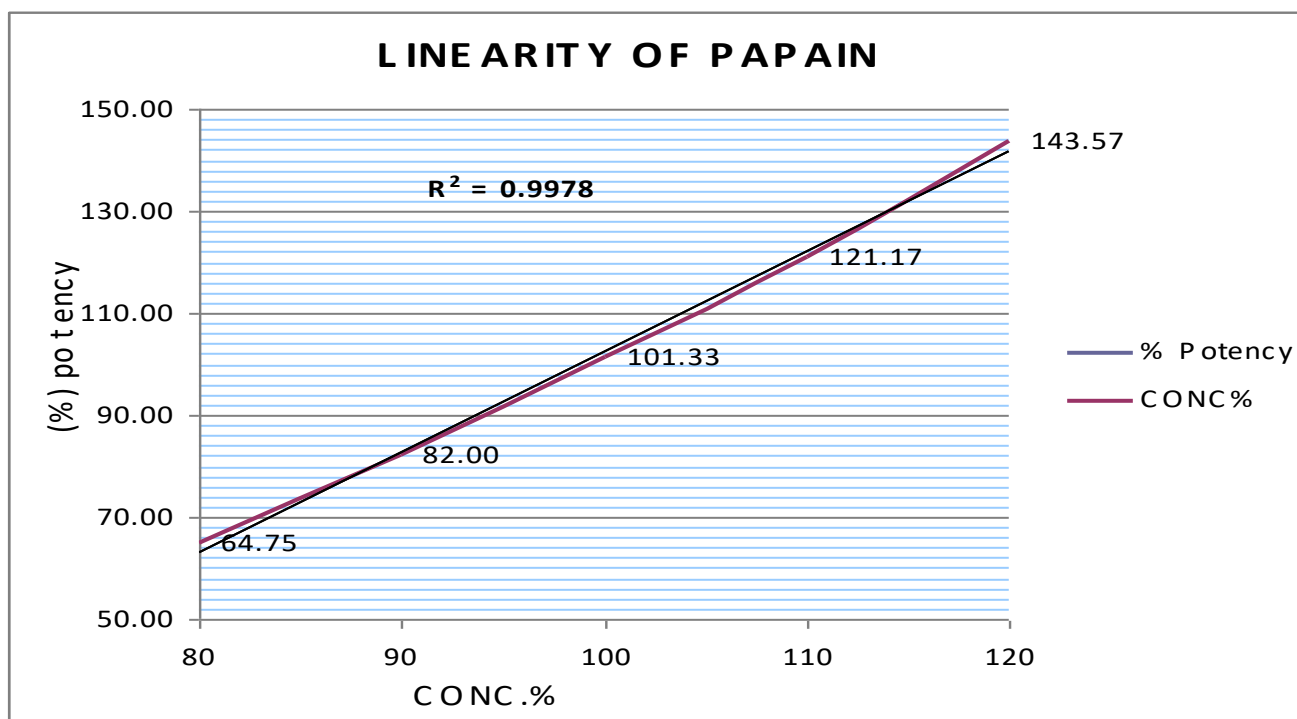


Table -12: Linearity of Alpha Amylase

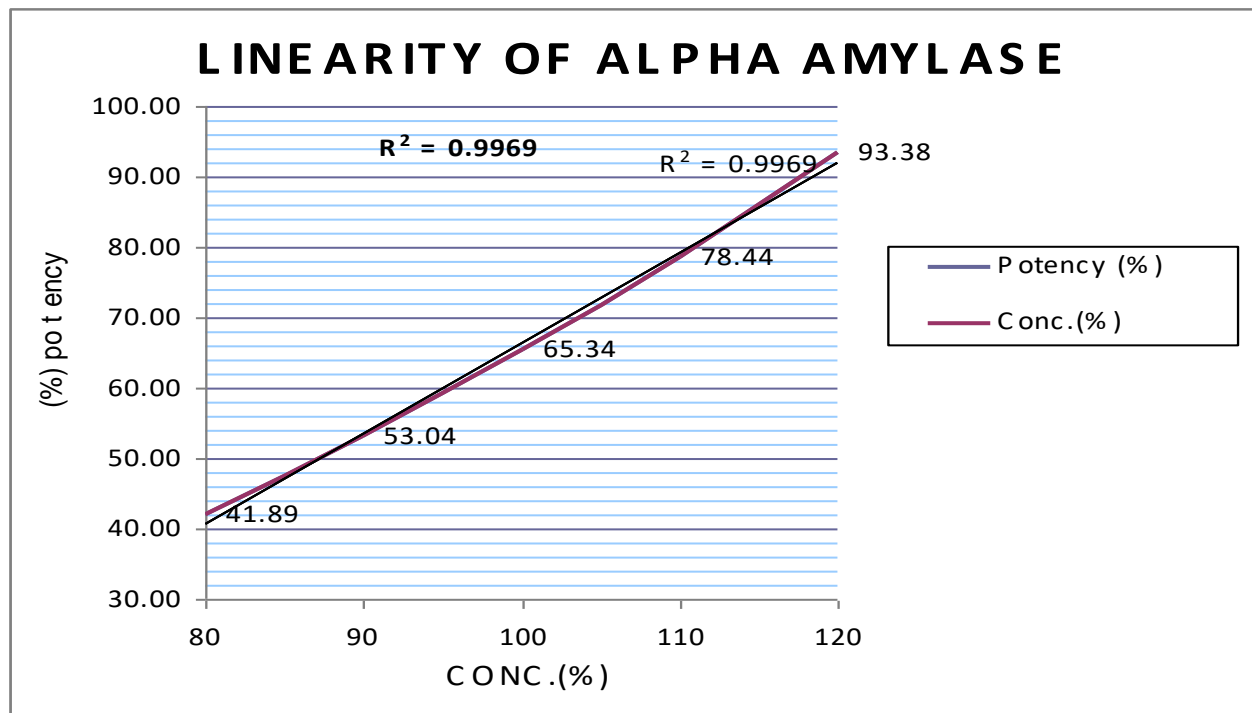
S.No.	Conc. (%)	Concentration (ppm)	Mean % Potency
1	80.0	72	41.89
2	90.0	81	53.04
3	100.0	90	65.34
4	110.0	99	78.44
5	120.0	108	93.38
Correlation coefficient (R²)		0.996	



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Conclusion: The Correlation Coefficient (R^2) is 0.996 for Alpha Amylase & 0.997 for Papain in Capsule. Hence method is linear in the range of 80 to 120% of specification level.

Conclusion of overall Study for Alpha amylase & Papain in Capsule Analytical Method Validation:

The assay by Microbiological Assay Method adopted for Alpha amylase & Papain in Capsule is validated, found to be precise, linear and accurate; it is also proved to be rugged, so this method can be used for routine analysis and stability studies.