

Appendix

DEMOGRAPHY: -

Table 2. Summary statistics for Demography, ITT population

| | PCA Capsule (N = 12) | Placebo (N = 14) | Overall (N = 26) | t/χ ² | Between Groups (P value) |
|----------------------|-------------------------|---------------------|---------------------|------------------|--------------------------------|
| @Age (years) | | | | | |
| N | 12 | 14 | 26 | | |
| Mean | 55.17 | 57.36 | 56.35 | -1.337 | 0.193 (NS) |
| SD | 04.24 | 04.07 | 04.21 | | |
| Median | 55.50 | 56.00 | 56.00 | | |
| Min | 50.00 | 52.00 | 50.00 | | |
| Max | 63.00 | 63.00 | 63.00 | | |
| #Gender-N (%) | 12 | 14 | 26 | | |
| Female | 08 (66.7) | 04 (28.6) | 12 (46.2) | 3.773 | 0.052 (NS) |
| Male | 04 (33.3) | 10 (71.4) | 14 (53.8) | | |

| | | | | | |
|--------------------------------|--------|--------|--------|-------|---------------|
| @Weight (kg) | | | | | |
| N | 12 | 14 | 26 | | |
| Mean | 65.42 | 64.87 | 65.13 | 0.122 | 0.903 (NS) |
| SD | 08.12 | 14.46 | 11.74 | | |
| Median | 67.20 | 64.96 | 66.96 | | |
| Min | 49.90 | 40.08 | 40.08 | | |
| Max | 77.01 | 88.03 | 88.03 | | |
| @Height (cm) | | | | | |
| N | 12 | 14 | 26 | | |
| Mean | 157.64 | 157.27 | 157.44 | 0.089 | 0.929 (NS) |
| SD | 010.74 | 010.48 | 010.39 | | |
| Median | 155.50 | 156.90 | 156.10 | | |
| Min | 144.30 | 143.00 | 143.00 | | |
| Max | 180.00 | 173.50 | 180.00 | | |
| @BMI (kg/m²) | | | | | |
| N | 12 | 14 | 26 | | |
| Mean | 26.46 | 26.32 | 26.38 | 0.083 | 0.934 (NS) |
| SD | 02.77 | 05.55 | 04.40 | | |

| | | | | | |
|---|------------|------------|------------|---|---------------|
| Median | 26.85 | 24.20 | 25.90 | | |
| Min | 21.60 | 19.50 | 19.50 | | |
| Max | 30.20 | 38.70 | 38.70 | | |
| #Race-N (%) | 12 | 14 | 26 | | |
| American Indian or Alaska Native | - | - | - | - | 1.000 (NS) |
| Asian | 12 (100.0) | 14 (100.0) | 26 (100.0) | | |
| Black or African American | - | - | - | | |
| Native Hawaiian or Other Pacific Islander | - | - | - | | |
| White | - | - | - | | |
| Other | - | - | - | | |
| #Ethnicity-N (%) | 12 | 14 | 26 | | |
| Hispanic or Latino | - | - | - | - | 1.000 (NS) |
| Not- Hispanic or Latino | 12 (100.0) | 14 (100.0) | 26 (100.0) | | |
| Not reported | - | - | - | | |
| Unknown | - | - | - | | |
| Other | - | - | - | | |

@By Student t Test
#By Chi – Square Test

($P \leq 0.0054$ is considered as Significant)

NS= Not Significant

- In this analysis, the age of the patients ranged from **50.00 – 63.00 yrs** with the average age being **56.35 yrs** among Overall groups. The average age was **55.17 yrs** among PCA capsule which was comparable to **57.36 yrs** among Placebo group and the difference was not significant.
- **53.8%** of the patients were male among Overall groups. **33.3%** of the patients were male among PCA capsule which was insignificantly less as compared to **71.4%** of males among Placebo group.
- The weight of the patients ranged from **40.08– 88.03 kgs** with the average being **65.13 kgs** among Overall groups. The average weight was **65.42 kgs** among PCA capsule which was comparable to **64.87 kgs** among Placebo group and the difference was not significant.
- The height of the patients ranged from **143.00– 180.00 cm** with the average being **157.44 cm** among Overall groups. The average height was **157.64 cm** among PCA capsule which was comparable to **157.27 cm** among Placebo group and the difference was not significant.
- BMI of the patients ranged from **19.50– 38.70 kg/m²** with the average being **26.38 kg/m²** among Overall groups. The average height was **26.46 kg/m²** among PCA capsule which was comparable to **26.32 kg/m²** among Placebo group and the difference was not significant.

SAFETY ANALYSIS: -

**Table 3. Summary of Adverse Events (AE) stratified by
causality and severity, ITT population**

| | Overall (N = 26) | | | PCA Capsule (N = 12) | | | Placebo (N = 14) | | | χ^2 | Between Groups (P value) |
|--------------------|---------------------|------|---|-------------------------|------|---|---------------------|---|--------|----------|--------------------------------|
| | No | % | Events | No | % | Events | No | % | Events | | |
| Any TEAE | 03 | 11.5 | Stomatitis, Hyperglycemia, Dyslipidemia | 03 | 25.0 | Stomatitis, Hyperglycemia, Dyslipidemia | - | - | - | - | 0.084 (NS) |
| Relatedness | | | | | | | | | | | |
| Related | 01 | 03.8 | Stomatitis | 01 | 08.3 | Stomatitis | - | - | - | - | 0.461 (NS) |
| Not related | 02 | 07.7 | Hyperglycemia, Dyslipidemia | 02 | 16.3 | Hyperglycemia, Dyslipidemia | - | - | - | - | 0.203 (NS) |

| Severity | | | | | | | | | | | |
|-------------|----|------|------------------------------------|----|------|------------------------------------|---|---|---|---|---------------|
| Mild | 01 | 03.8 | Stomatitis | 01 | 08.3 | Stomatitis | - | - | - | - | 0.461 (NS) |
| Moderate | 02 | 07.7 | Hyperglycem ia, Dyslipidemia | 02 | 16.3 | Hyperglycem ia, Dyslipidemia | - | - | - | - | 0.203 (NS) |
| Severe | - | - | - | - | - | - | - | - | - | - | - |
| Any TESAE | - | - | - | - | - | - | - | - | - | - | - |
| Related | - | - | - | - | - | - | - | - | - | - | - |
| Not related | - | - | - | - | - | - | - | - | - | - | - |
| | | | | | | | | | | | |
| Mild | - | - | - | - | - | - | - | - | - | - | - |
| Moderate | - | - | - | - | - | - | - | - | - | - | - |
| Severe | - | - | - | - | - | - | - | - | - | - | - |

By Fisher's exact test

NS = Not Significant

According to this study, **11.5%** of the cases had Adverse event among overall group. **25.0%** of the cases had adverse event among PCA capsule which was more as compared to **none** of the cases among Placebo group but the difference was not significant. Severity of event was mild to moderate among PCA capsule group which were resolved during the treatment.

HAEMATOLOGICAL PARAMETER: -

Table 4. Summary statistics of Hemoglobin (g/dL) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Hemoglobin (g/dL) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|------------------|----|------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 13.92 \pm 1.61 | 14 | 14.28 \pm 2.15 | 0.630 (NS) |
| 14 | 12 | 13.91 \pm 1.60 | 14 | 13.81 \pm 1.88 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | -00.01 (00.11) | 14 | -00.47 (00.17) | 0.030 |
| (p value) | | (0.931) NS | | (0.014)NS | (NS) |

By Student t test

NS = Not Significant

- This result reveals that at baseline, mean Hemoglobin was **13.92 g/dL** among PCA Capsule which was comparable to **14.28 g/dL** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, mean Hemoglobin showed an insignificant fall of **0.1%** among PCA Capsule and **3.3%** in Placebo group from baseline. If compared, the change was insignificantly less among PCA Capsule than Placebo group.

Figure 1: Mean change in Hemoglobin (g/dL) from baseline by treatment group, ITT population

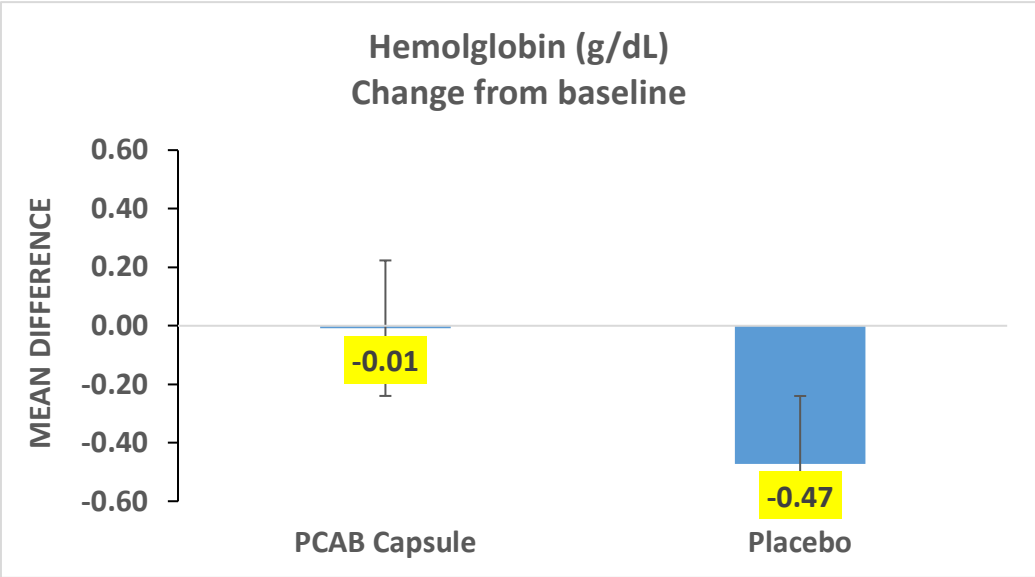


Table 5. Summary statistics of Platelet Count (cells/cumm) and change from baseline by treatment, ITT population

| Duration | Mean Platelet Count (cells/cumm) ($\bar{X} \pm SD$) | | | | Between (P value) |
|-----------------------------------|--|---------------------------|----|---------------------------|----------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 262583.33 \pm 062568.45 | 14 | 276500.00 \pm 080252.25 | 0.624 (NS) |
| 14 | 12 | 277000.00 \pm 106670.27 | 14 | 289857.14 \pm 101504.72 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | 14416.67 (15945.20) | 14 | 13357.14 (10783.39) | 0.956 |
| (p value) | | (0.385) NS | | (0.237) NS | (NS) |

By Student t test

NS = Not Significant

- As per this study at baseline, mean Platelet Count was **262583.33 cells/cumm** among PCA Capsule which was insignificantly less as compared to **276500.00 cells/cumm** among Placebo group.
- After 14 days of treatment, mean Platelet Count showed an insignificant rise of **5.5%** among PCA Capsule and **4.8%** in Placebo group from baseline. If compared, the change was comparable between the groups and the difference was not significant.

Figure 2: Mean change in Platelet Count (cells/cumm) from baseline by treatment group, ITT population

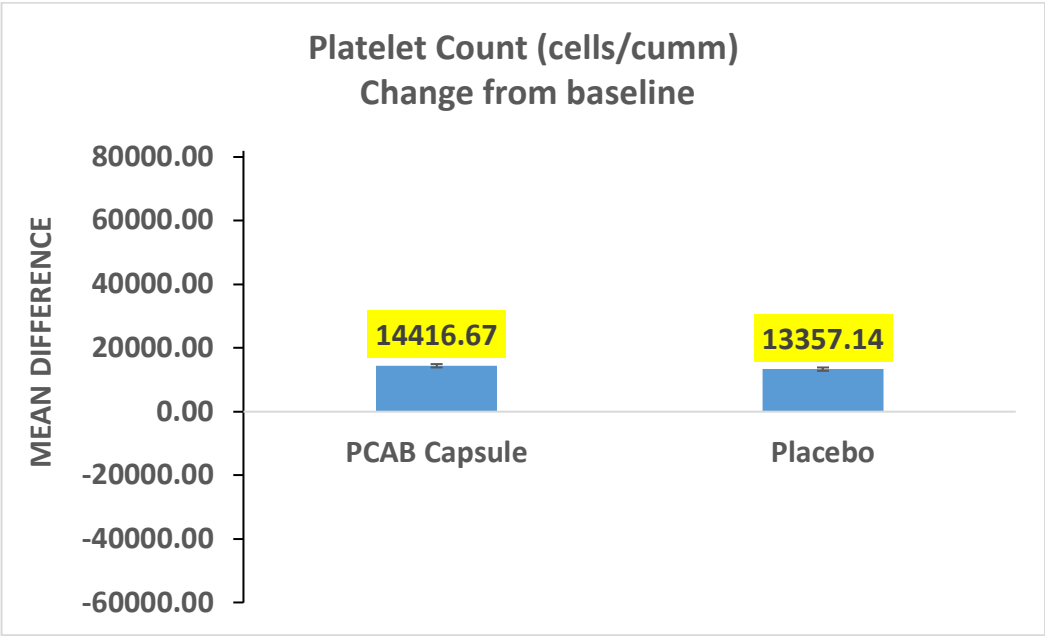


Table6. Summary statistics of TotalRBCCount($10^6/\mu\text{L}$) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Total RBC Count ($10^6/\mu\text{L}$) | | | | Between Groups (P value) |
|-----------------------------------|---|----------------------------|----|---------------------------|--------------------------------|
| | N | | N | Placebo | |
| Baseline | 12 | 4.66 ± 0.46 | 14 | 4.83 ± 0.48 | 0.366 (NS) |
| 14 | 12 | 4.67 ± 0.51 | 14 | 4.67 ± 0.41 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | 0.003 (0.04) (0.946) NS | 14 | -0.16 (0.06) (0.013)NS | 0.030 (NS) |
| By Student t test | | NS = Not Significant | | | |

- In this profile at baseline, mean Total RBC Count was **$4.66 \times 10^6/\mu\text{L}$** among PCA Capsule which was comparable to **$4.83 \times 10^6/\mu\text{L}$** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, mean Total RBC Count showed an insignificant rise of **0.1%** among PCA Capsule and an insignificant fall of **3.3%** in Placebo group from baseline. If compared, the change was insignificantly more among PCA Capsule than Placebo group.

Figure 3: Mean change in Total RBC Count ($10^6/\mu\text{L}$) from baseline by treatment group, ITT population

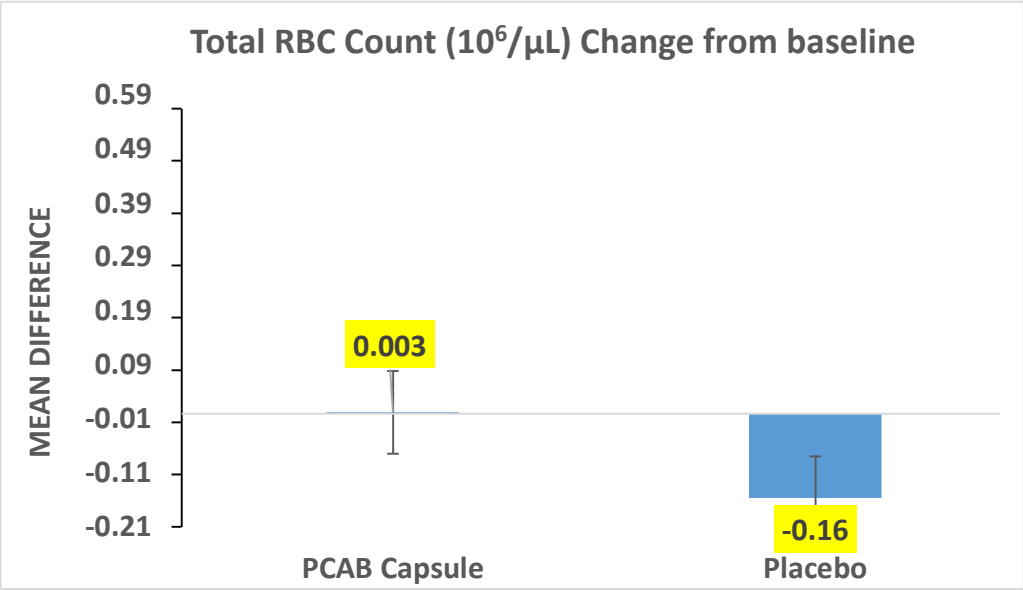


Table 7. Summary statistics of Total Leucocytes Count (cells/cumm) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Total Leucocytes Count (cells/cumm) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|-------------------------------|----|--------------------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 6141.67 \pm 1126.28 | 14 | 6811.43 \pm 1796.63 | 0.259 (NS) |
| 14 | 12 | 6105.83 \pm 1162.75 | 14 | 6490.00 \pm 1972.34 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | -35.83 (380.36) (0.926) NS | 14 | -321.43 (401.56) (0.438) NS | 0.610 (NS) |

By Student t test

NS = Not Significant

- As per this analysis at baseline, mean Total Leucocytes Count was **6141.67 cells/cumm** among PCA Capsule which was insignificantly less as compared to **6811.43 cells/cumm** among Placebo group.
- After 14 days of treatment, mean Total Leucocytes Count showed an insignificant fall of **0.6%** among PCA Capsule and **4.7%** in Placebo group from baseline. If compared, the change was comparable between the groups and the difference was not significant.

Figure 4: Mean change in Total Leucocytes Count (cells/cumm) from baseline by treatment group, ITT population

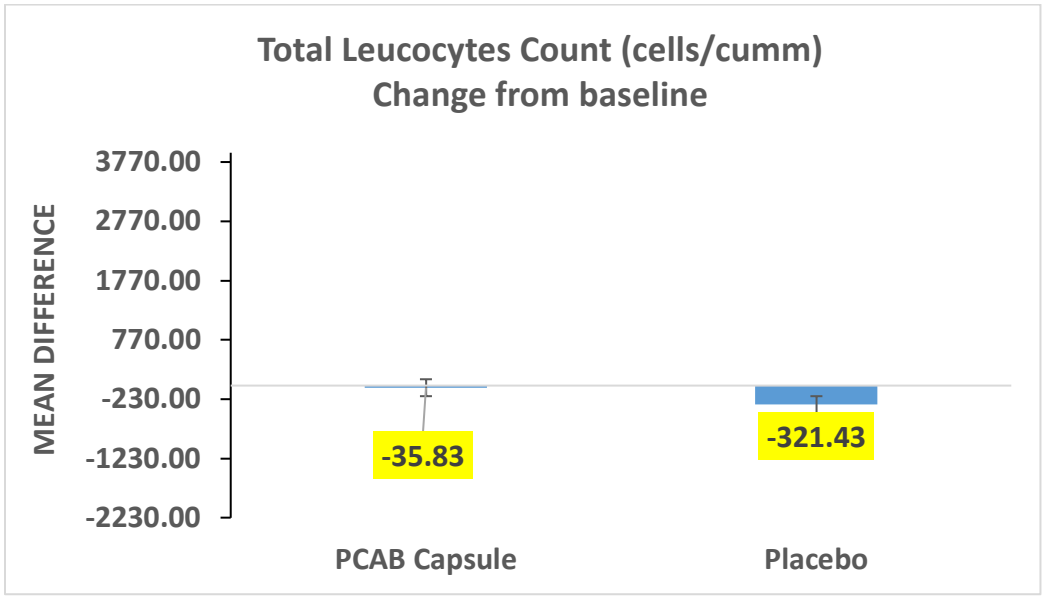


Table 8. Summary statistics of Neutrophils (%) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Neutrophils (%) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|------------------------------|----|------------------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 59.26 \pm 08.20 | 14 | 62.76 \pm 12.10 | 0.391 (NS) |
| 14 | 12 | 59.22 \pm 10.12 | 14 | 59.02 \pm 07.50 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | -00.04 (01.69) (0.982) NS | 14 | -03.74 (02.63) (0.178) NS | 0.248 (NS) |

By Student t test

NS = Not Significant

- According to this study at baseline, mean Neutrophils was **59.26%** among PCA Capsule which was comparable to **62.76%** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, mean Neutrophils showed an insignificant fall of **0.1%** among PCA Capsule and **6.0%** in Placebo group from baseline. If compared, the change was less among PCA Capsule than Placebo group, but the difference was not significant.

Figure 5: Mean change in Neutrophils (%) from baseline by treatment group, ITT population

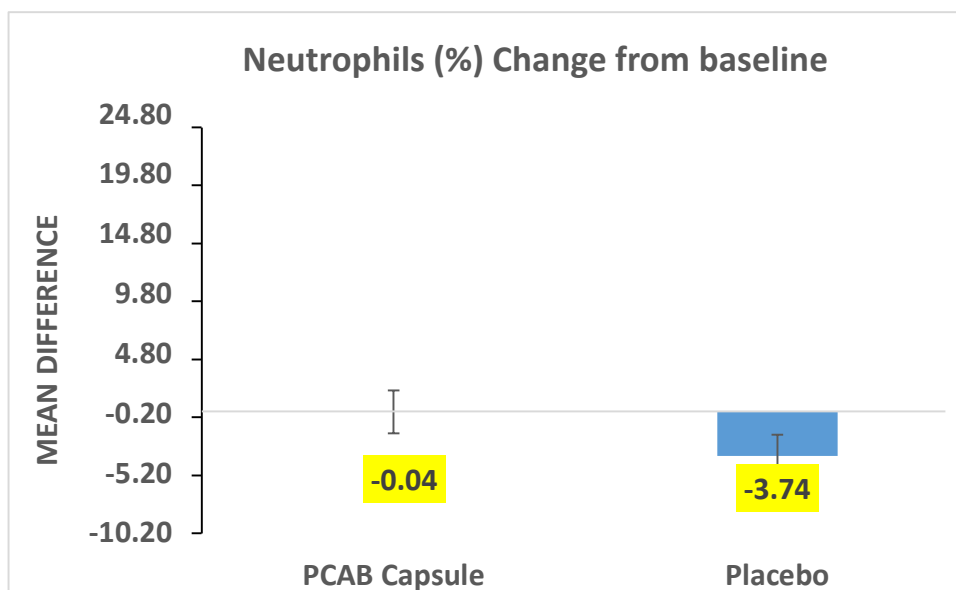


Table 9. Summary statistics of Neutrophils (absolute) (cells/cumm) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Neutrophils (absolute) (cells/cumm) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|------------------------------|----|--------------------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 3672.00 \pm 0964.93 | 14 | 4380.36 \pm 1740.18 | 0.203 (NS) |
| 14 | 12 | 3676.83 \pm 1165.71 | 14 | 3829.71 \pm 1248.63 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | 04.83 (336.91) (0.988) NS | 14 | -550.64 (413.42) (0.206) NS | 0.308 (NS) |

By Student t test

NS = Not Significant

- This result reveals that at baseline, mean Neutrophils (absolute) was **3672.00 cells/cumm** among PCA Capsule which was less as compared to **4380.36 cells/cumm** among Placebo group, but the difference was not significant.
- After 14 days of treatment, mean Neutrophils (absolute) showed an insignificant rise of **0.1%** among PCA Capsule and an insignificant fall of **12.6%** in Placebo group from baseline. If compared, the change was insignificantly more among PCA Capsule than Placebo group.

Figure 6: Mean change in Neutrophils (absolute) (cells/cumm) from baseline by treatment group, ITT population

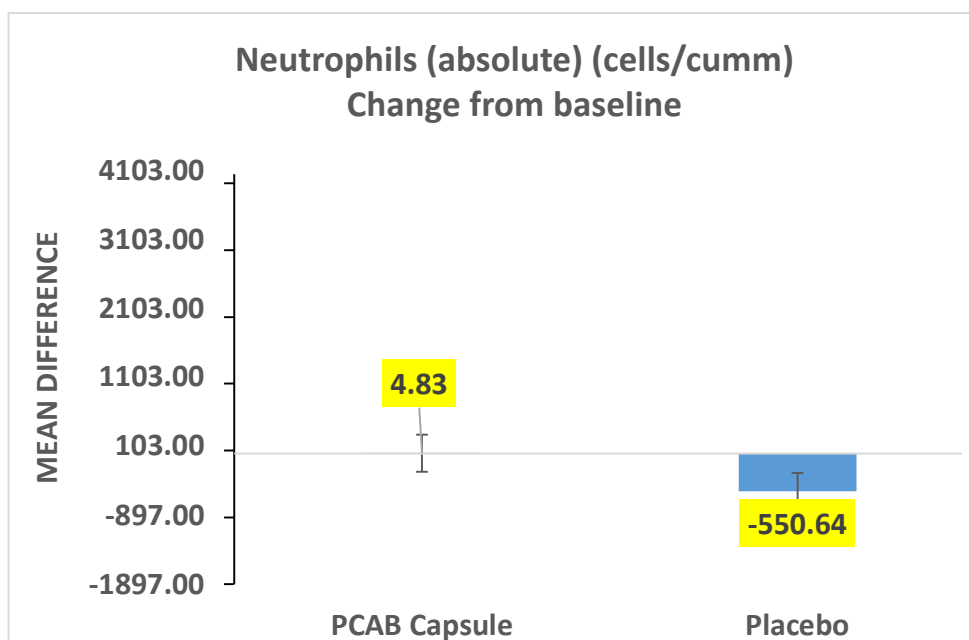


Table 10. Summary statistics of Lymphocytes (%) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Lymphocytes (%) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|----------------------------|----|---------------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 30.68 ± 06.69 | 14 | 26.17 ± 10.87 | 0.208 (NS) |
| 14 | 12 | 31.17 ± 08.90 | 14 | 33.12 ± 11.60 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | 00.49 (1.29) (0.712) NS | 14 | 06.95 (2.77) (0.026)NS | 0.045 (NS) |

By Student t test

NS = Not Significant

- This data suggest that at baseline, mean Lymphocytes was **30.68%** among PCA Capsule which was comparable to **26.17%** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, mean Lymphocytes showed an insignificant rise of **1.6%** among PCA Capsule and **26.6%** in Placebo group from baseline. If compared, the change was insignificantly more among Placebo than PCA Capsule group.

Figure 7: Mean change in Lymphocytes (%) from baseline by treatment group, ITT population

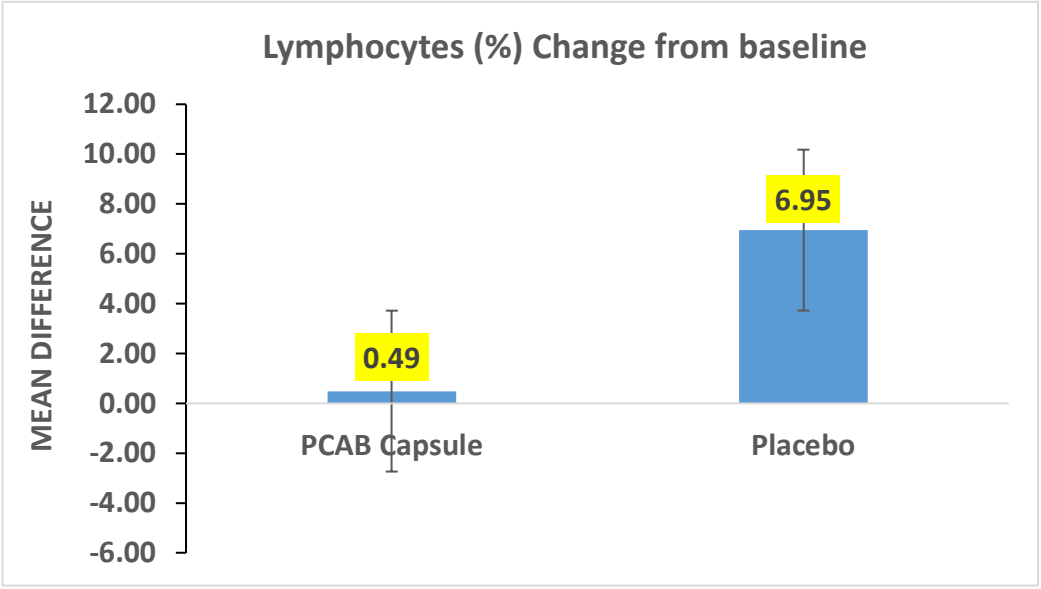


Table 11. Summary statistics of Lymphocytes (absolute) (cells/cumm) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Lymphocytes (absolute) (cells/cumm) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|----------------------|----|----------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 1868.67 \pm 426.80 | 14 | 1725.07 \pm 795.55 | 0.564 (NS) |
| 14 | 12 | 1853.33 \pm 448.65 | 14 | 2035.64 \pm 870.13 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | -15.33 (62.21) | 14 | 310.57 (127.43) | 0.030 |
| (p value) | | (0.810) NS | | (0.029)NS | (NS) |

By Student t test

NS = Not Significant

- The above table states that at baseline, mean Lymphocytes (absolute) was **1868.67 cells/cumm** among PCA Capsule which was more as compared to **1725.07 cells/cumm** among Placebo group but the difference was not significant.
- After 14 days of treatment, mean Lymphocytes (absolute) showed an insignificant fall of **0.8%** among PCA Capsule and an insignificant rise of **18.0%** in Placebo group from baseline. If compared, the change was insignificantly less among PCA Capsule than Placebo group.

Figure 8: Mean change in Lymphocytes (absolute) (cells/cumm) from baseline by treatment group, ITT population

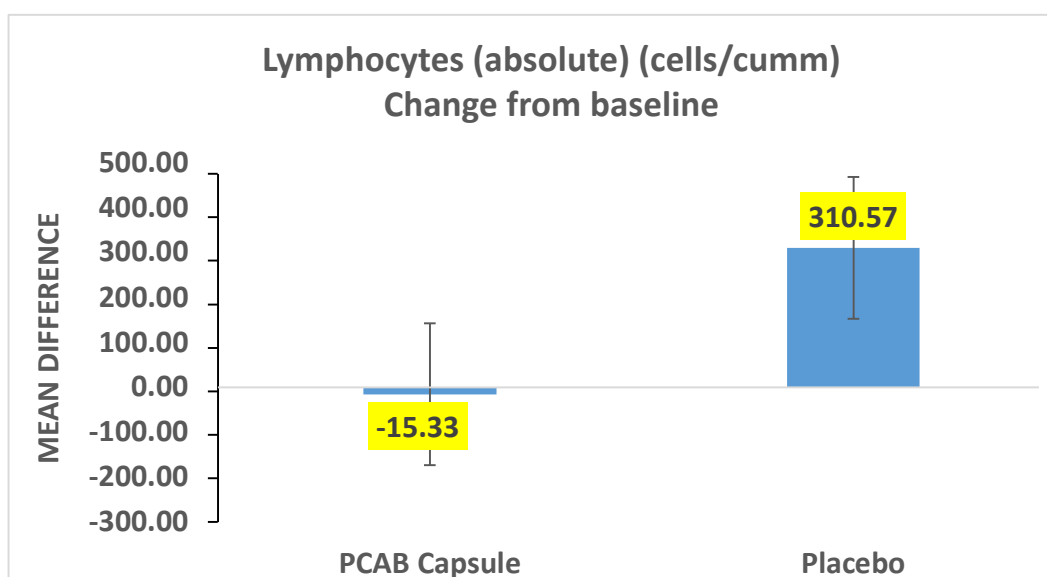


Table 12. Summary statistics of Monocytes (%) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Monocytes (%) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|---------------------------|----|----------------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 5.33 ± 0.96 | 14 | 6.35 ± 2.73 | 0.203 (NS) |
| 14 | 12 | 5.44 ± 1.19 | 14 | 6.20 ± 2.10 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | 0.12 (0.31) (0.707) NS | 14 | -0.15 (0.75) (0.844) NS | 0.742 (NS) |

By Student t test

NS = Not Significant

- In this analysis at baseline, mean Monocytes was **5.33%** among PCA Capsule which was comparable to **6.35%** among Placebo group and the difference was not significant.
- After 14 days of treatment, mean Monocytes showed an insignificant rise of **2.3%** among PCA Capsule and an insignificant fall of **2.4%** in Placebo group from baseline. If compared, the change was insignificantly more among PCA Capsule than Placebo group.

Figure 9: Mean change in Monocytes (%) from baseline by treatment group, ITT population

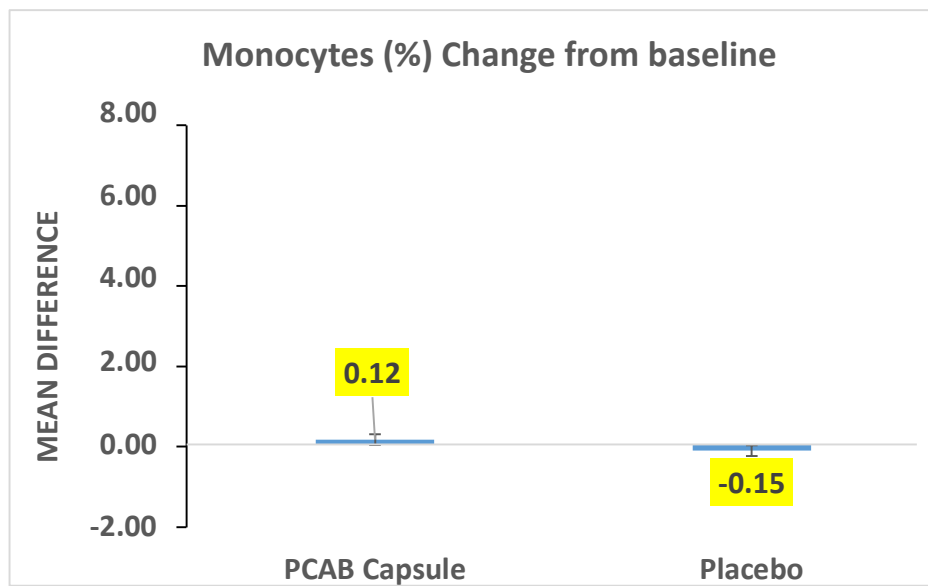


Table 13. Summary statistics of Monocytes (absolute) (cells/cumm) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Monocytes (absolute) (cells/cumm) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|----------------------------|----|----------------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 322.42 \pm 57.83 | 14 | 402.07 \pm 109.32 | 0.026 (NS) |
| 14 | 12 | 324.58 \pm 60.15 | 14 | 404.43 \pm 186.52 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | 2.17 (23.01) (0.926) NS | 14 | 2.36 (46.19) (0.960) NS | 0.997 (NS) |

By Student t test

NS = Not Significant

- This data reveals that at baseline, mean Monocytes (absolute) was **322.42 cells/cumm** among PCA Capsule which was insignificantly less as compared to **402.07 cells/cumm** among Placebo group.
- After 14 days of treatment, mean Monocytes (absolute) showed an insignificant rise of **0.7%** among PCA Capsule and **0.6%** in Placebo group from baseline. If compared, the change was comparable between the groups and the difference was not significant.

Figure 10: Mean change in Monocytes (absolute) (cells/cumm) from baseline by treatment group, ITT population

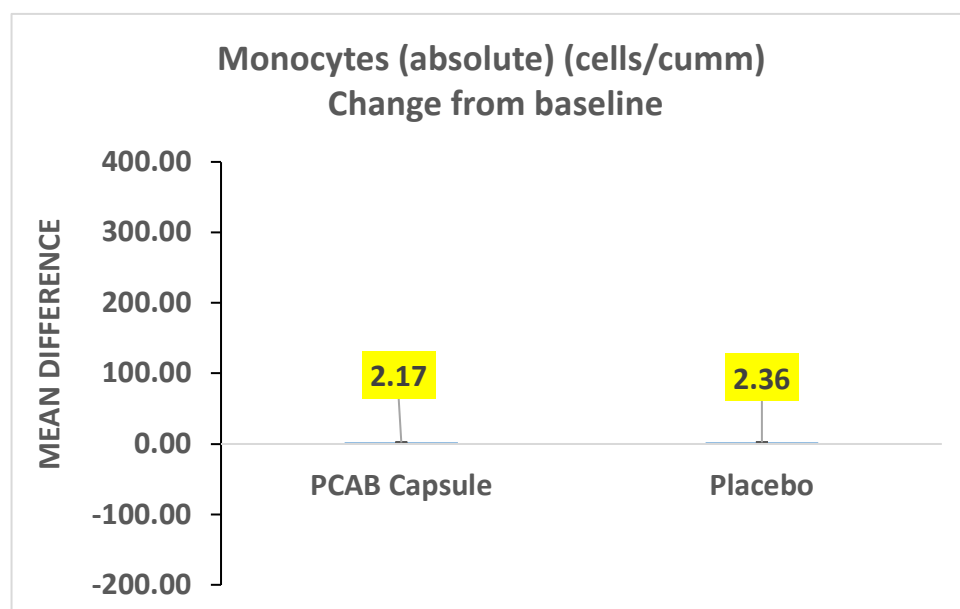


Table 14. Summary statistics of Eosinophils (%) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Eosinophils (%) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|----------------------------|----|----------------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 3.58 ± 2.07 | 14 | 3.86 ± 3.06 | 0.784 (NS) |
| 14 | 12 | 3.17 ± 1.64 | 14 | 2.96 ± 1.80 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | -0.42 (0.29) (0.173) NS | 14 | -0.89 (0.59) (0.154) NS | 0.479 (NS) |

By Student t test

NS = Not Significant

- In this study at baseline, mean Eosinophils was **3.58%** among PCA Capsule which was comparable to **3.86%** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, mean Eosinophils showed an insignificant fall of **11.7%** among PCA Capsule and **23.1%** in Placebo group from baseline. If compared, the change was insignificantly more among Placebo than PCA Capsule group.

Figure 11: Mean change in Eosinophils (%) from baseline by treatment group, ITT population

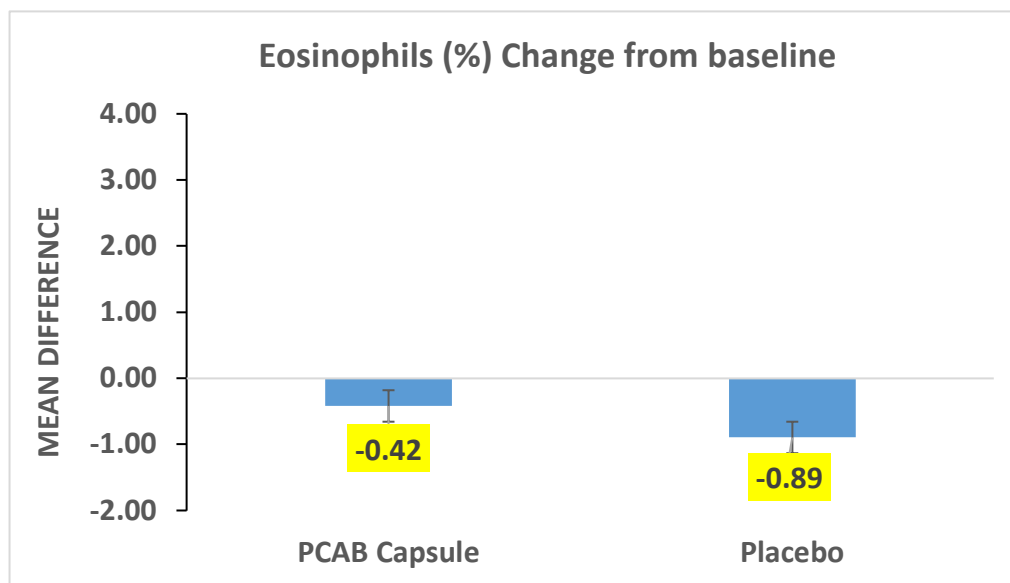


Table 15. Summary statistics of Eosinophils (absolute) (cells/cumm) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Eosinophils (absolute) (cells/cumm) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|------------------------------|----|------------------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 208.92 \pm 106.86 | 14 | 248.50 \pm 199.13 | 0.526 (NS) |
| 14 | 12 | 191.17 \pm 103.53 | 14 | 180.86 \pm 101.23 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | -17.75 (14.84) (0.256) NS | 14 | -67.64 (38.89) (0.105) NS | 0.242 (NS) |

By Student t test

NS = Not Significant

- This profile states that at baseline, mean Eosinophils (absolute) was **208.92 cells/cumm** among PCA Capsule which was insignificantly less as compared to **248.50 cells/cumm** among Placebo group.
- After 14 days of treatment, mean Eosinophils (absolute) showed an insignificant fall of **8.5%** among PCA Capsule and **27.2%** in Placebo group from baseline. If compared, the change was insignificantly less among PCA Capsule than Placebo group.

Figure 12: Mean change in Eosinophils (absolute) (cells/cumm) from baseline by treatment group, ITT population

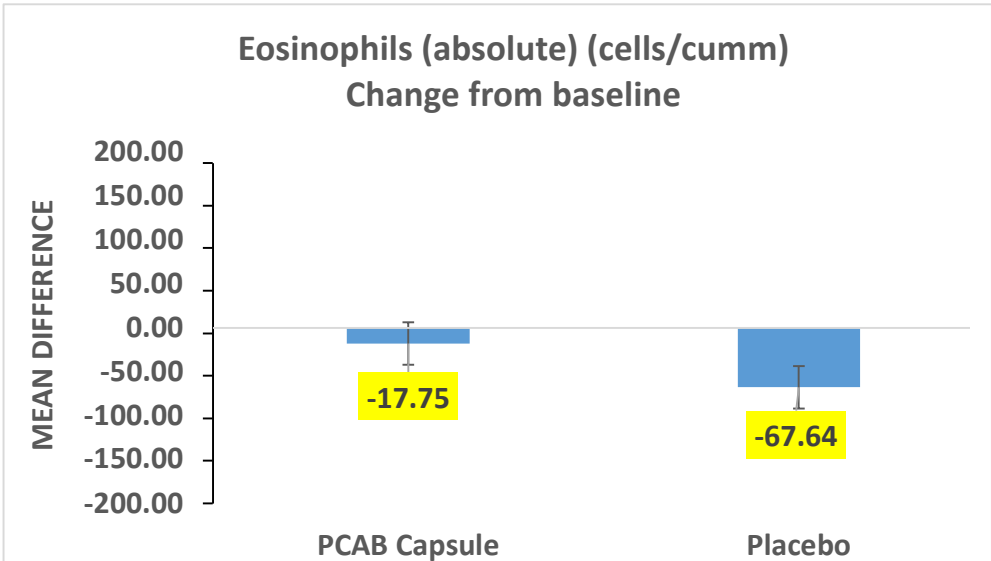


Table 16. Summary statistics of Basophils (%) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Basophils (%) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|----------------------------|----|---------------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 1.16 ± 0.32 | 14 | 0.86 ± 0.37 | 0.036 (NS) |
| 14 | 12 | 1.01 ± 0.28 | 14 | 0.92 ± 0.64 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | -0.15 (0.09) (0.121) NS | 14 | 0.06 (0.20) (0.772) NS | 0.353 (NS) |

By Student t test

NS = Not Significant

- According to this profile at baseline, mean Basophils was **1.16%** among PCA Capsule which was insignificantly more as compared to **0.86%** among Placebo group.
- After 14 days of treatment, mean Basophils showed an insignificant fall of **12.9%** among PCA Capsule and an insignificant rise of **7.0%** in Placebo group from baseline. If compared, the change was insignificantly more among Placebo than PCA Capsule group.

Figure 13: Mean change in Basophils (%) from baseline by treatment group, ITT population

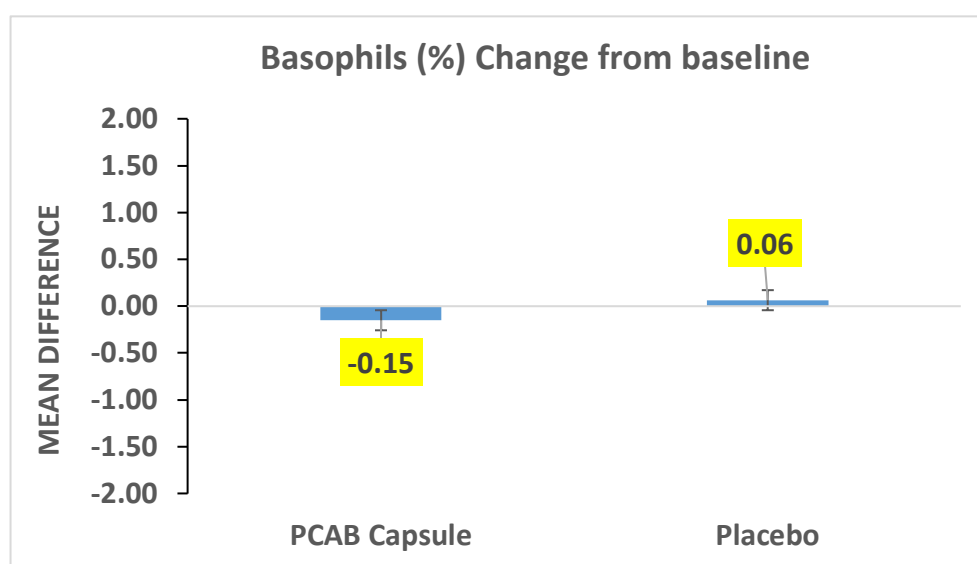


Table 17. Summary statistics of Basophils (absolute) (cells/cumm) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Basophils (absolute) (cells/cumm) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|----------------------------------|----|----------------------------------|------------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 69.77 \pm 18.82 | 14 | 55.73 \pm 20.83 | 0.083 (NS) |
| 14 | 12 | 59.85 \pm 13.79 | 14 | 47.71 \pm 16.32 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | -09.92 (07.01) (0.185) NS | 14 | -08.02 (05.85) (0.193) NS | 0.836 (NS) |

By Student t test

NS = Not Significant

- This result reveals that at baseline, mean Basophils (absolute) was **69.77 cells/cumm** among PCA Capsule which was more as compared to **55.73 cells/cumm** among Placebo group but the difference was not significant.
- After 14 days of treatment, mean Basophils (absolute) showed an insignificant fall of **14.2%** among PCA Capsule and **14.4%** in Placebo group from baseline. If compared, the change was comparable between the groups and the difference was not significant.

Figure 14: Mean change in Basophils (absolute) (cells/cumm) from baseline by treatment group, ITT population

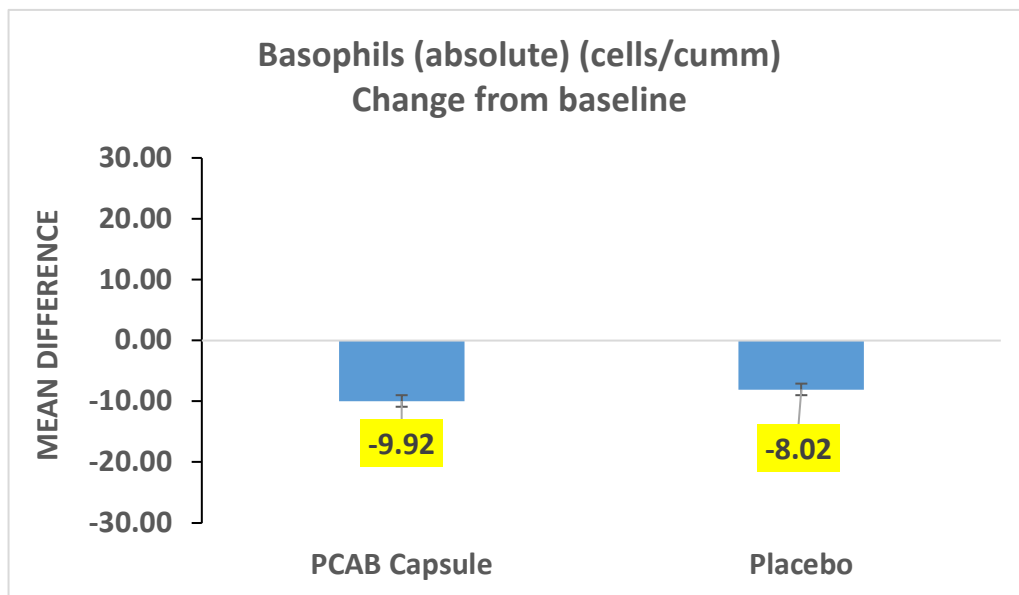


Table 18. Summary statistics of ESR(mm/hr) and change from baseline by treatment, ITT population

| Duration (Days) | Mean ESR (mm/hr) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|--|--|---------------|----|----------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 10.83 ± 07.83 | 14 | 13.50 ± 11.61 | 0.493 (NS) |
| 14 | 12 | 18.25 ± 16.93 | 14 | 31.93 ± 24.77 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | 07.42 (04.60) | 14 | *18.43 (04.59) | 0.103 |
| (p value) | | (0.135) NS | | (0.001) | (NS) |

By Student t test

NS = Not Significant

*Significant

- This data suggests that at baseline, mean ESR was **10.83 mm/hr** among PCA Capsule which was comparable to **13.50 mm/hr** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, mean ESR showed an insignificant rise of **68.5%** among PCA Capsule and a significant rise of **1.3 times** in Placebo group from baseline. If compared, the change was more among Placebo than PCA Capsule group, but the difference was not significant.

Figure 15: Mean change in ESR(mm/hr) from baseline by treatment group, ITT population

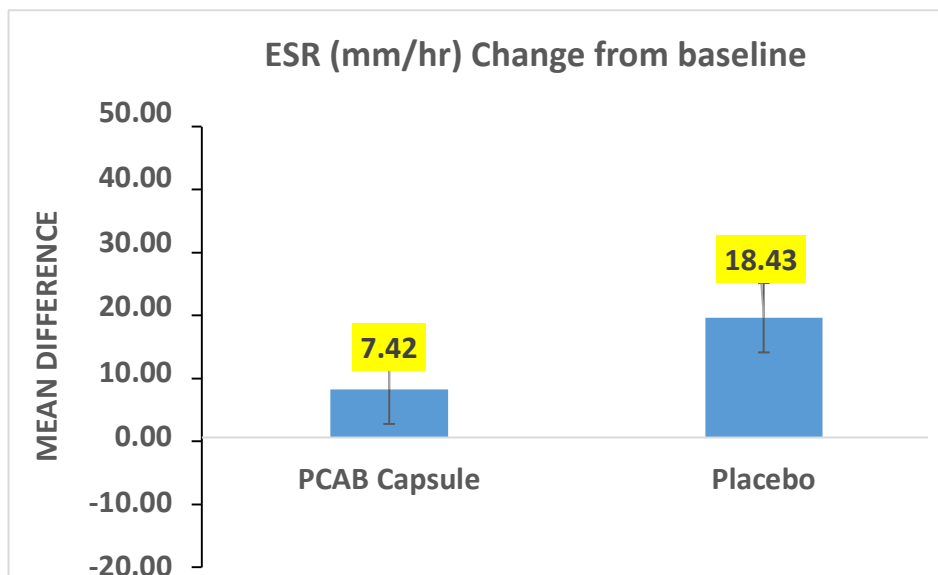


Table 19. Summary statistics of MCV (fL) and change from baseline by treatment, ITT population

| Duration (Days) | Mean MCV (fL) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|--|---------------------------------------|-------------------|----|-------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 85.98 \pm 04.43 | 14 | 86.18 \pm 11.25 | 0.951 (NS) |
| 14 | 12 | 85.66 \pm 04.13 | 14 | 85.01 \pm 12.44 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | -00.33 (00.17) | 14 | -01.17 (01.06) | 0.442 |
| (p value) | | (0.078) NS | | (0.290) NS | (NS) |

By Student t test

NS = Not Significant

- This result reveals that at baseline, the mean MCV was **85.98 fL** among PCA Capsule which was comparable to **86.18 fL** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, the mean MCV showed an insignificant fall of **0.4%** among PCA Capsule and **1.4%** in Placebo group from baseline. If compared, the change was comparable between the groups and the difference was not significant.

Figure 16: Mean change in MCV (fL) from baseline by treatment group, ITT population

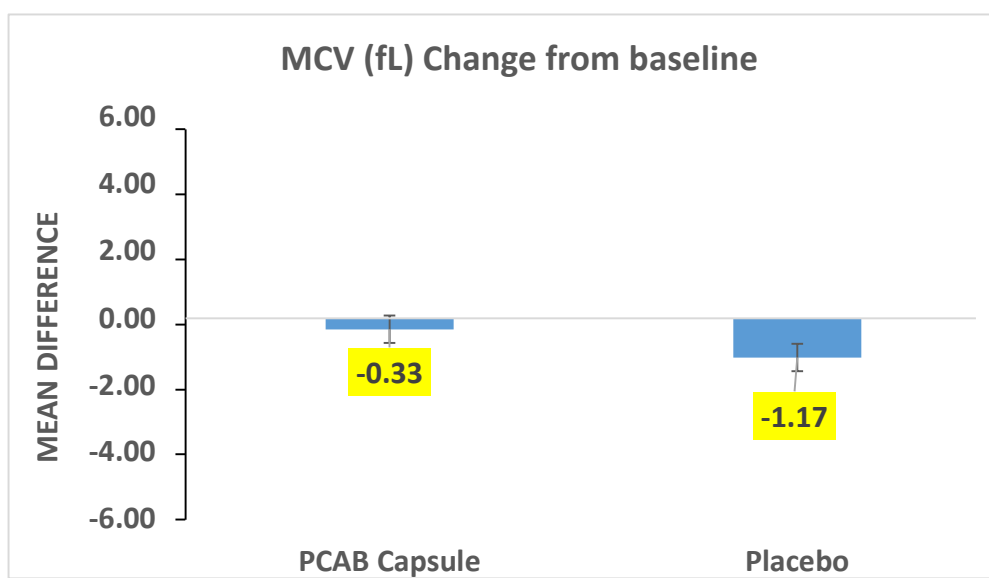


Table 20. Summary statistics of MCH (Pg) and change from baseline by treatment, ITT population

| Duration (Days) | Mean MCH (Pg) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|--|---------------------------------------|------------------------------|----|----------------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 29.83 \pm 1.64 | 14 | 29.71 \pm 4.63 | 0.928 (NS) |
| 14 | 12 | 29.81 \pm 1.70 | 14 | 30.69 \pm 5.28 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | -00.03 (00.12) (0.809) NS | 14 | 00.99 (1.04) (0.355) NS | 0.337 (NS) |

By Student t test

NS = Not Significant

- This result reveals that at baseline, the mean MCH was **29.83 Pg** among PCA Capsule which was comparable to **29.71 Pg** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, the mean MCH showed an insignificant fall of **0.1%** among PCA Capsule and insignificant rise of **3.3%** in Placebo group from baseline. If compared, the change was more among Placebo than PCA Capsule group, but the difference was not significant.

Figure 17: Mean change in MCH (Pg) from baseline by treatment group, ITT population

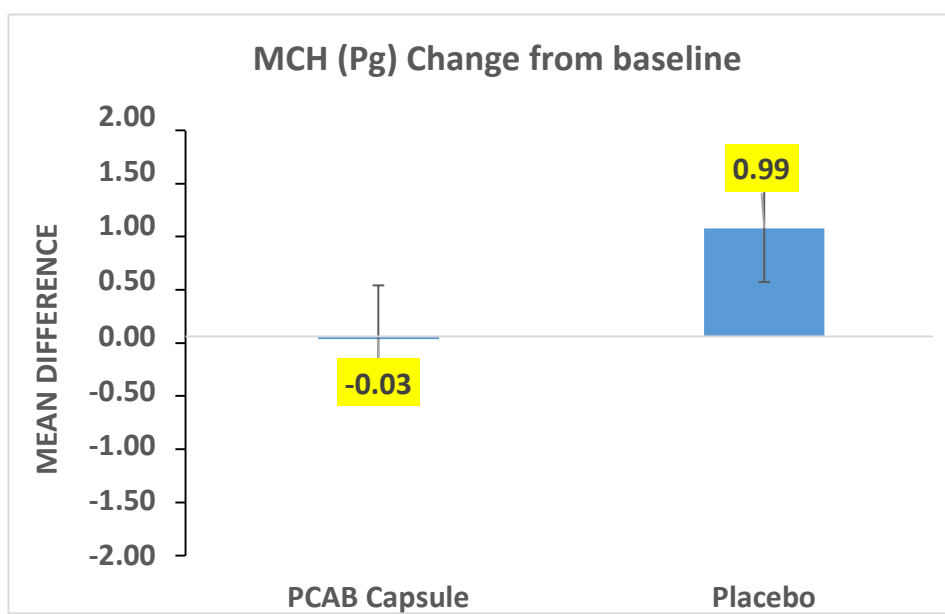


Table 21. Summary statistics of MCHC (g/dL) and change from baseline by treatment, ITT population

| Duration (Days) | Mean MCHC (g/dL) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|--|--|------------------|----|-------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 34.71 \pm 0.46 | 14 | 34.36 \pm 01.18 | 0.316 (NS) |
| 14 | 12 | 34.83 \pm 0.49 | 14 | 34.44 \pm 01.01 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | 00.12 (00.19) | 14 | 00.07 (00.11) | 0.822 |
| (p value) | | (0.547) NS | | (0.524) NS | (NS) |

By Student t test

NS = Not Significant

- This result reveals that at baseline, the mean MCHC was **34.71 g/dL** among PCA Capsule which was comparable to **34.36 g/dL** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, the mean MCHC showed an insignificant rise of **0.3%** among PCA Capsule and **0.2%** in Placebo group from baseline. If compared, the change was comparable between the groups and the difference was not significant.

Figure 18: Mean change in MCHC (g/dL) from baseline by treatment group, ITT population

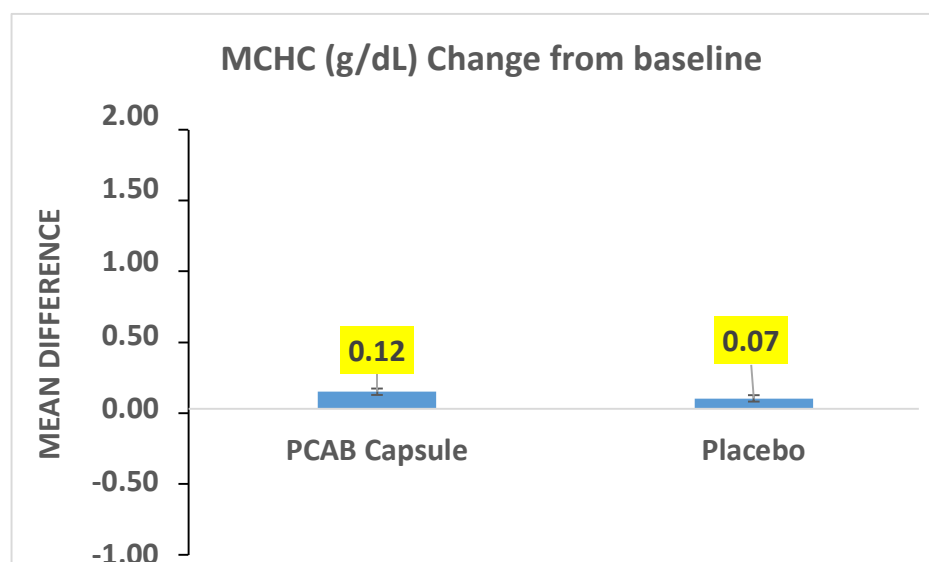


Table 22. Summary statistics of RDW (%) and change from baseline by treatment, ITT population

| Duration (Days) | Mean RDW (%) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|--|--------------------------------------|------------------|----|------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 12.97 \pm 1.13 | 14 | 13.99 \pm 2.37 | 0.165 (NS) |
| 14 | 12 | 12.80 \pm 1.10 | 14 | 13.80 \pm 2.04 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | -00.17 (00.18) | 14 | -00.19 (00.18) | 0.937 |
| (p value) | | (0.370) NS | | (0.301) | (NS) |

By Student t test

NS = Not Significant

- This data suggests that at baseline, the mean RDW was **12.97%** among PCA Capsule which was comparable to **13.99%** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, the mean RDW showed an insignificant fall of **1.3%** among PCA Capsule and **1.4%** in Placebo group from baseline. If compared, the change was comparable between the groups and the difference was not significant.

Figure 19: Mean change in RDW (%) from baseline by treatment group, ITT population

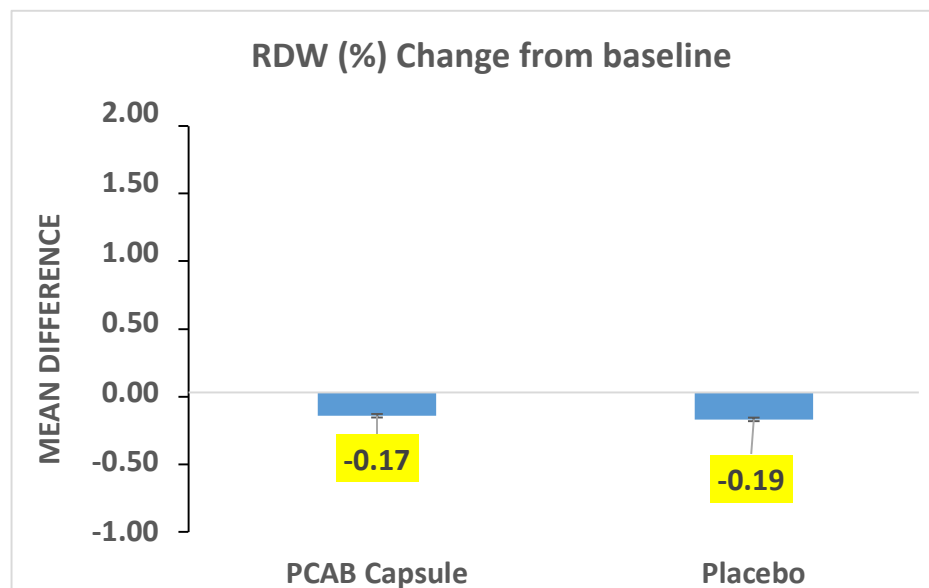


Table 23. Summary statistics of RBC Morphology and change from baseline by treatment, ITT population

| Parameters | RBC Morphology | | | | | | | |
|----------------------------|-----------------------|-------|-----|-------|-------------------|-------|------------|-------|
| | PCA Capsule (N=12) | | | | Placebo (N=14) | | | |
| | Baseline | | 14 | | Baseline | | 14 | |
| | No. | % | No. | % | No. | % | No. | % |
| Normocytic Normochromic | 12 | 100.0 | 12 | 100.0 | 14 | 100.0 | 14 | 100.0 |
| P value (Within group) | 1.000 (NS) | | | | 1.000 (NS) | | | |
| P value (Betwn group) | | | | | 1.000 (NS) | | 1.000 (NS) | |

By Fisher's exact test

NS = Not significant

- In this analysis at Baseline **100.0%** of the cases among both groups showed RBC Morphology Normocytic Normochromic which was same, and the difference was not significant.
- At Day 14, **100.0%** of the cases among PCA Capsule and Placebo group had RBC Morphology Normocytic Normochromic showed an insignificant change in both the groups from baseline. If compared change was same and difference was not significant.

Figure 20: Percentage change in RBC Morphology from baseline by treatment group, ITT population

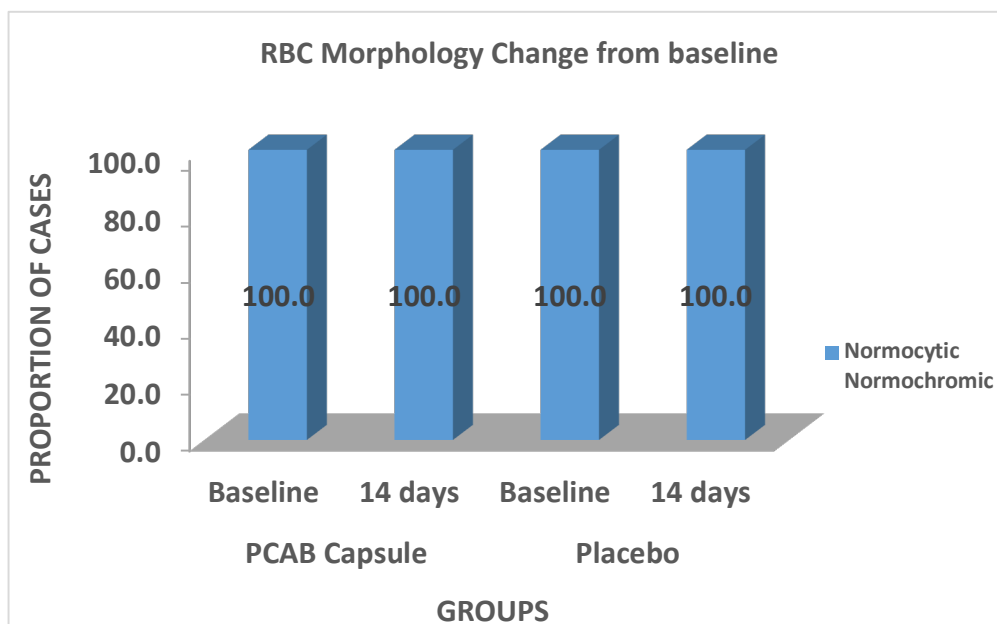


Table 24. Summary statistics of WBC Morphology and change from baseline by treatment, ITT population

| Parameters | WBC Morphology | | | | | | | |
|---------------------------|-----------------------|-------|-----|-------|-------------------|------|------------|------|
| | PCA Capsule (N=12) | | | | Placebo (N=14) | | | |
| | Baseline | | 14 | | Baseline | | 14 | |
| | No. | % | No. | % | No. | % | No. | % |
| Within normal limit | 12 | 100.0 | 12 | 100.0 | 12 | 85.7 | 13 | 92.9 |
| Mild lymphopenia | - | - | - | - | 01 | 07.1 | - | - |
| Neutrophilia | - | - | - | - | 01 | 07.1 | - | - |
| Lymphopenia | - | - | - | - | - | - | 01 | 07.1 |
| P value (Within group) | 1.000 (NS) | | | | 1.000 (NS) | | | |
| P value (Betwn group) | | | | | 0.483 (NS) | | 1.000 (NS) | |

By Fisher's exact test

NS = Not significant

- According to this study at Baseline **100.0%** of the cases among PCA Capsule group showed WBC Morphology Within normal limit which was more as compared to **85.7%** in Placebo group, but the difference was not significant.
- At Day 14, **100.0%** of the cases among PCA Capsule and **92.9%** cases in Placebo group had WBC Morphology Within normal limit showed an insignificant change in both the groups from baseline. If compared change was more among PCA Capsule than Placebo group but the difference was not significant.

Figure 21: Percentage change in WBC Morphology from baseline by treatment group, ITT population

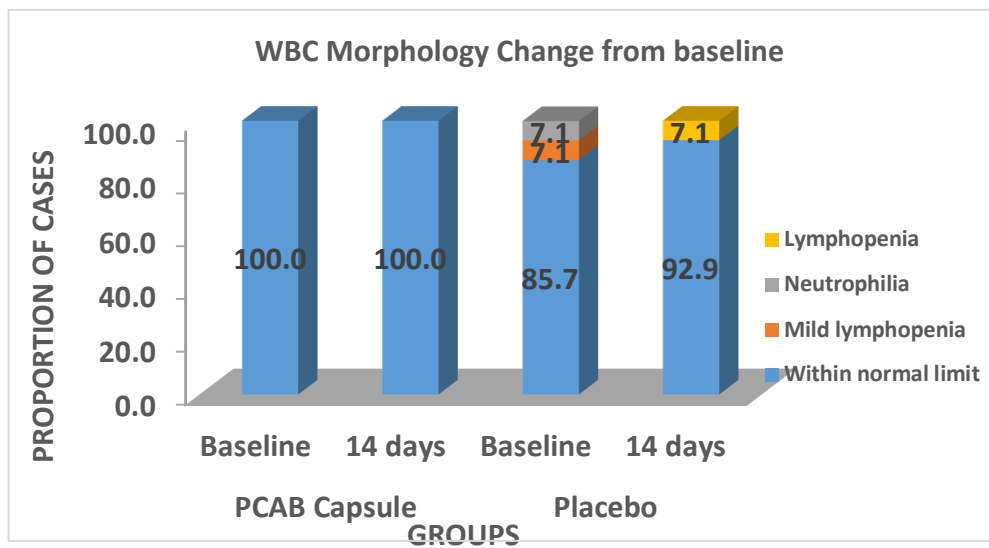


Table 25. Summary statistics of Platelet Morphology and change from baseline by treatment, ITT population

| Parameters | Mean Platelet Morphology | | | | | | | |
|---------------------------|--------------------------|------|-----|------|-------------------|-------|------------|------|
| | PCA Capsule (N=12) | | | | Placebo (N=14) | | | |
| | Baseline | | 12 | | Baseline | | 14 | |
| | No. | % | No. | % | No. | % | No. | % |
| Adequate on smear | 11 | 91.7 | 11 | 91.7 | 14 | 100.0 | 13 | 92.9 |
| Mild Thrombocytosis | 01 | 08.3 | - | - | - | - | - | - |
| Thrombocytosis | - | - | 01 | 8.3 | - | - | 01 | 07.1 |
| P value (Within group) | 1.000 (NS) | | | | 1.000 (NS) | | | |
| P value (Betwn group) | | | | | 0.461 (NS) | | 1.000 (NS) | |

By Fisher's exact test

NS = Not significant

- As per this profile at Baseline **91.7%** of the cases among PCA Capsule group showed Platelet Morphology Adequate on smear which was less as compared to **100.0%** in Placebo group but the difference was not significant.
- At Day 14, **91.7%** of the cases among PCA Capsule and **92.9%** cases in Placebo group had Platelet Morphology Adequate on smear showed an insignificant change in both the groups from baseline. If compared change was comparable between the groups and difference was not significant.

Figure 22: Percentage change in Platelet Morphology from baseline by treatment group, ITT population

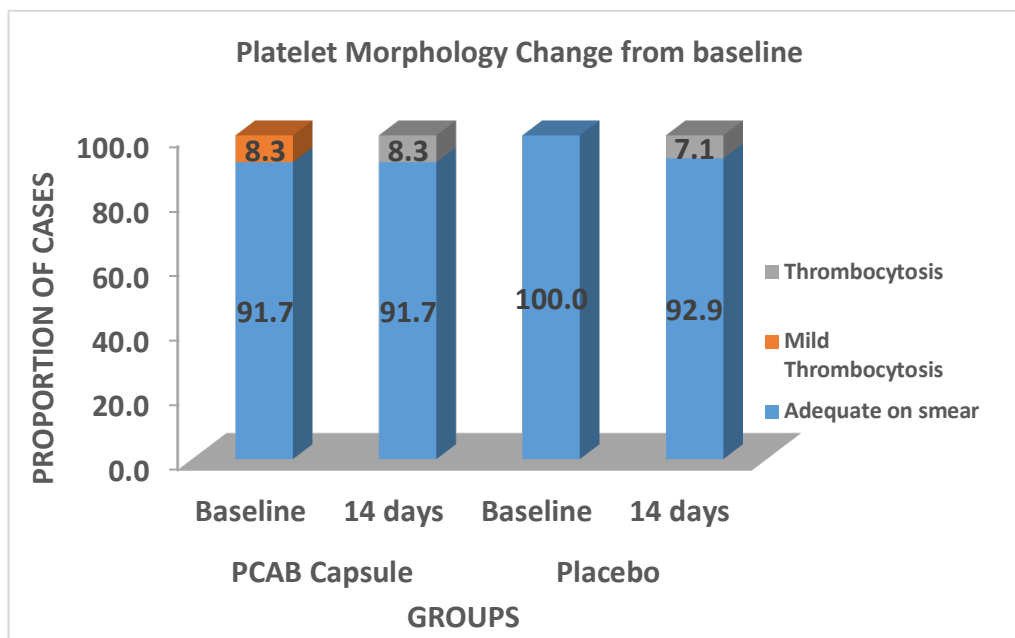


Table 26. Summary statistics of Mean Platelet Volume and change from baseline by treatment, ITT population

| Duration (Days) | Mean Platelet Volume ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|-----------------|----|-----------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 9.09 \pm 0.85 | 14 | 8.89 \pm 0.73 | 0.529 (NS) |
| 14 | 12 | 8.93 \pm 0.81 | 14 | 8.74 \pm 0.62 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | -0.17 (0.09) | 14 | -0.16 (0.07) | 0.932 |
| (p value) | | (0.084) NS | | (0.045) NS | (NS) |

By Student t test

NS = Not Significant

- This data suggests that at baseline, mean Platelet Volume was **9.09 fL** among PCA Capsule which was comparable to **8.89 fL** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, mean Platelet Volume showed an insignificant fall of **1.9%** among PCA Capsule and **1.8%** in Placebo group from baseline. If compared, the change was comparable between the groups and the difference was not significant.

Figure 23: Mean change in Mean Platelet Volume from baseline by treatment group, ITT population

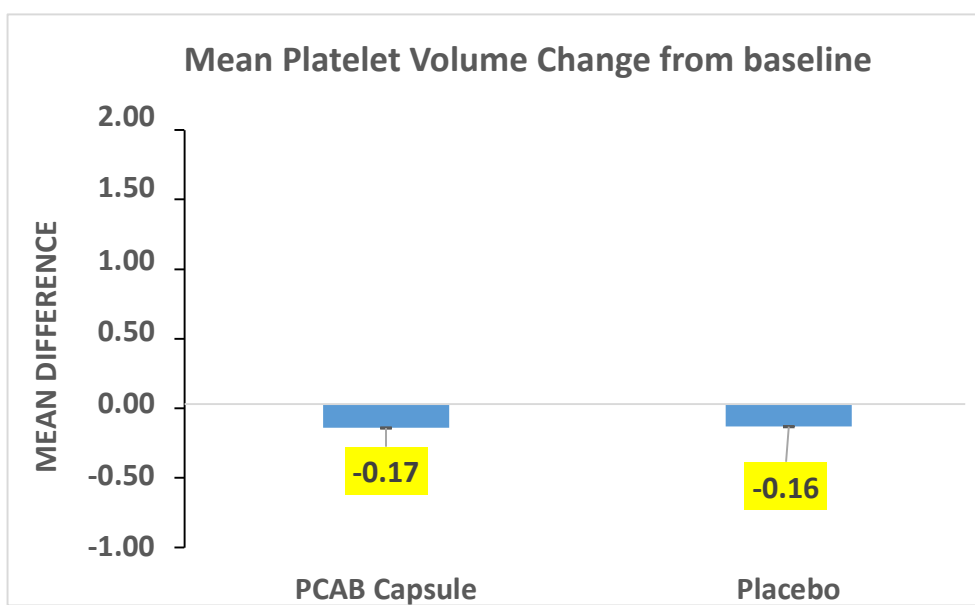


Table 27. Summary statistics of PDW and change from baseline by treatment, ITT population

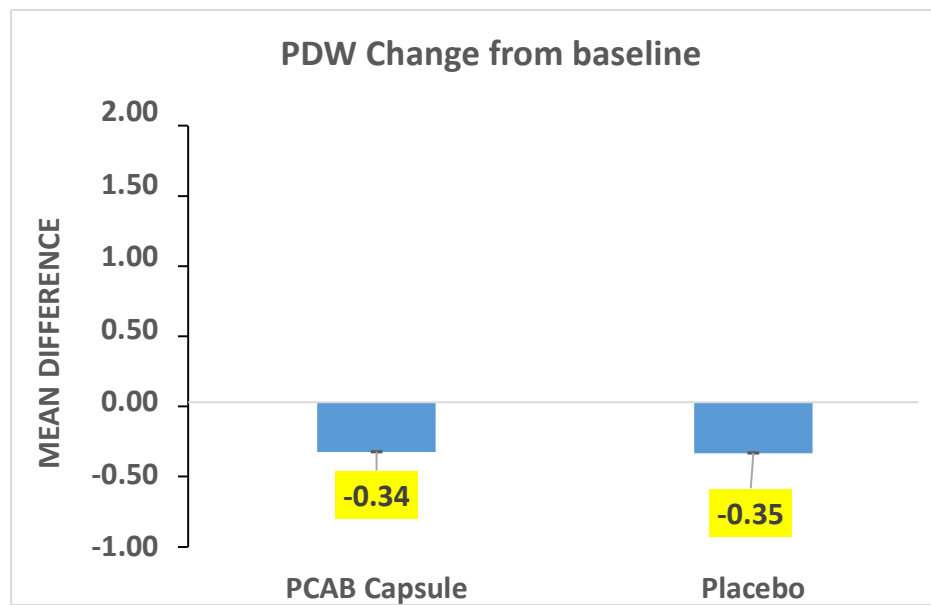
| Duration (Days) | Mean PDW ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|----------------------------------|------------------------------|----|------------------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 15.11 \pm 2.72 | 14 | 14.51 \pm 2.31 | 0.553 (NS) |
| 14 | 12 | 14.77 \pm 2.62 | 14 | 14.16 \pm 2.11 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | -00.34 (00.26) (0.222) NS | 14 | -00.35 (00.30) (0.267) NS | 0.980 (NS) |

By Student t test

NS = Not Significant

- This result reveals that at baseline, the mean PDW was **15.11%** among PCA Capsule which was comparable to **14.51%** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, the mean PDW showed an insignificant fall of **2.3%** among PCA Capsule and **2.4%** in Placebo group from baseline. If compared, the change was comparable between the groups and the difference was not significant.

Figure 24: Mean change in PDW from baseline by treatment group, ITT population



BIOCHEMICAL PARAMETER: -

Table 28. Summary statistics of Serum Creatinine (mg/dL) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Serum Creatinine (mg/dL) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|---|----------------------------|----|-----------------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 0.811 \pm 0.218 | 14 | 0.881 \pm 0.191 | 0.396 (NS) |
| 14 | 12 | 0.812 \pm 0.212 | 14 | 0.879 \pm 0.211 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | 0.001 (0.01) (0.948) NS | 14 | -0.002 (0.02) (0.899) NS | 0.890 (NS) |

By Student t test

NS = Not Significant

- This result reveals that at baseline, the mean Serum Creatinine was **0.811 mg/dL** among PCA Capsule which was comparable to **0.881 mg/dL** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, the mean Serum Creatinine showed an insignificant rise of **0.1%** among PCA Capsule and an insignificant fall of **0.2%** in Placebo group from baseline. If compared, the change was more among PCA Capsule than Placebo group, but the difference was not significant

**Figure 25: Mean change in Serum Creatinine (mg/dL) from baseline
by treatment group, ITT population**

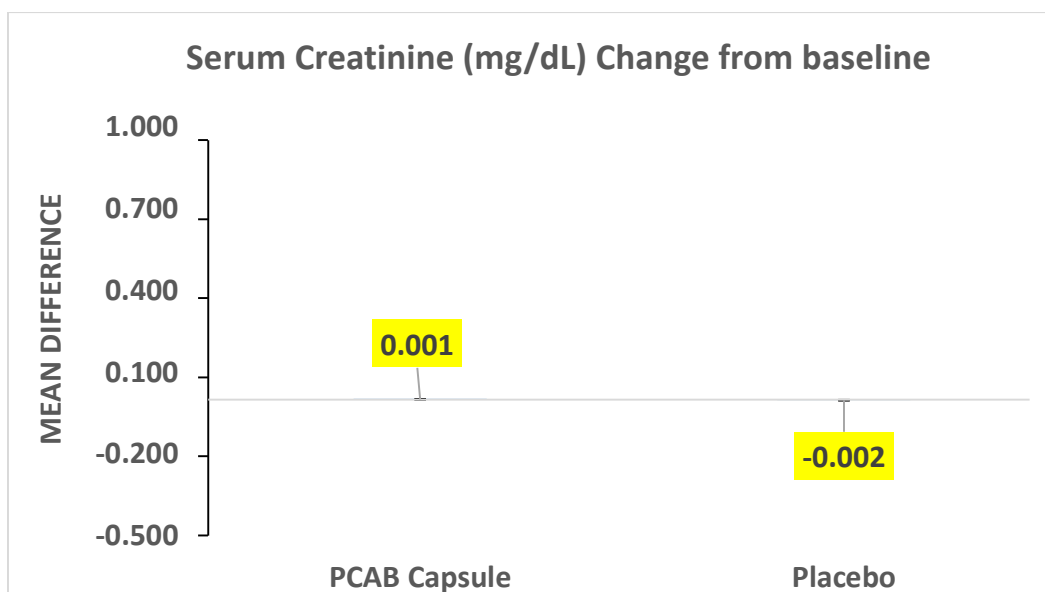


Table 29. Summary statistics of Serum Blood Urea (mg/dL) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Serum Blood Urea (mg/dL) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|---|----------------------------|----|-----------------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 21.19 \pm 5.97 | 14 | 22.10 \pm 5.50 | 0.691 (NS) |
| 14 | 12 | 21.69 \pm 6.89 | 14 | 21.64 \pm 4.77 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | 00.50 (1.40) (0.728) NS | 14 | -00.46 (1.15) (0.695) NS | 0.601 (NS) |

By Student t test

NS = Not Significant

- This result reveals that at baseline, the mean Serum Blood Urea was **21.19 mg/dL** among PCA Capsule which was comparable to **22.10 mg/dL** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, the mean Serum Blood Urea showed an insignificant rise of **2.4%** among PCA Capsule and an insignificant fall of **2.1%** in Placebo group from baseline. If compared, the change was more among PCA Capsule than Placebo group, but the difference was not significant.

Figure 26: Mean change in Serum Blood Urea (mg/dL) from baseline by treatment group, ITT population

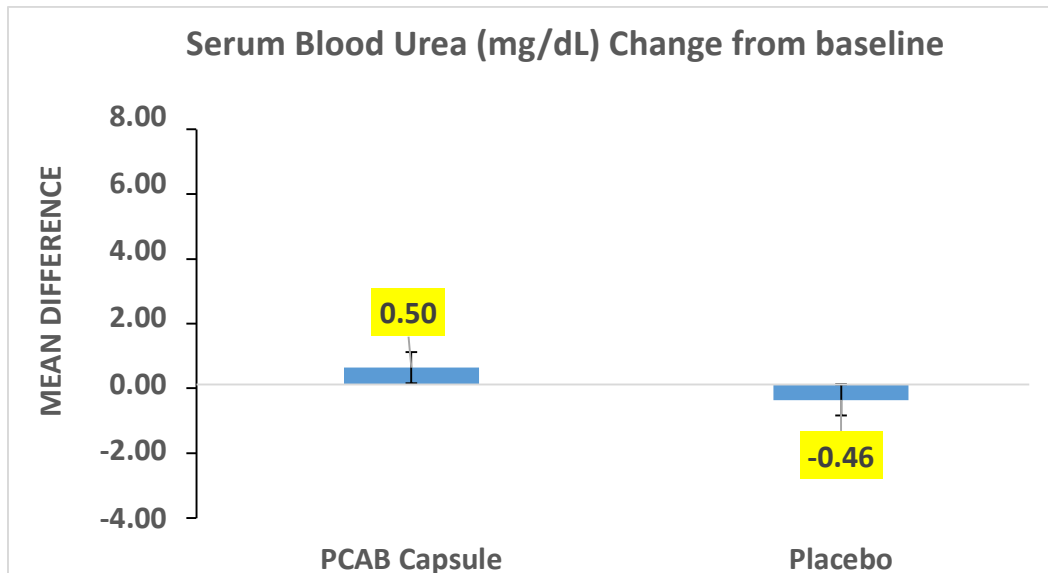


Table 30. Summary statistics of Blood Urea Nitrogen (mg/dL) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Blood Urea Nitrogen (mg/dL) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|------------------|----|------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 09.90 \pm 2.79 | 14 | 10.33 \pm 2.57 | 0.688 (NS) |
| 14 | 12 | 10.13 \pm 3.22 | 14 | 10.11 \pm 2.23 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | 00.23 (0.66) | 14 | -00.21 (0.54) | 0.608 |
| (p value) | | (0.732) NS | | (0.702) NS | (NS) |

By Student t test

NS = Not Significant

- This result reveals that at baseline, the mean Blood Urea Nitrogen was **9.90 mg/dL** among PCA Capsule which was comparable to **10.33 mg/dL** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, the mean Blood Urea Nitrogen showed an insignificant rise of **2.3%** among PCA Capsule and an insignificant fall of **2.0%** in Placebo group from baseline. If compared, the change was more among PCA Capsule than Placebo group, but the difference was not significant.

Figure 27: Mean change in Blood Urea Nitrogen (mg/dL) from baseline by treatment group, ITT population

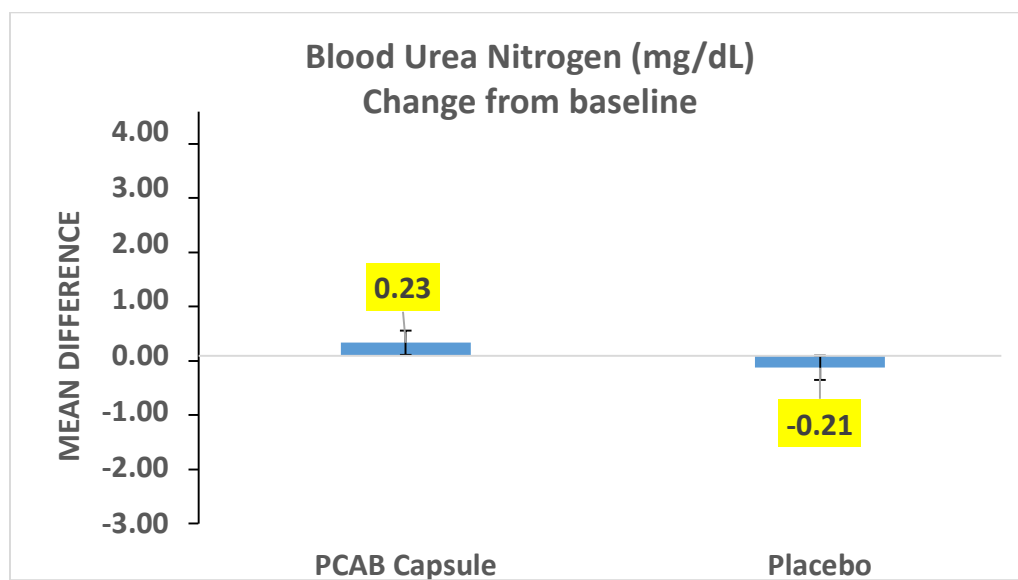


Table 31. Summary statistics of Serum Calcium (mg/dL) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Serum Calcium (mg/dL) ($\bar{X} \pm SD$) | | | | Between Groups |
|-----------------------------------|--|---------------------------|----|----------------------------|-------------------|
| | N | PCA Capsule | N | Placebo | (P value) |
| Baseline | 12 | 9.75 \pm 0.37 | 14 | 9.61 \pm 0.55 | 0.448 (NS) |
| 14 | 12 | 9.81 \pm 0.38 | 14 | 9.40 \pm 0.45 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | 0.06 (0.13) (0.653) NS | 14 | -0.21 (0.10) (0.048) NS | 0.107 (NS) |

By Student t test

NS = Not Significant

- This data suggests that at baseline, mean Serum Calcium was **9.75 mg/dL** among PCA Capsule which was comparable to **9.61 mg/dL** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, mean Serum Calcium showed an insignificant rise of **0.6%** among PCA Capsule and an insignificant fall of **2.2%** in Placebo group from baseline. If compared, the change was more among PCA Capsule than Placebo group, but the difference was not significant.

Figure 28: Mean change in Serum Calcium (mg/dL) from baseline by treatment group, ITT population

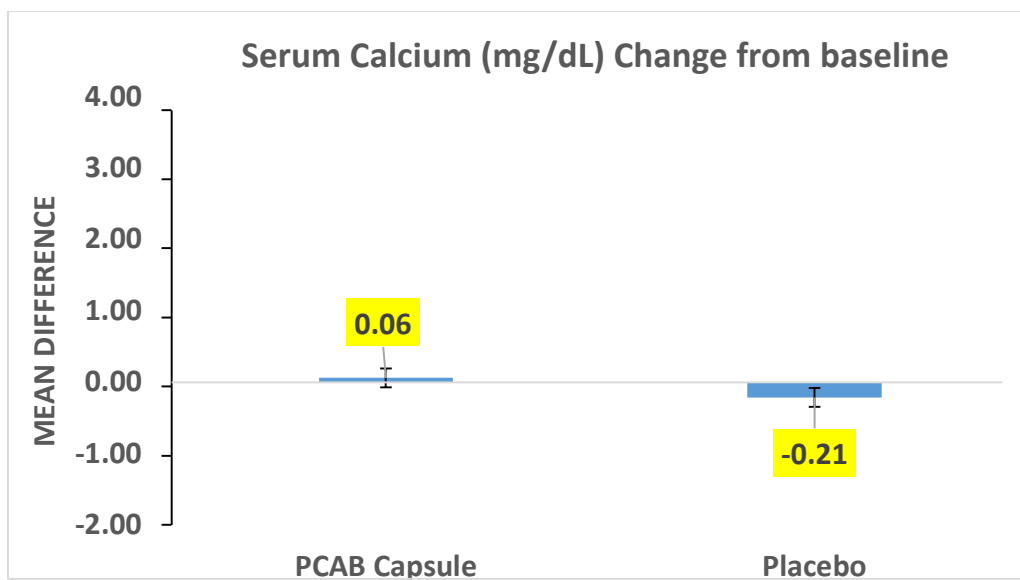


Table 32. Summary statistics of Sodium (mmol/L) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Sodium (mmol/L) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|-------------------|----|-------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 139.25 \pm 2.86 | 14 | 138.50 \pm 3.70 | 0.565 (NS) |
| 14 | 12 | 138.50 \pm 4.06 | 14 | 137.00 \pm 3.19 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | -000.75 (1.11) | 14 | -001.50 (0.80) | 0.587 |
| (p value) | | (0.513) NS | | (0.082) NS | (NS) |

By Student t test

NS = Not Significant

- This result reveals that at baseline, the mean Sodium was **139.25 mmol/L** among PCA Capsule which was comparable to **138.50 mmol/L** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, the mean Sodium showed an insignificant fall of **0.5%** among PCA Capsule and **1.1%** in Placebo group from baseline. If compared, the change was comparable between the groups and the difference was not significant.

**Figure 29: Mean change in Sodium (mmol/L) from baseline
by treatment group, ITT population**

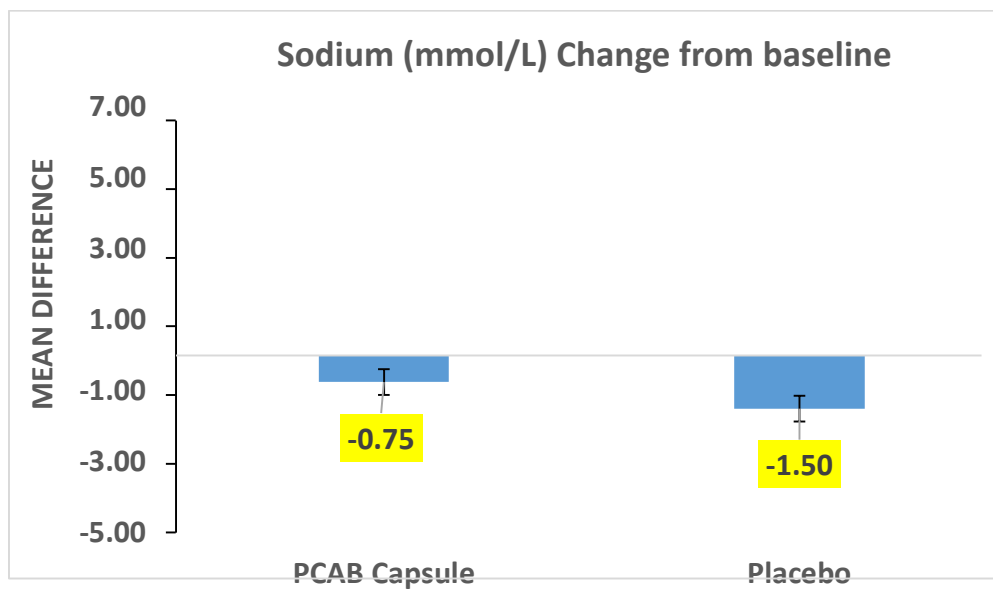


Table 33. Summary statistics of Potassium (mmol/L) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Potassium (mmol/L) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|---|-------------------|----|-------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 5.052 \pm 0.533 | 14 | 5.022 \pm 0.308 | 0.864 (NS) |
| 14 | 12 | 4.953 \pm 0.503 | 14 | 5.023 \pm 0.591 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | -0.099 (0.19) | 14 | 0.001 (0.18) | 0.705 |
| (p value) | | (0.618) NS | | (0.995) NS | (NS) |

By Student t test

NS = Not Significant

- This result reveals that at baseline, the mean Potassium was **5.05 mmol/L** among PCA Capsule which was comparable to **5.02 mmol/L** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, the mean Potassium showed an insignificant fall of **2.0%** among PCA Capsule and an insignificant rise of **0.02%** in Placebo group from baseline. If compared, the change was insignificantly more among Placebo than PCA Capsule group.

**Figure 30: Mean change in Potassium (mmol/L) from baseline
by treatment group, ITT population**

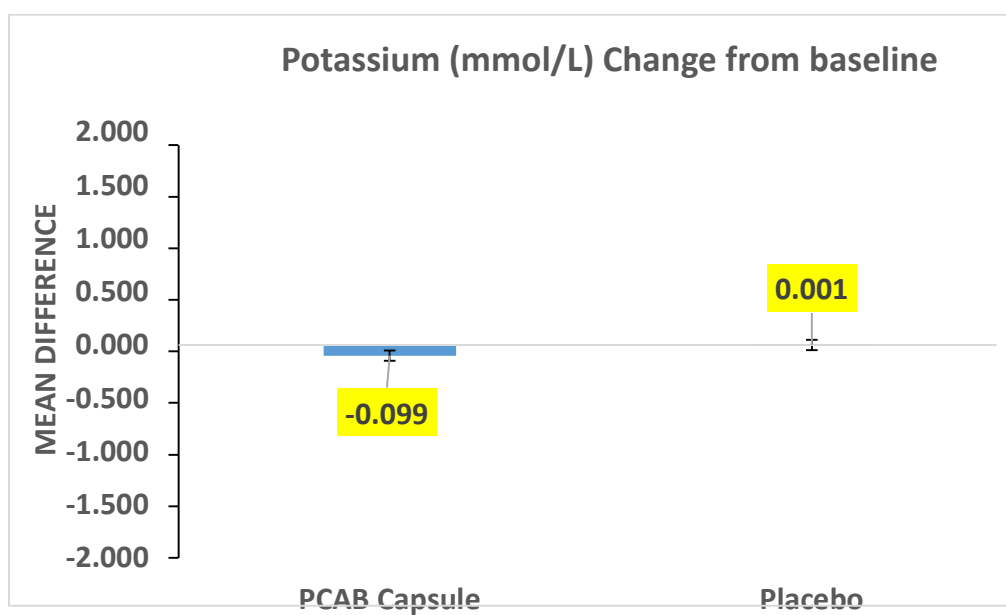


Table 34. Summary statistics of Chloride (mmol/L) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Chloride (mmol/L) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|------------------------------|----|------------------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 103.21 \pm 2.96 | 14 | 101.68 \pm 3.98 | 0.273 (NS) |
| 14 | 12 | 102.91 \pm 3.18 | 14 | 101.61 \pm 3.58 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | -000.30 (0.74) (0.691) NS | 14 | -000.06 (0.62) (0.924) NS | 0.804 (NS) |

By Student t test

NS = Not Significant

- This result reveals that at baseline, the mean Chloride was **103.21 mmol/L** among PCA Capsule which was comparable to **101.68 mmol/L** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, the mean Chloride showed an insignificant fall of **0.3%** among PCA Capsule and **0.1%** in Placebo group from baseline. If compared, the change was comparable between the groups and the difference was not significant.

**Figure 31: Mean change in Chloride (mmol/L) from baseline
by treatment group, ITT population**

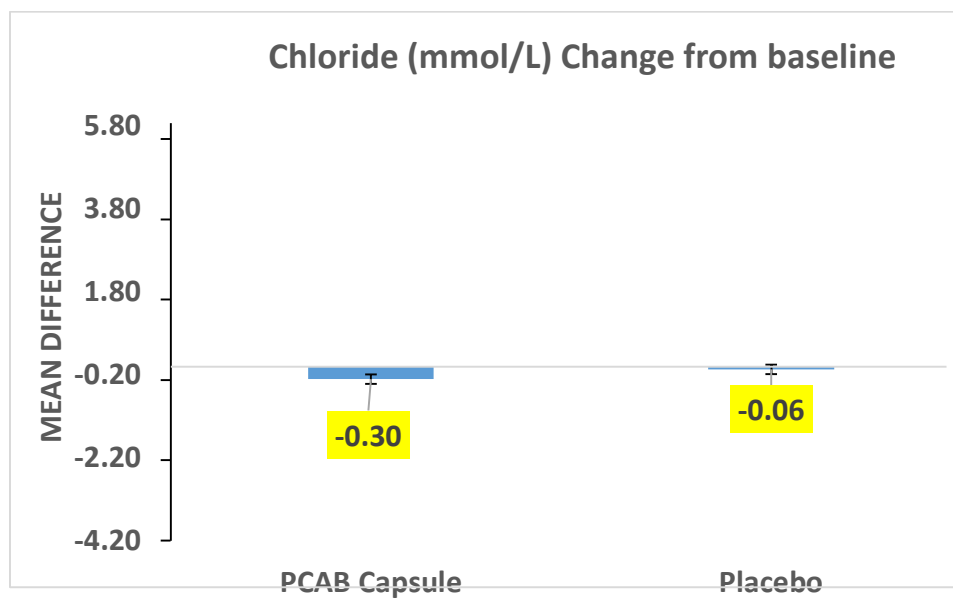


Table 35. Summary statistics of Bilirubin (Total) (mg/dL) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Bilirubin (Total) (mg/dL) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|-------------|----|--------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 0.60 ± 0.17 | 14 | 0.82 ± 0.42 | 0.085 (NS) |
| 14 | 12 | 0.68 ± 0.32 | 14 | 0.79 ± 0.40 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | 0.09 (0.11) | 14 | -0.03 (0.06) | 0.344 |
| (p value) | | (0.429) NS | | (0.618) NS | (NS) |

By Student t test

NS = Not Significant

- Above table reveals that at baseline, mean Bilirubin (Total) was **0.60 mg/dL** among PCA Capsule which was comparable to **0.82 mg/dL** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, mean Bilirubin (Total) showed an insignificant rise of **15.0%** among PCA Capsule and an insignificant fall of **3.7%** in Placebo group from baseline. If compared, the change was more among PCA Capsule than Placebo, but the difference was not significant.

**Figure 32: Mean change in Bilirubin (Total) (mg/dL) from baseline
by treatment group, ITT population**

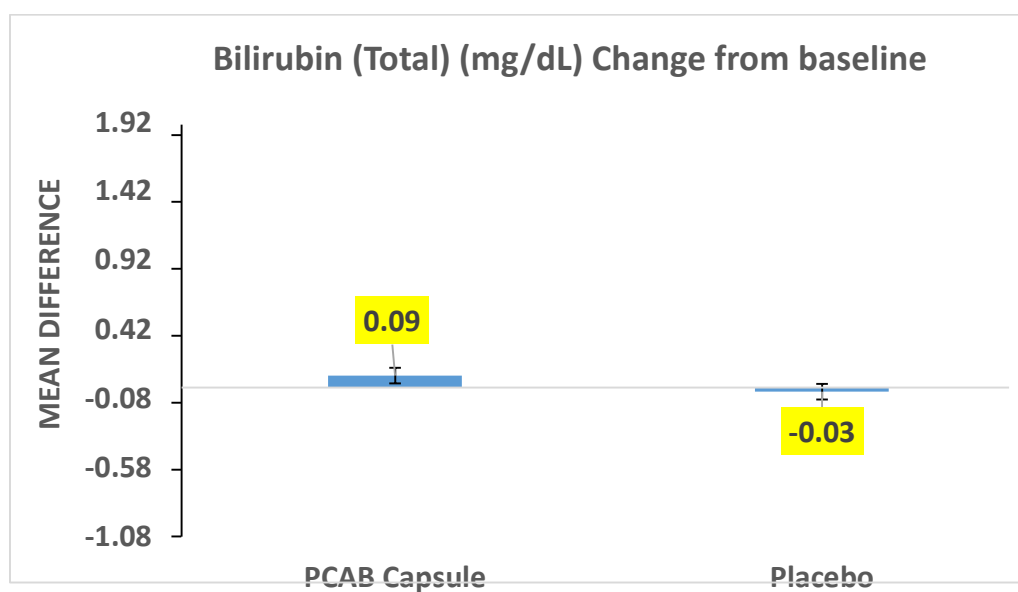


Table 36. Summary statistics of Direct Bilirubin (mg/dL) and change from baseline by treatment, ITT population

| Duration | Mean Direct Bilirubin (mg/dL) | Between |
|-----------------|--------------------------------------|----------------|
| (Days) | ($\bar{X} \pm SD$) | Groups |

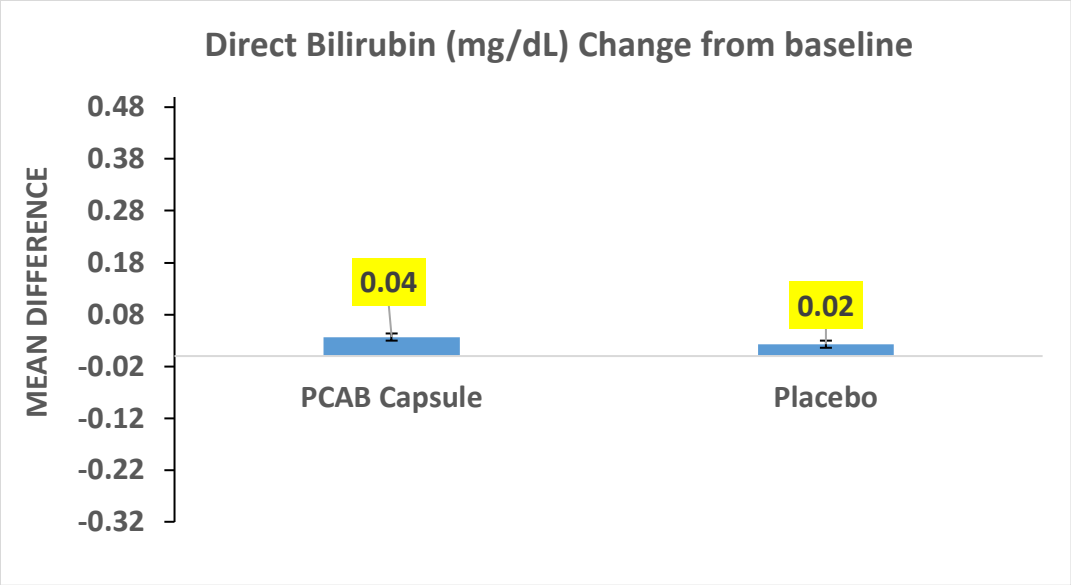
| | N | PCA Capsule | N | Placebo | (P value) |
|-----------------------------------|----|-------------|----|-------------|---------------|
| Baseline | 12 | 0.17 ± 0.06 | 14 | 0.23 ± 0.12 | 0.112 (NS) |
| 14 | 12 | 0.21 ± 0.07 | 14 | 0.26 ± 0.15 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | 0.04 (0.02) | 14 | 0.02 (0.04) | 0.636 |
| (p value) | | (0.111) NS | | (0.574) NS | (NS) |

By Student t test

NS = Not Significant

- In this study at baseline, mean Direct Bilirubin was **0.17 mg/dL** among PCA Capsule which was comparable to **0.23 mg/dL** among Placebo group and the difference was not significant.
- After 14 days of treatment, mean Direct Bilirubin showed an insignificant rise of **23.5%** among PCA Capsule and **8.7%** in Placebo group from baseline. If compared, the change was more among PCA Capsule than Placebo, but the difference was not significant.

**Figure 33: Mean change in Direct Bilirubin (mg/dL) from baseline
by treatment group, ITT population**



**Table 37. Summary statistics of Indirect Bilirubin (mg/dL) and change
from baseline by treatment, ITT population**

| Duration | Mean Indirect Bilirubin (mg/dL) | Between |
|-----------------|---|----------------|
| (Days) | ($\bar{X} \pm \text{SD}$) | Groups |

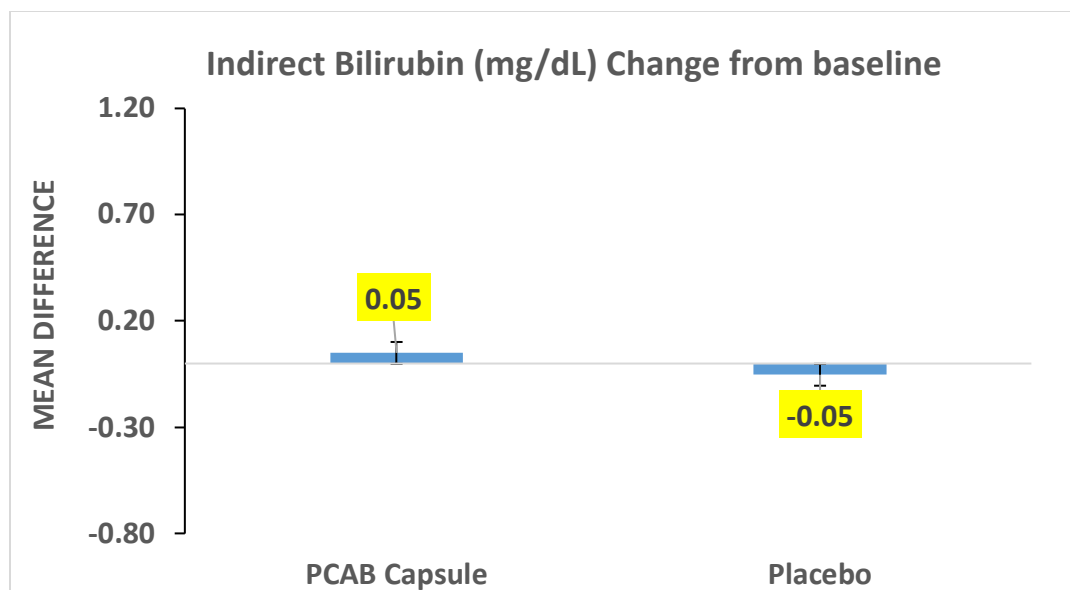
| | N | PCA Capsule | N | Placebo | (P value) |
|-----------------------------------|----|-------------|----|--------------|---------------|
| Baseline | 12 | 0.42 ± 0.15 | 14 | 0.59 ± 0.32 | 0.088 (NS) |
| 14 | 12 | 0.47 ± 0.27 | 14 | 0.54 ± 0.30 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | 0.05 (0.09) | 14 | -0.05 (0.06) | 0.359 |
| (p value) | | (0.587) NS | | (0.410) NS | (NS) |

By Student t test

NS = Not Significant

- This table states that at baseline, mean Indirect Bilirubin was **0.42 mg/dL** among PCA Capsule which was comparable to **0.59 mg/dL** among Placebo group and the difference was not significant.
- After 14 days of treatment, mean Indirect Bilirubin showed an insignificant rise of **11.9%** among PCA Capsule and an insignificant fall of **8.5%** in Placebo group from baseline. If compared, the change was insignificantly more among PCA Capsule than Placebo group.

**Figure 34: Mean change in Indirect Bilirubin (mg/dL) from baseline
by treatment group, ITT population**



**Table 38. Summary statistics of SGPT(U/Lt) and change from
baseline by treatment, ITT population**

| Duration (Days) | Mean SGPT(U/Lt) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|---|-------------------------------|----------------------|--------------------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 19.84 \pm 06.63 | 14 | 16.76 \pm 5.92 | 0.226 (NS) |
| 14 | 12 | 27.78 \pm 10.96 | 14 | 15.03 \pm 4.46 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | 7.93 (2.75) (0.014) NS | 14 | -1.73 (0.68) (0.024) NS | *0.002 |
| By Student t test | | *Significant | NS = Not Significant | | |

- This result reveals that at baseline, mean SGPT was **19.84 U/Lt** among PCA Capsule which was comparable to **16.76 U/Lt** among Placebo group and the difference was not statistically significant.

- After 14 days of treatment, mean SGPT showed an insignificant rise of **40.0%** among PCA Capsule and an insignificant fall of **10.3%** in Placebo group from baseline. If compared, the change was significantly more among PCA Capsule than Placebo group.

Figure 35: Mean change in SGPT (U/Lt) from baseline

by treatment group, ITT population

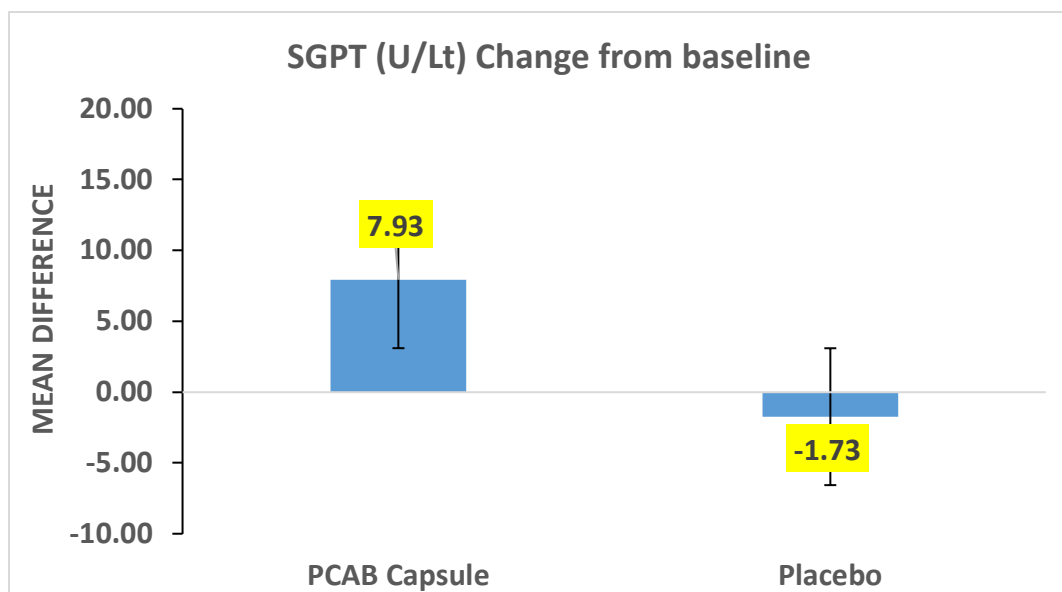


Table 39. Summary statistics of SGOT (U/Lt) and change from baseline by treatment, ITT population

| Duration (Days) | Mean SGOT (U/Lt) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|------------------|----|------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 25.69 \pm 7.06 | 14 | 25.11 \pm 8.13 | 0.847 (NS) |
| 14 | 12 | 23.60 \pm 5.99 | 14 | 18.34 \pm 5.22 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | -2.09 (2.81) | 14 | *-6.77 (1.58) | 0.159 |
| (p value) | | (0.473) NS | | (0.001) | (NS) |

By Student t test

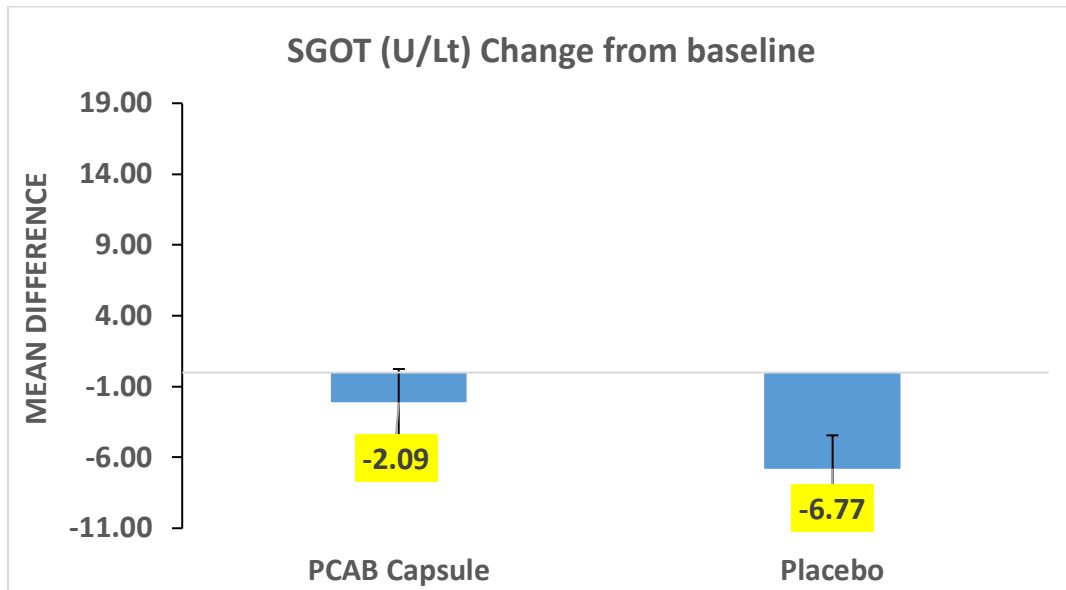
*Significant

NS = Not Significant

- In this profile at baseline, mean SGOT was **25.69 U/Lt** among PCA Capsule which was comparable to **25.11 U/Lt** among Placebo group and the difference was not significant.

- After 14 days of treatment, mean SGOT showed an insignificant fall of **8.1%** among PCA Capsule and a significant fall of **27.0%** in Placebo group from baseline. If compared, the change was insignificantly more among Placebo than PCA Capsule group.

Figure 36: Mean change in SGOT (U/Lt) from baseline
by treatment group, ITT population



**Table 40. Summary statistics of Alkaline Phosphatase(U/Lt) and
change from baseline by treatment, ITT population**

| Duration (Days) | Mean Alkaline Phosphatase (U/Lt) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|-------------------------------|----------------------|--------------------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 95.92 \pm 17.38 | 14 | 82.57 \pm 22.94 | 0.104 (NS) |
| 14 | 12 | 99.83 \pm 18.54 | 14 | 77.36 \pm 20.94 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | 3.92 (1.81) (0.052) NS | 14 | -5.21 (1.60) (0.006) NS | *0.001 |
| By Student t test | | *Significant | NS = Not Significant | | |

- This analysis states that at baseline, mean Alkaline Phosphatase was **95.92 U/Lt** among PCA Capsule which was insignificantly more as compared to **82.57 U/Lt** among Placebo group.

- After 14 days of treatment, mean Alkaline Phosphatase showed an insignificant rise of **4.1%** among PCA Capsule and an insignificant fall of **6.3%** in Placebo group from baseline. If compared, the change was significantly more among PCA Capsule than Placebo group.

**Figure 37: Mean change in Alkaline Phosphatase(U/Lt) from
baseline by treatment group, ITT population**

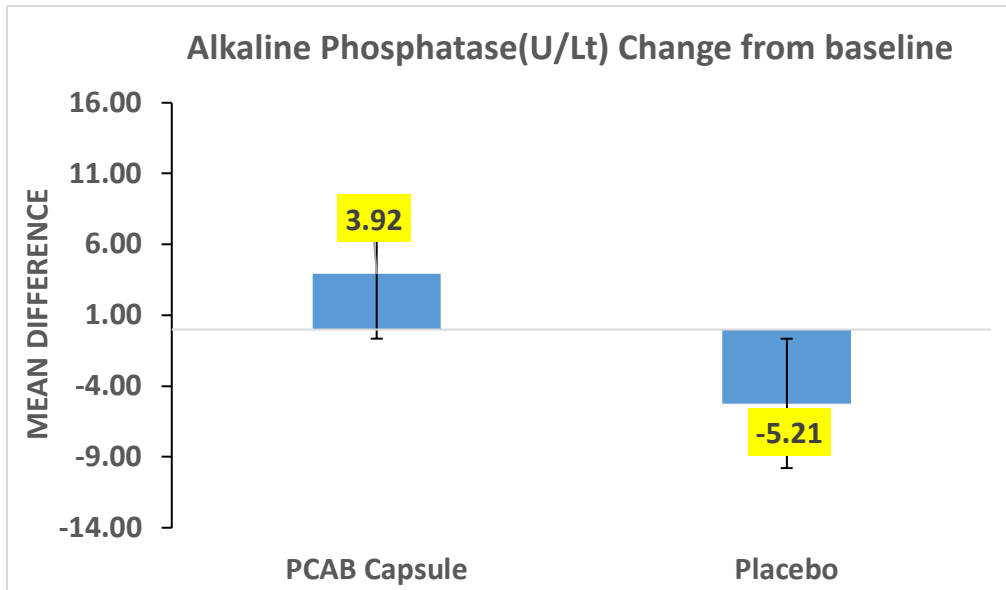


Table 41. Summary statistics of Total Protein (g/dL) and change from baseline by treatment, ITT population

| Duration | Mean Total Protein (g/dL) | |
|----------|---------------------------|--|
|----------|---------------------------|--|

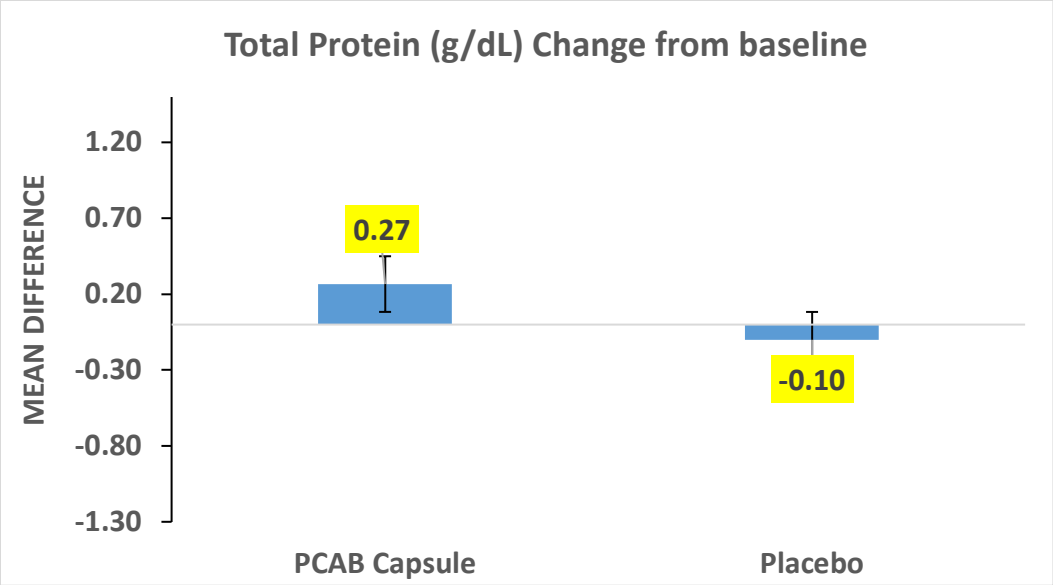
| (Days) | ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|----------------------|-----------------|----|-----------------|--------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 7.38 \pm 0.45 | 14 | 7.42 \pm 0.40 | 0.814 (NS) |
| 14 | 12 | 7.65 \pm 0.51 | 14 | 7.32 \pm 0.53 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | 0.27 (0.10) | 14 | -0.10 (0.12) | 0.028 |
| (p value) | | (0.021) NS | | (0.430) NS | (NS) |

By Student t test

NS = Not Significant

- According to this study at baseline, mean Total Protein was **7.38 g/dL** among PCA Capsule which was comparable to **7.42 g/dL** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, mean Total Protein showed an insignificant rise of **3.7%** among PCA Capsule and an insignificant fall of **1.3%** in Placebo group from baseline. If compared, the change was insignificantly less among Placebo than PCA Capsule.

Figure 38: Mean change in Total Protein (g/dL) from baseline
by treatment group, ITT population



**Table 42. Summary statistics of Albumin (g/dL) and change
from baseline by treatment, ITT population**

| Duration (Days) | Mean Albumin (g/dL) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|---|-----------------|----|-----------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 4.50 \pm 0.30 | 14 | 4.41 \pm 0.30 | 0.453 (NS) |
| 14 | 12 | 4.58 \pm 0.25 | 14 | 4.29 \pm 0.22 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | 0.08 (0.08) | 14 | -0.12 (0.08) | 0.087 |
| (p value) | | (0.359) NS | | (0.132) NS | (NS) |

By Student t test

NS = Not Significant

- The above table states that at baseline, mean Albumin was **4.50 g/dL** among PCA Capsule which was comparable to **4.41 g/dL** among Placebo group and the difference was not significant.

- After 14 days of treatment, mean Albumin showed an insignificant rise of **1.8%** among PCA Capsule and an insignificant fall of **2.7%** in Placebo group from baseline. If compared, the change was insignificantly more among PCA Capsule than Placebo group.

Figure 39: Mean change in Albumin (g/dL) from baseline

by treatment group, ITT population

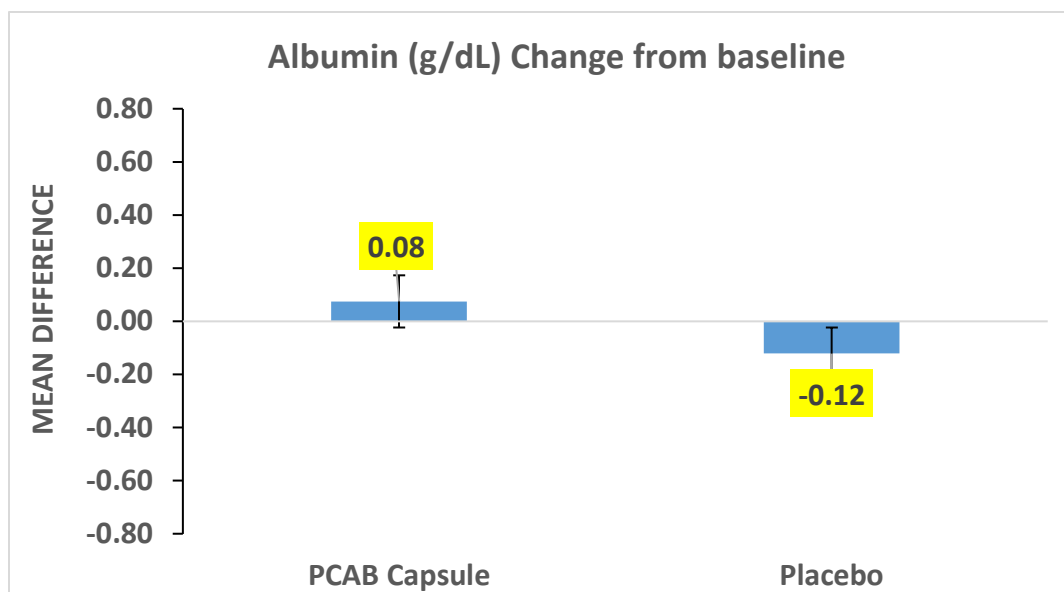


Table 43. Summary statistics of Globulin (g/dL) and change

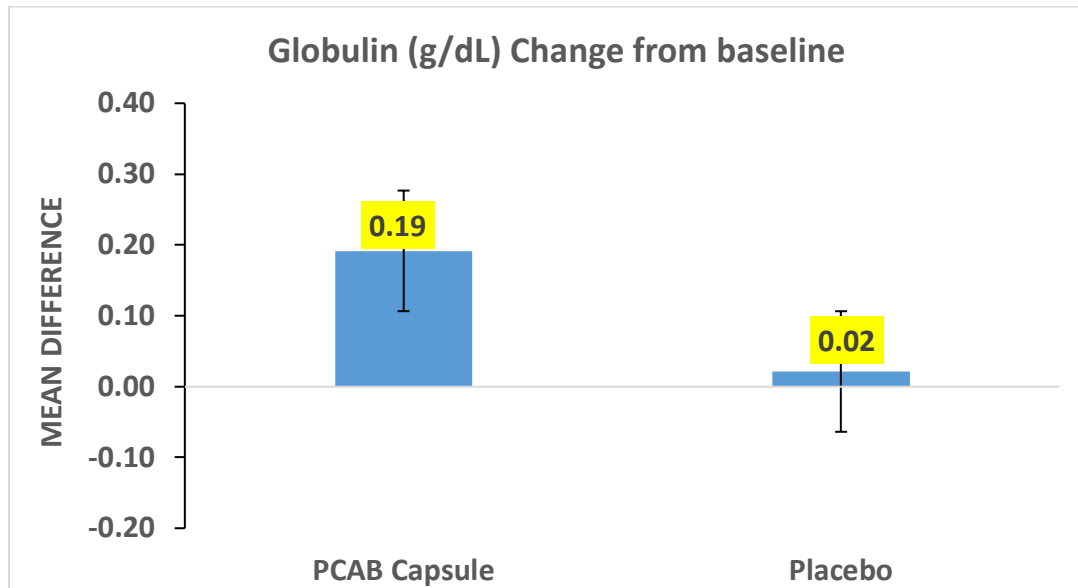
from baseline by treatment, ITT population

| Duration (Days) | Mean Globulin (g/dL) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|-----------------------------|----------------------|-------------------------------|--|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 2.88 ± 0.35 | 14 | 3.01 ± 0.36 | 0.120 (NS) |
| 14 | 12 | 3.08 ± 0.39 | 14 | 3.04 ± 0.39 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | *0.19 (0.05) (0.001) | 14 | 0.02 (0.09) (0.834) NS | 0.116 (NS) |
| By Student t test | | *Significant | NS = Not Significant | | |

- As per this study at baseline, mean Globulin was **2.88 g/dL** among PCA Capsule which was comparable to **3.01 g/dL** among Placebo group and the difference was not significant.

- After 14 days of treatment, mean Globulin showed a significant rise of **6.6%** among PCA Capsule and an insignificant rise of **0.7%** in Placebo group from baseline. If compared, the change was insignificantly more among PCA Capsule than Placebo group.

Figure 40: Mean change in Globulin (g/dL) from baseline
by treatment group, ITT population



LIPID PROFILE PARAMETER: -

Table 44. Summary statistics of Total Serum Cholesterol (mg/dL) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Total Serum Cholesterol (mg/dL) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|------------------------------|----|--------------------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 194.75 \pm 31.95 | 14 | 173.21 \pm 56.25 | 0.233 (NS) |
| 14 | 12 | 212.92 \pm 34.66 | 14 | 166.71 \pm 50.36 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | *18.17 (3.22) (0.001) | 14 | -6.50 (3.91) (0.120) NS | *0.001 |

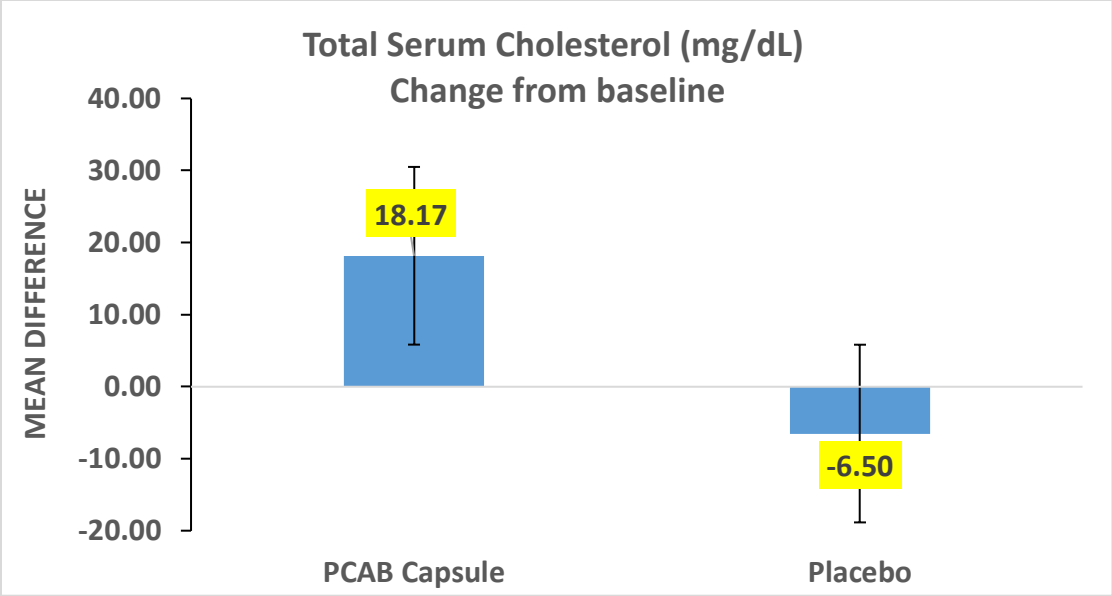
By Student t test

*Significant

NS = Not Significant

- This profile states that at baseline, mean Total Serum Cholesterol was **194.75 mg/dL** among PCA Capsule which was insignificantly more as compared to **173.21 mg/dL** among Placebo group.
- After 14 days of treatment, mean Total Serum Cholesterol showed a significant rise of **9.3%** among PCA Capsule and an insignificant fall of **3.8%** in Placebo group from baseline. If compared, the change was significantly more among PCA Capsule than Placebo group.

**Figure 41: Mean change in Total Serum Cholesterol (mg/dL) from
baseline by treatment group, ITT population**



**Table 45. Summary statistics of Serum Triglycerides (mg/dL) and
change from baseline by treatment, ITT population**

| Duration | Mean Serum Triglycerides (mg/dL) | Between |
|-----------------|---|----------------|
| (Days) | ($\bar{X} \pm \text{SD}$) | Groups |

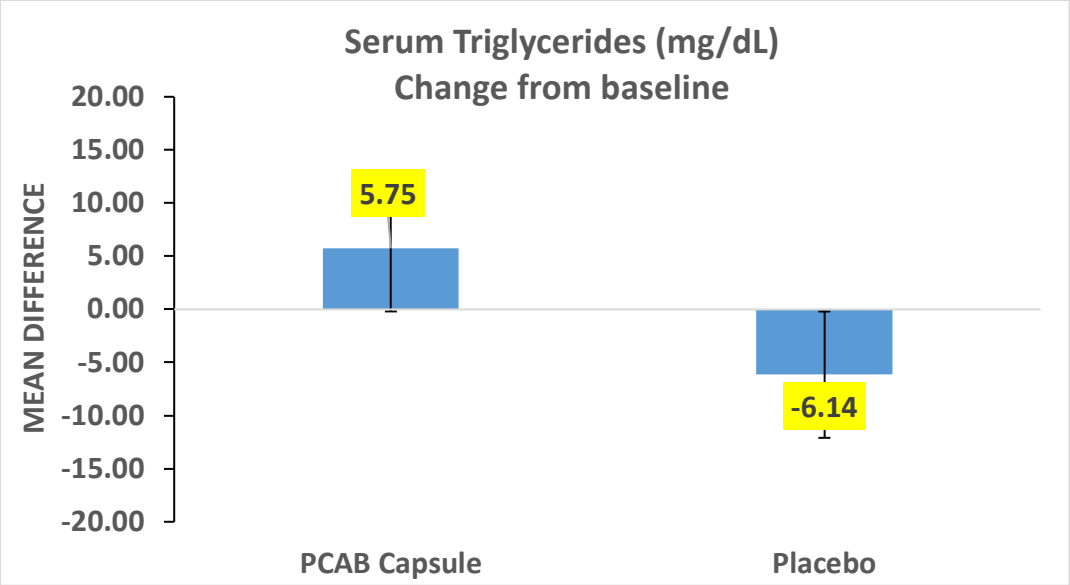
| | N | PCA Capsule | N | Placebo | (P value) |
|-----------------------------------|----|----------------|----|----------------|---------------|
| Baseline | 12 | 162.00 ± 71.66 | 14 | 146.64 ± 57.57 | 0.556 (NS) |
| 14 | 12 | 167.75 ± 93.11 | 14 | 140.50 ± 58.86 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | 5.75 (12.92) | 14 | -6.14 (16.09) | 0.569 |
| (p value) | | (0.664) NS | | (0.709) NS | (NS) |

By Student t test

NS = Not Significant

- This data reveals that at baseline, mean Serum Triglycerides was **162.00 mg/dL** among PCA Capsule which was more as compared to **146.64 mg/dL** among Placebo group, but the difference was not significant.
- After 14 days of treatment, mean Serum Triglycerides showed an insignificant rise of **3.5%** among PCA Capsule and an insignificant fall of **4.2%** in Placebo group from baseline. If compared, the change was insignificantly more among PCA Capsule than Placebo group.

**Figure 42: Mean change in Serum Triglycerides (mg/dL) from
baseline by treatment group, ITT population**



**Table 46. Summary statistics of HDL Cholesterol (mg/dL) and
change from baseline by treatment, ITT population**

| Duration (Days) | Mean HDL Cholesterol (mg/dL) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|------------------|----|------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 41.63 \pm 9.23 | 14 | 43.86 \pm 9.28 | 0.546 (NS) |
| 14 | 12 | 40.91 \pm 8.29 | 14 | 39.42 \pm 7.83 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | -0.73 (1.91) | 14 | -4.44 (1.50) | 0.139 |
| (p value) | | (0.710) NS | | (0.011) NS | (NS) |

By Student t test

NS = Not Significant

- In this table at baseline, mean HDL Cholesterol was **41.63 mg/dL** among PCA Capsule which was comparable to **43.86 mg/dL** among Placebo group and the difference was not significant.
- After 14 days of treatment, mean HDL Cholesterol showed an insignificant fall of **1.8%** among PCA Capsule and **10.1%** in Placebo group from baseline. If compared, the change was insignificantly less among PCA Capsule than Placebo group.

**Figure 43: Mean change in HDL Cholesterol (mg/dL) from
baseline by treatment group, ITT population**

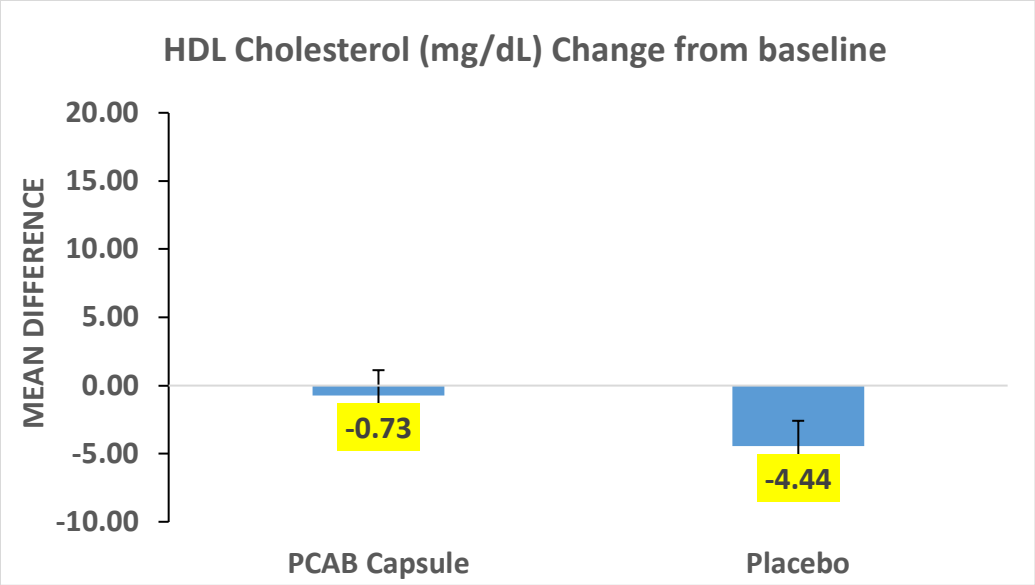


Table 47. Summary statistics of Non-HDL Cholesterol (mg/dL) and change from baseline by treatment, ITT population

| Duration | Mean Non-HDL Cholesterol (mg/dL) | |
|----------|----------------------------------|--|
|----------|----------------------------------|--|

| (Days) | ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|----------------------|------------------------------|----|--------------------------------|--------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 153.12 \pm 34.06 | 14 | 129.36 \pm 53.28 | 0.182 (NS) |
| 14 | 12 | 172.01 \pm 37.35 | 14 | 127.29 \pm 46.54 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | *18.89 (2.97) (0.001) | 14 | -2.06 (4.11) (0.624) NS | *0.001 |

By Student t test

*Significant

NS = Not Significant

- This analysis states that at baseline, mean Non-HDL Cholesterol was **153.12 mg/dL** among PCA Capsule which was more as compared to **129.36 mg/dL** among Placebo group, but the difference was not significant.
- After 14 days of treatment, mean Non-HDL Cholesterol showed a significant rise of **12.3%** among PCA Capsule and an insignificant fall of **1.6%** in Placebo group from baseline. If compared, the change was significantly more among PCA Capsule than Placebo group.

**Figure 44: Mean change in Non-HDL Cholesterol (mg/dL) from
baseline by treatment group, ITT population**

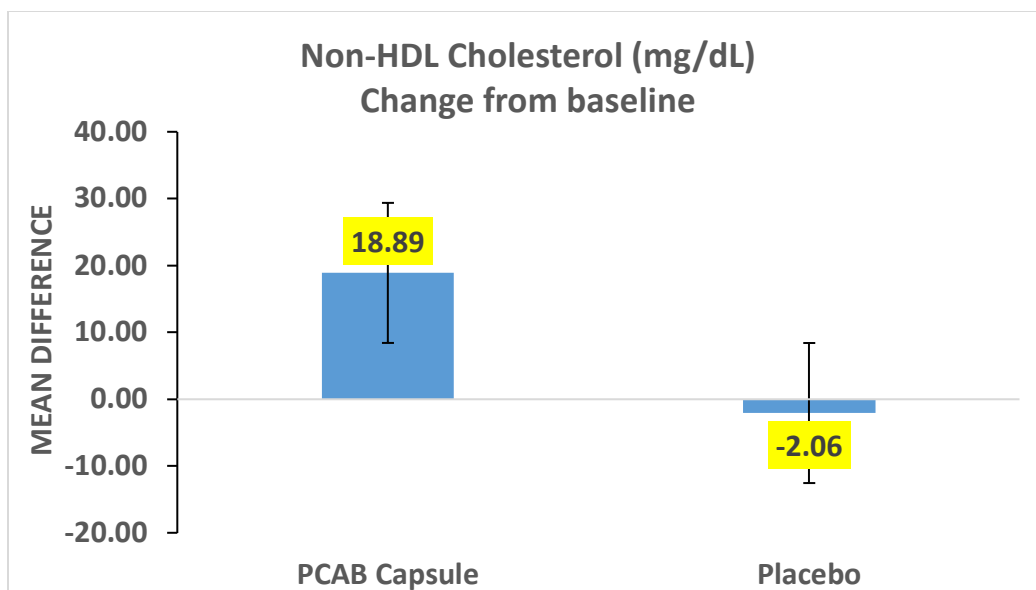


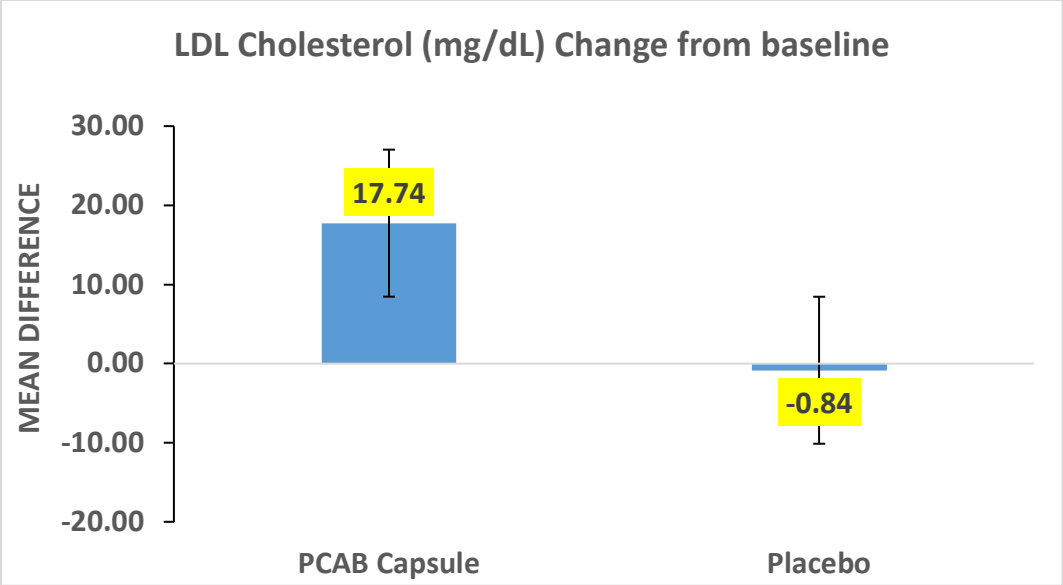
Table 48. Summary statistics of LDL Cholesterol (mg/dL) and change from baseline by treatment, ITT population

| Duration | Mean LDL Cholesterol (mg/dL) | Between |
|-----------------|---|----------------|
| (Days) | ($\bar{X} \pm \text{SD}$) | Groups |

| | N | PCA Capsule | N | Placebo | (P value) |
|-----------------------------------|----|------------------------------|----------------------|--------------------------------|---------------|
| Baseline | 12 | 120.72 ± 27.67 | 14 | 100.03 ± 50.62 | 0.200 (NS) |
| 14 | 12 | 138.46 ± 29.53 | 14 | 99.19 ± 41.40 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | *17.74 (3.02) (0.001) | 14 | -0.84 (4.31) (0.849) NS | *0.001 |
| By Student t test | | *Significant | NS = Not Significant | | |

- As per this study at baseline, mean LDL Cholesterol was **120.72 mg/dL** among PCA Capsule which was insignificantly more as compared to **100.03 mg/dL** among Placebo group.
- After 14 days of treatment, mean LDL Cholesterol showed a significant rise of **14.7%** among PCA Capsule and an insignificant fall of **0.8%** in Placebo group from baseline. If compared, the change was significantly less among Placebo than PCA Capsule group.

**Figure 45: Mean change in LDL Cholesterol (mg/dL) from
baseline by treatment group, ITT population**



**Table 49. Summary statistics of VLDL Cholesterol (mg/dL) and
change from baseline by treatment, ITT population**

| Duration | Mean VLDL Cholesterol (mg/dL) | |
|-----------------|--------------------------------------|--|
|-----------------|--------------------------------------|--|

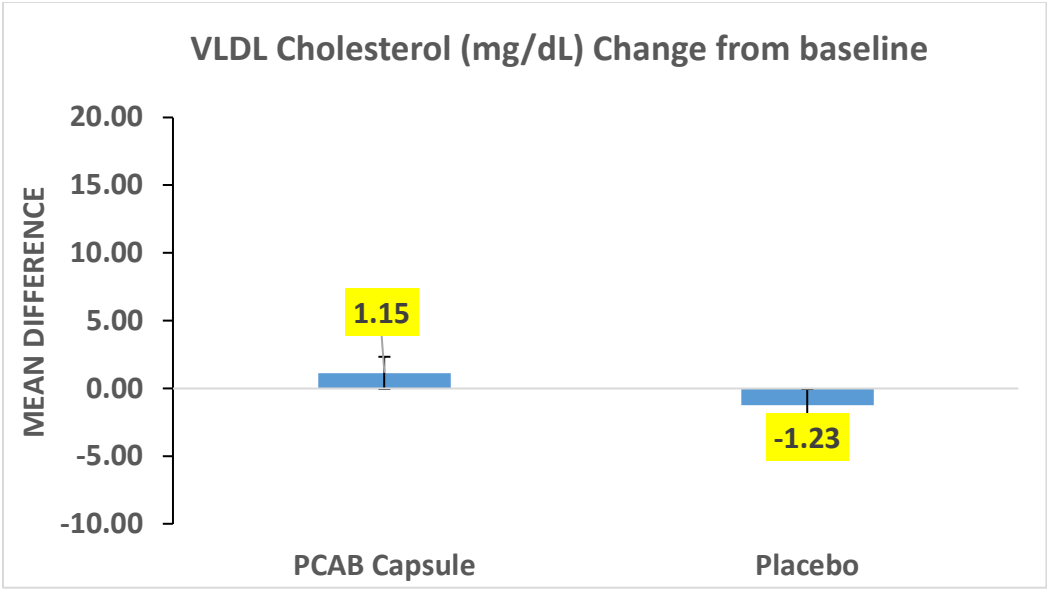
| (Days) | ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|----------------------|-------------------|----|-------------------|--------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 32.40 \pm 14.33 | 14 | 29.33 \pm 11.51 | 0.557 (NS) |
| 14 | 12 | 33.55 \pm 18.62 | 14 | 28.10 \pm 11.77 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | 1.15 (2.58) | 14 | -1.23 (3.22) | 0.569 |
| (p value) | | (0.664) NS | | (0.708) NS | (NS) |

By Student t test

NS = Not Significant

- According to this profile at baseline, mean VLDL Cholesterol was **32.40 mg/dL** among PCA Capsule which was comparable to **29.33 mg/dL** among Placebo group and the difference was not significant.
- After 14 days of treatment, mean VLDL Cholesterol showed an insignificant rise of **3.5%** among PCA Capsule and an insignificant fall of **4.2%** in Placebo group from baseline. If compared, the change was insignificantly more among PCA Capsule than Placebo group.

**Figure 46: Mean change in VLDL Cholesterol (mg/dL) from
baseline by treatment group, ITT population**



COAGULATION: -

Table 50. Summary statistics of Prothrombin time (Sec) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Prothrombin time (Sec) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|---|------------------|----|------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 11.97 \pm 1.00 | 14 | 12.20 \pm 0.90 | 0.546 (NS) |
| 14 | 12 | 12.49 \pm 0.81 | 14 | 12.60 \pm 1.24 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | 0.53 (0.32) | 14 | 0.40 (0.29) | 0.764 |
| (p value) | | (0.120) NS | | (0.192) NS | (NS) |

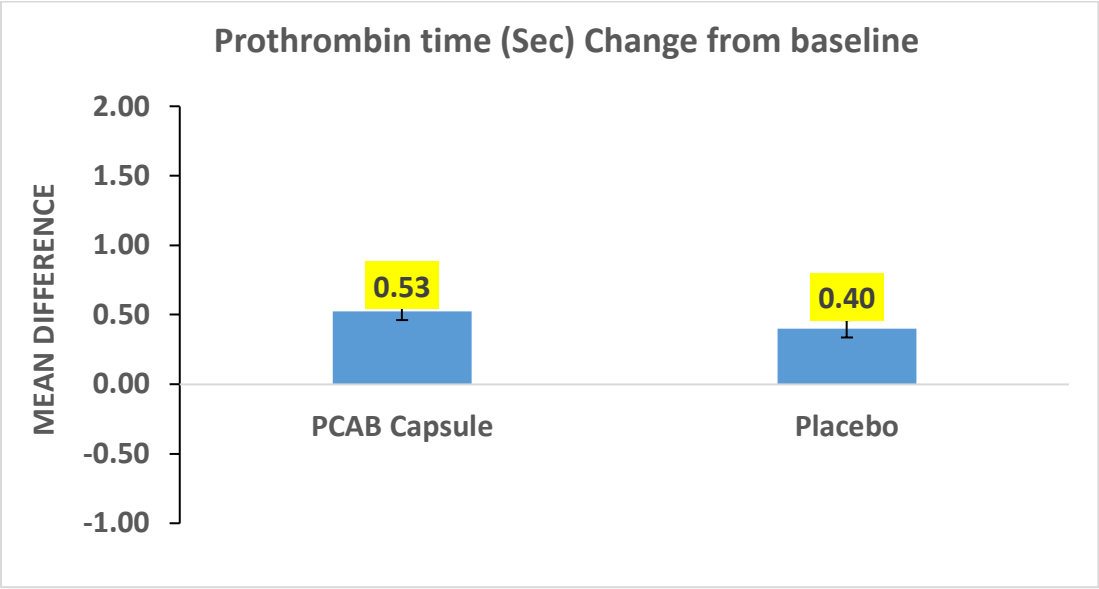
By Student t test

NS = Not Significant

- This data suggest that at baseline, mean Prothrombin time was **11.97 sec** among PCA Capsule which was comparable to **12.20 sec** among Placebo group and the difference was not significant.
- After 14 days of treatment, mean Prothrombin time showed an insignificant rise of **4.4%** among PCA Capsule and **3.3%** in Placebo group from baseline. If compared, the change was comparable between the groups and the difference was not significant.

Figure 47: Mean change in Prothrombin time (Sec) from baseline

by treatment group, ITT population



VITAL SIGNS PARAMETER: -

Table 51. Summary statistics of SBP (mmHg) and change from baseline by treatment, ITT population

| Duration (Days) | Mean SBP (mmHg) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|---|--------------------|----|--------------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 135.17 \pm 14.98 | 14 | 136.00 \pm 15.77 | 0.892 (NS) |
| 14 | 12 | 123.33 \pm 11.35 | 14 | 129.50 \pm 14.04 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | *-11.83 (3.21) | 14 | -6.50 (4.61) | 0.352 |
| (p value) | | (0.003) | | (0.182) NS | (NS) |

By Student t Test

*Significant

NS = Not Significant

- This table states that at baseline, mean SBP was **135.17 mmHg** among PCA Capsule which was comparable to **136.00 mmHg** among Placebo group and the difference was not significant.

- After 14 days of treatment, mean SBP showed a significant fall of **8.8%** among PCA Capsule and an insignificant fall of **4.8%** in Placebo group from baseline. If compared, the change was comparable between the groups and the difference was not significant.

**Figure 48: Mean change in SBP (mmHg) from baseline
by treatment group, ITT population**

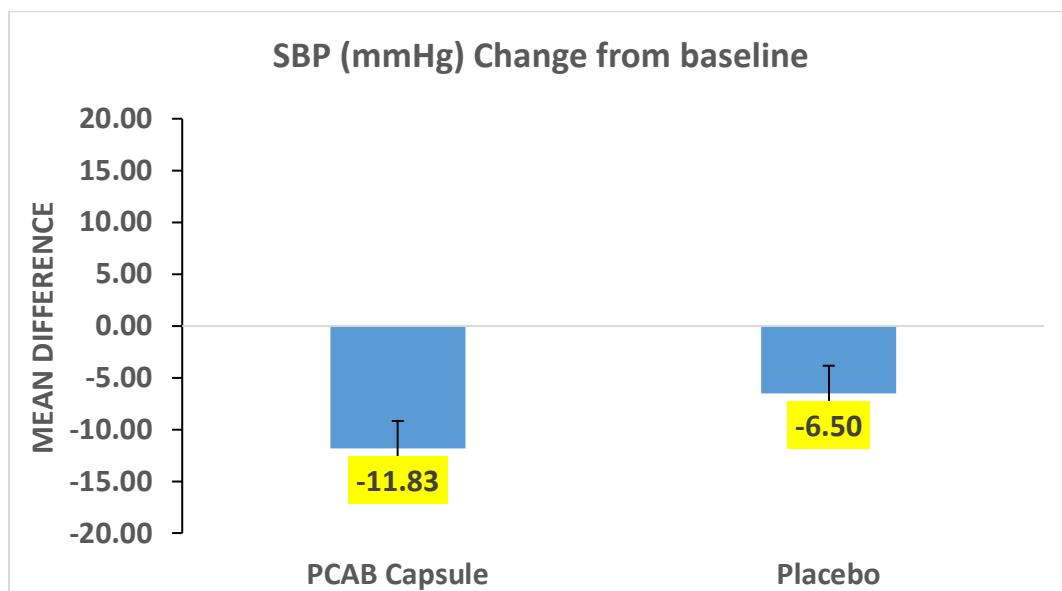


Table 52. Summary statistics of DBP (mmHg) and change from baseline by treatment, ITT population

| Duration (Days) | Mean DBP (mmHg) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|------------------------|---|-------------|---|---------|------------------------------------|
| | N | PCA Capsule | N | Placebo | |
| | | | | | |

| | | | | | |
|-----------------------------------|----|---------------|----|--------------|---------------|
| Baseline | 12 | 81.83 ± 10.50 | 14 | 84.43 ± 9.52 | 0.518 (NS) |
| 14 | 12 | 81.42 ± 8.90 | 14 | 81.29 ± 6.01 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | -0.42 (2.50) | 14 | -3.14 (2.55) | 0.454 |
| (p value) | | (0.870) NS | | (0.240) NS | (NS) |

By Student t test

NS = Not Significant

- This result reveals that at baseline, mean DBP was **81.83 mmHg** among PCA Capsule which was comparable to **84.43 mmHg** among Placebo group and the difference was not significant.
- After 14 days of treatment, mean DBP showed an insignificant fall of **0.5%** among PCA Capsule and **3.7%** in Placebo group from baseline. If compared, the change was comparable between the groups and the difference was not significant.

Figure 49: Mean change in DBP (mmHg) from baseline

by treatment group, ITT population

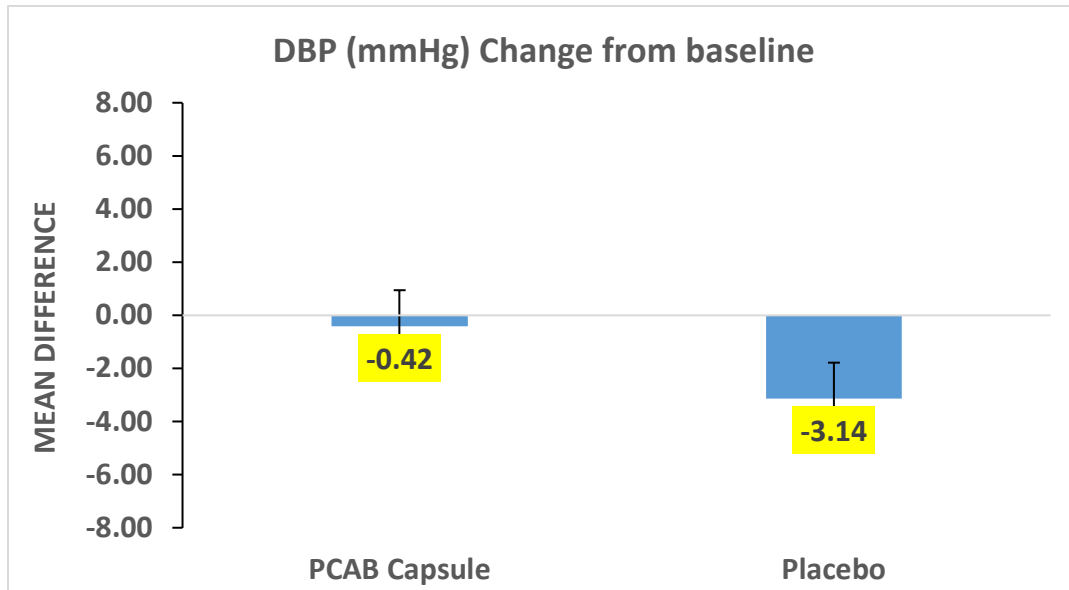


Table 53. Summary statistics of Pulse Rate (beats/min) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Pulse Rate (beats/min) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|---|--------------|----|---------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 84.00 ± 6.93 | 14 | 87.50 ± 14.32 | 0.425 (NS) |
| 14 | 12 | 81.58 ± 8.60 | 14 | 77.07 ± 08.38 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | -2.42 (2.18) | 14 | -10.43 (4.56) | 0.125 |
| (p value) | | (0.290) NS | | (0.039) NS | (NS) |

By Student t Test

NS = Not Significant

- In this profile at baseline, mean Pulse Rate was **84.00 beats/min** among PCA Capsule which was comparable to **87.50 beats/min** among Placebo group and the difference was not significant.

- After 14 days of treatment, mean Pulse Rate showed an insignificant fall of **2.9%** among PCA Capsule and **11.9%** in Placebo group from baseline. If compared, the change was insignificantly less among PCA Capsule than Placebo group.

Figure 50: Mean change in Pulse Rate (beats/min) from baseline
by treatment group, ITT population

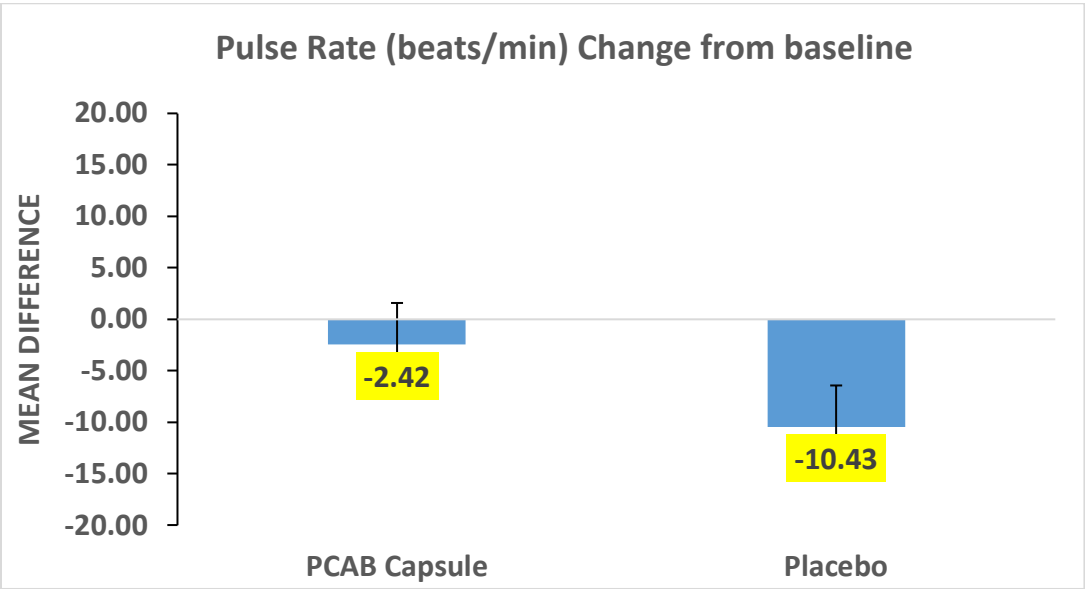


Table 54. Summary statistics of Respiration Rate (breath/min) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Respiration Rate (breath/min) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|------------------------|--|-------------|---|---------|------------------------------------|
| | N | PCA Capsule | N | Placebo | |
| | | | | | |

| | | | | | |
|-----------------------------------|----|--------------|----|--------------|---------------|
| Baseline | 12 | 19.42 ± 2.19 | 14 | 20.43 ± 4.18 | 0.439 (NS) |
| 14 | 12 | 19.50 ± 2.28 | 14 | 18.43 ± 1.99 | - |
| Change from baseline within group | | | | | |
| Mean (SE) | 12 | 0.08 (0.47) | 14 | -2.00 (1.20) | 0.118 |
| (p value) | | (0.867) NS | | (0.118) NS | (NS) |

By Student t test

NS = Not Significant

- According to this study at baseline, mean Respiration Rate was **19.42 breath/min** among PCA Capsule which was comparable to **20.43 breath/min** among Placebo group and the difference was not significant.
- After 14 days of treatment, mean Respiration Rate showed an insignificant rise of **0.4%** among PCA Capsule and an insignificant fall of **9.8%** in Placebo group from baseline. If compared, the change was more among PCA Capsule than Placebo group, but the difference was not significant.

**Figure 51: Mean change in Respiration Rate (breath/min) from
Baseline by treatment group, ITT population**

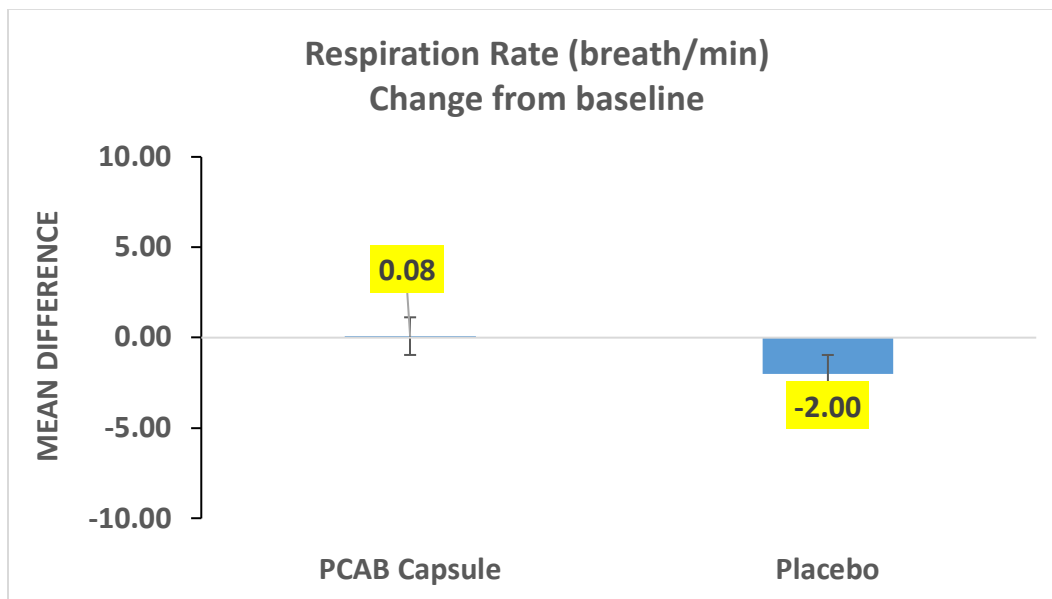


Table 55. Summary statistics of Body Temperature (°C) and change from baseline by treatment, ITT population

| Duration (Days) | Mean Body Temperature (°C) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|--------------|----|--------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 36.98 ± 0.42 | 14 | 37.00 ± 0.48 | 0.910 (NS) |
| 14 | 12 | 36.33 ± 0.84 | 14 | 36.18 ± 1.49 | - |
| Change from baseline within group | | | | | |

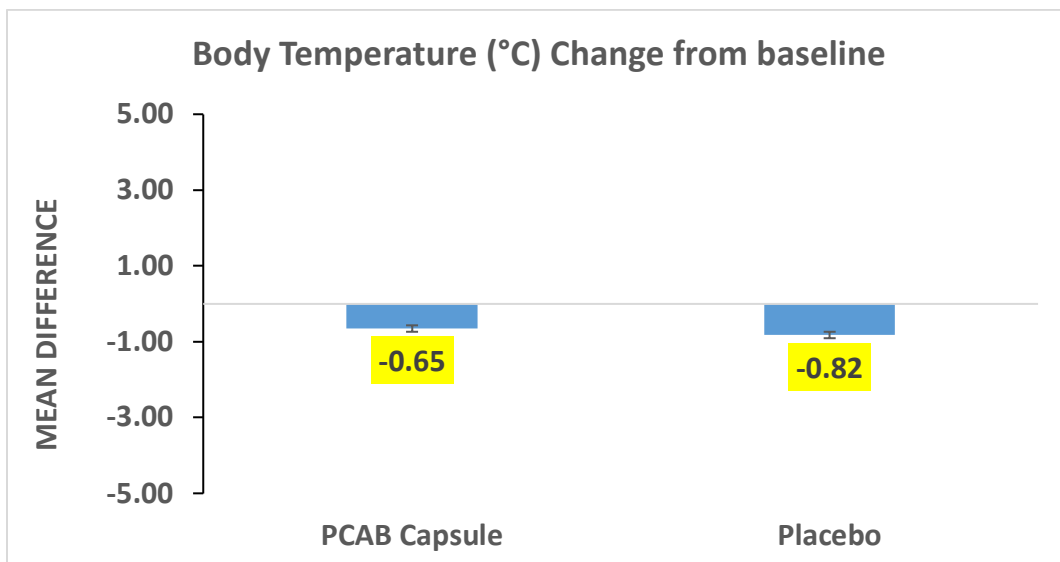
| | | | | | |
|-----------|----|--------------|----|--------------|-------|
| Mean (SE) | | -0.65 (0.23) | | -0.82 (0.37) | 0.700 |
| (p value) | 12 | (0.016) NS | 14 | (0.045) NS | (NS) |

By Student t Test

NS = Not Significant

- This table states that at baseline, mean Body Temperature was **36.98 °C** among PCA Capsule which was comparable to **37.00 °C** among Placebo group and the difference was not significant.
- After 14 days of treatment, mean Body Temperature showed an insignificant fall of **1.8%** among PCA Capsule and **2.2%** in Placebo group from baseline. If compared, the change was comparable between the groups and the difference was not significant.

Figure 52: Mean change in Body Temperature (°C) from baseline
by treatment group, ITT population



EFFICACY ANALYSIS: -

Table 56. Descriptive table for SF-36 score, PP population

| Duration (Days) | Mean SF-36 score ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|--|--|--------------------|----------|------------------|--|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 12.58 \pm 02.50 | 14 | 13.19 \pm 2.24 | 0.521 (NS) |
| 14 | 12 | 10.96 \pm 02.02 | 14 | 11.73 \pm 2.86 | - |
| Change from baseline within group | | | | | |

| | | | | | |
|-------------------------------|---------------|--------------|--------------|--------------|---|
| Mean (SE) | 12 | -1.61 (0.99) | 14 | -1.47 (0.96) | - |
| (p value) | | (0.131) NS | | (0.151) NS | |
| Between group | | | | | |
| LS Mean (SE) | 10.95 (0.74) | | 11.74 (0.69) | | - |
| LS Mean Difference (SE) | 0.79 (1.02) | | | | - |
| 95% CI for LS Mean Difference | (-1.31, 2.90) | | | | |
| p-value | 0.443 (NS) | | | | |

By Student t test

NS = Not Significant

By ANCOVA

- This data reveals that at baseline, mean SF-36 score was **12.58** among PCA Capsule which was comparable to **13.19** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, mean SF-36 score showed an insignificant fall of **12.8%** among PCA Capsule and **11.1%** in Placebo group from baseline. If compared, the change was comparable between the groups and the difference was not significant.

**Figure 56: Mean change in SF-36 score from baseline by
treatment group, PP population**

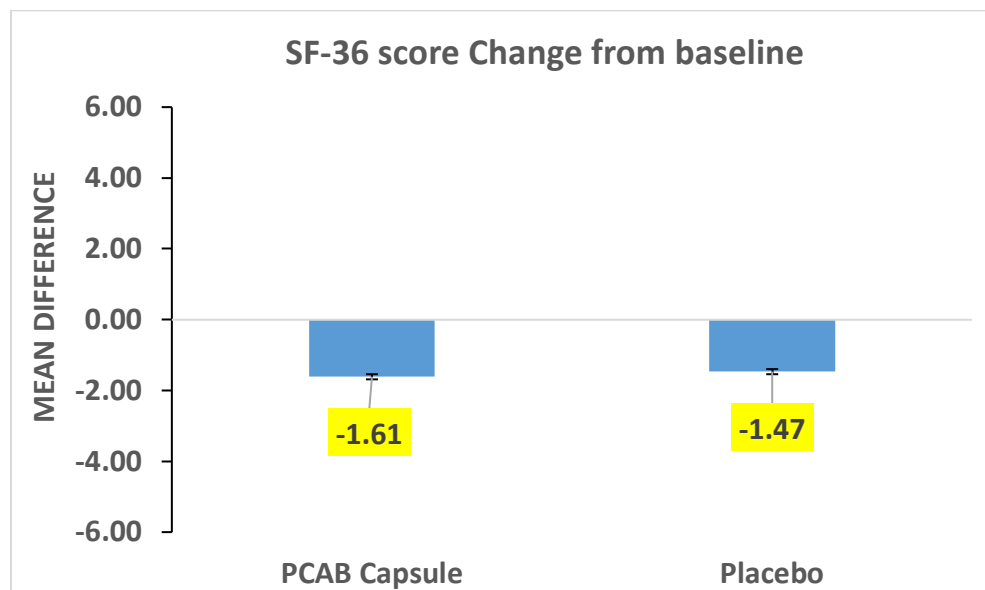


Table 57. Descriptive table for HBA1c (%), PP population

| Duration (Days) | Mean HBA1c (%) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|-------------------------------|-------------|-----------------------------|------------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 5.83 ± 0.50 | 14 | 5.85 ± 0.89 | 0.943 (NS) |
| 14 | 12 | 6.68 ± 1.64 | 14 | 6.57 ± 0.86 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | 0.84 (0.43) (0.075) NS | 14 | *0.72 (0.21) (0.004) | - |
| Between group | | | | | |
| LS Mean (SE) | 6.68 (0.32) | | 6.57 (0.31) | | - |
| LS Mean Difference (SE) | 0.12 (0.46) | | | | - |
| 95% CI for LS Mean Difference | (-0.84, 1.07) | | | | |

| | | |
|---------|------------|--|
| p-value | 0.803 (NS) | |
|---------|------------|--|

By Student t test

*Significant

NS = Not Significant

By ANCOVA

- According to this study at baseline, mean HBA1c was **5.83%** among PCA Capsule which was comparable to **5.85%** among Placebo group and the difference was not significant.
- After 14 days of treatment, mean HBA1c showed an insignificant rise of **14.4%** among PCA Capsule and a significant rise **12.3%** in Placebo group from baseline. If compared, the change was comparable between the groups and the difference was not significant.

Figure 57: Mean change in HbA1c (%) from baseline
by treatment group, PP population

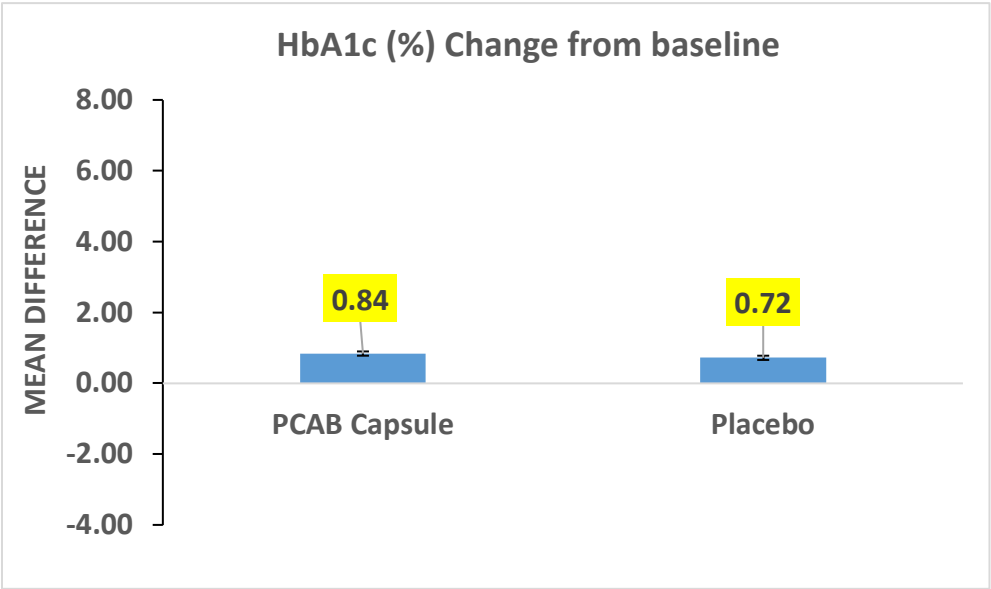


Table 59. Descriptive table for Fasting Blood

Glucose (mg/dL), PP population

| Duration (Days) | Mean Fasting Blood Glucose (mg/dL) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|---------------------------------|---------------|---------------------------------|--|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 114.08 ± 38.27 | 14 | 110.14 ± 16.92 | 0.744 (NS) |
| 14 | 12 | 107.83 ± 40.06 | 14 | 100.93 ± 19.21 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | -6.25 (03.81) (0.129) NS | 14 | -9.21 (06.26) (0.165) NS | - |
| Between group | | | | | |
| LS Mean (SE) | 106.06 (5.57) | | 102.45 (5.15) | | - |
| LS Mean Difference (SE) | 3.60 (7.59) | | | | - |
| 95% CI for LS Mean Difference | (-12.11, 19.31) | | | | |

| | | |
|---------|------------|--|
| p-value | 0.640 (NS) | |
|---------|------------|--|

By Student t test

NS = Not Significant

By ANCOVA

- In this analysis at baseline, mean Fasting Blood Glucose was **114.08 mg/dL** among PCA Capsule which was comparable to **110.14 mg/dL** among Placebo group and the difference was not significant.
- After 14 days of treatment, mean Fasting Blood Glucose showed an insignificant fall of **5.5%** among PCA Capsule and **8.4%** in Placebo group from baseline. If compared, the change was comparable between the groups and the difference was not significant.

Figure 58: Mean change in Fasting blood glucose (mg/dL)

from baseline by treatment group, PP population

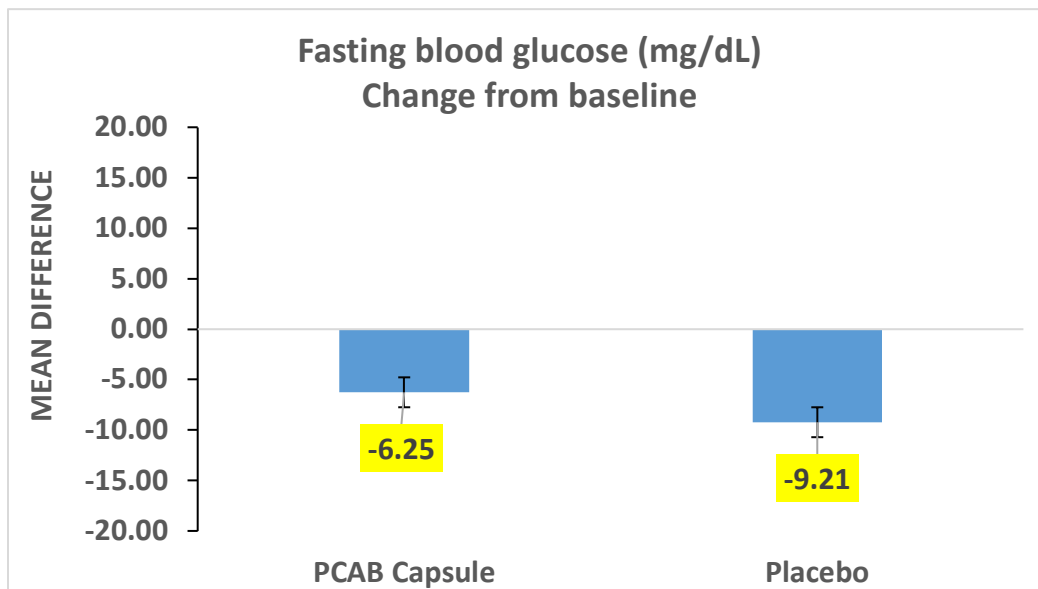


Table 60. Descriptive table for Post Prandial

Glucose (mg/dL), PP population

| Duration (Days) | Mean Post Prandial Glucose (mg/dL) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|--------------------------------|----------------|---------------------------------|--|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 135.42 ± 45.24 | 14 | 141.14 ± 49.20 | 0.760 (NS) |
| 14 | 12 | 136.08 ± 59.88 | 14 | 135.00 ± 38.54 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | 0.67 (09.15) (0.943) NS | 14 | -6.14 (11.55) (0.604) NS | - |
| Between group | | | | | |
| LS Mean (SE) | 138.29 (10.61) | | 133.11 (09.82) | | - |
| LS Mean Difference (SE) | 5.19 (14.47) | | | | - |
| 95% CI for LS Mean Difference | (-24.75, 35.13) | | | | |
| p-value | 0.723 (NS) | | | | |

By Student t test

NS = Not Significant

By ANCOVA

- This profile states that at baseline, mean Post Prandial Glucose was **135.42 mg/dL** among PCA Capsule which was insignificantly less as compared to **141.14 mg/dL** among Placebo group.
- After 14 days of treatment, mean Post Prandial Glucose showed an insignificant rise of **0.5%** among PCA Capsule and an insignificant fall of **4.4%** in Placebo group from baseline. If compared, the change was insignificantly more among PCA Capsule than Placebo group.

Figure 59: Mean change in Post prandial glucose (mg/dL)

from baseline by treatment group PP population

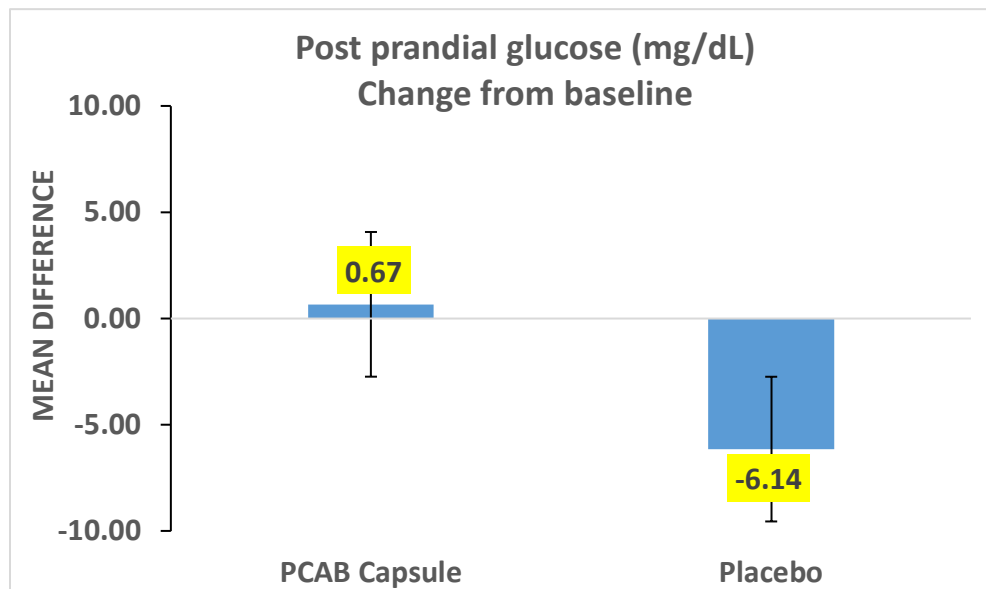


Table 61. Descriptive table for Hs CRP (mg/L), PP population

| Duration | Mean Hs CRP (mg/L) | |
|-----------------|---------------------------|--|
|-----------------|---------------------------|--|

| (Days) | ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|----------------------|--------------------------------|-------------|---------------------------------|------------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 4.90 ± 9.92 | 14 | 8.26 ± 23.05 | 0.659 (NS) |
| 14 | 12 | 2.24 ± 1.11 | 14 | 5.15 ± 08.14 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | -2.66 (3.03) (0.936) NS | 14 | -3.11 (04.40) (0.509) NS | - |
| Between group | | | | | |
| LS Mean (SE) | 2.71 (1.11) | | 4.75 (1.03) | | - |
| LS Mean Difference (SE) | 2.04 (1.52) | | | | - |
| 95% CI for LS Mean Difference | (-1.10, 5.18) | | | | |
| p-value | 0.192 (NS) | | | | |

By Wilcoxon Signed-rank Test

NS = Not Significant

By Mann Whitney U Test (Betn groups)

By ANCOVA

- In this analysis at baseline, mean Hs CRP was **4.90 mg/L** among PCA Capsule which was comparable to **8.26 mg/L** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, mean Hs CRP showed an insignificant fall of **54.3%** among PCA Capsule and **37.7%** in Placebo group from baseline. If compared, the change was more among PCA Capsule than Placebo group, but the difference was not significant.

Figure 60: Mean change in Hs CRP (mg/L) from baseline

by treatment group, PP population

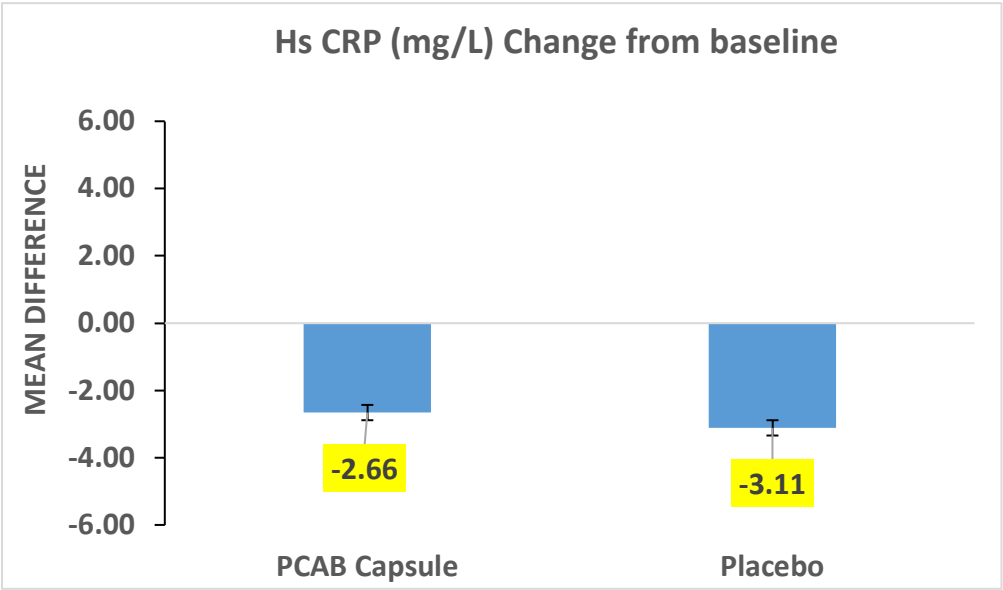


Table 62. Descriptive table for IGF-1 (ng/mL), PP population

| Duration (Days) | Mean IGF-1 (ng/mL) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|------------------------|--|-------------|---|---------|--|
| | N | PCA Capsule | N | Placebo | |
| | | | | | |

| | | | | | |
|-----------------------------------|-----------------|---------------------------------|---------------|--------------------------------|---------------|
| | | | | | |
| Baseline | 12 | 126.26 ± 16.46 | 14 | 117.02 ± 14.08 | 0.140 (NS) |
| 14 | 12 | 125.03 ± 19.15 | 14 | 119.17 ± 14.81 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | -1.23 (04.13) (0.772) NS | 14 | 2.15 (03.78) (0.579) NS | - |
| Between group | | | | | |
| LS Mean (SE) | 121.63 (4.05) | | 122.08 (3.73) | | - |
| LS Mean Difference (SE) | 0.45 (5.64) | | | | - |
| 95% CI for LS Mean Difference | (-11.21, 12.10) | | | | |
| p-value | 0.938 (NS) | | | | |

By Student t test

NS = Not Significant

By ANCOVA

- This result states that at baseline, mean IGF-1 was **126.26 ng/mL** among PCA Capsule which was more as compared to **117.02 ng/mL** among Placebo group, but the difference was not significant.
- After 14 days of treatment, mean IGF-1 showed an insignificant fall of **1.0%** among PCA Capsule and an insignificant rise of **1.8%** in Placebo group from baseline. If compared, the change was insignificantly less among PCA Capsule than Placebo group.

Figure 61: Mean change in IGF-1 (ng/mL) from baseline

by treatment group, PP population

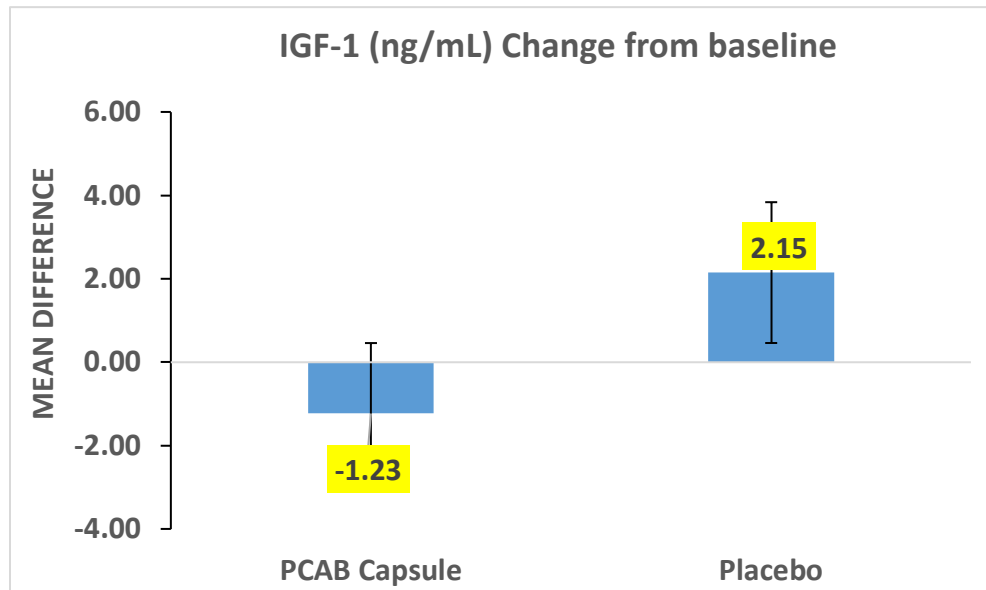


Table 63. Descriptive table for IgA (g/L), PP population

| Duration | Mean IgA (g/L) | |
|----------|----------------|--|
|----------|----------------|--|

| (Days) | ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|----------------------|--------------------------------|-------------|---------------------------------|---------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 2.487 ± 0.796 | 14 | 2.863 ± 1.109 | 0.326 (NS) |
| 14 | 12 | 2.493 ± 0.979 | 14 | 2.621 ± 0.689 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | 0.007 (0.12) (0.955) NS | 14 | -0.242 (0.16) (0.143) NS | - |
| Between group | | | | | |
| LS Mean (SE) | 2.64 (0.13) | | 2.50 (0.12) | | - |
| LS Mean Difference (SE) | 0.15 (0.18) | | | | - |
| 95% CI for LS Mean Difference | (-0.23, 0.52) | | | | |
| p-value | 0.429 (NS) | | | | |

By Student t test

NS = Not Significant

By ANCOVA

- As per this study at baseline, mean IgA was **2.49 g/L** among PCA Capsule which was comparable to **2.86 g/L** among Placebo group and the difference was not statistically significant.
- After 14 days of treatment, mean IgA showed an insignificant rise of 0.3% among Placebo group and an insignificant fall of **8.5%** in PCA Capsule group from baseline. If compared, the change was insignificantly more among PCA Capsule than Placebo group.

Figure 62: Mean change in IgA (g/L) from baseline

by treatment group, PP population

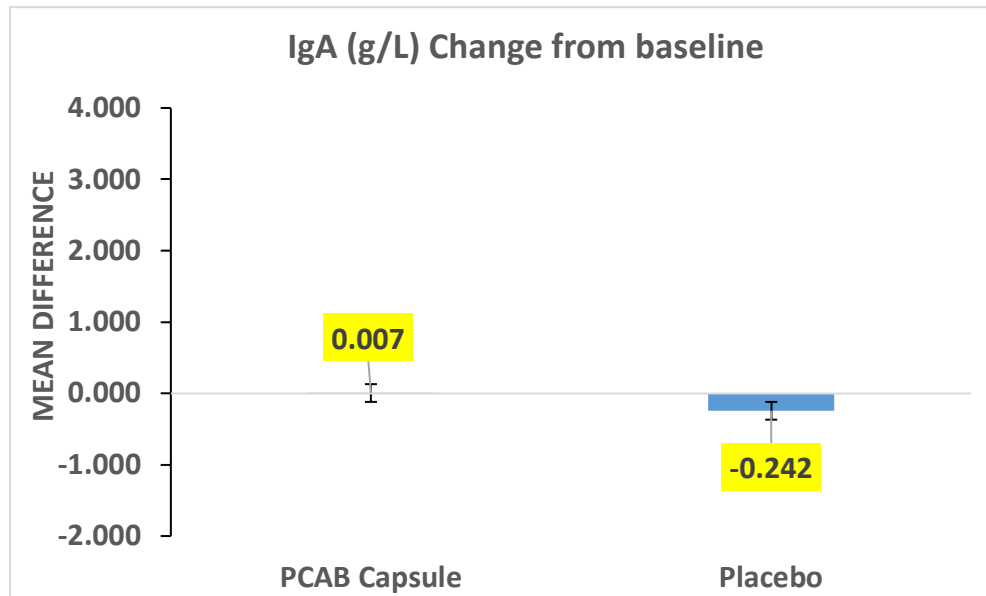


Table 64. Descriptive table for IgG (g/L), PP Population

| Duration (Days) | Mean IgG (g/L) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|--------------------------------|--------------|-------------------------------|--|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 12.78 ± 2.30 | 14 | 12.71 ± 2.42 | 0.940 (NS) |
| 14 | 12 | 12.39 ± 2.02 | 14 | 12.84 ± 2.24 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | -0.39 (0.43) (0.381) NS | 14 | 0.13 (0.42) (0.760) NS | - |
| Between group | | | | | |
| LS Mean (SE) | 12.37 (0.40) | | 12.86 (0.37) | | - |
| LS Mean Difference (SE) | 0.49 (0.54) | | | | - < |

By Student t test

NS = Not Significant

By ANCOVA

- This profile reveals that at baseline, mean IgG was **12.78 g/L** among PCA Capsule which was comparable to **12.71 g/L** among Placebo group and the difference was not significant.
- After 14 days of treatment, mean IgG showed an insignificant fall of **3.1%** among PCA Capsule and an insignificant rise of **1.0%** in Placebo group from baseline. If compared, the change was insignificantly more among Placebo than PCA Capsule group.

Figure 63: Mean change in IgG (g/L) from baseline

by treatment group, PP population

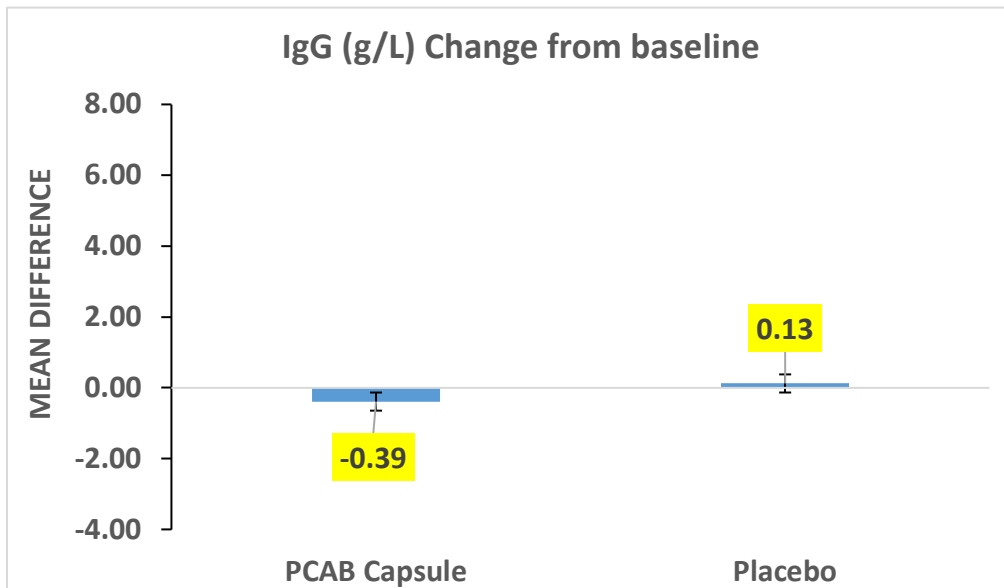


Table 66. Descriptive table for CXCL9 (pg/mL), PP Population

| Duration (Days) | Mean CXCL9 (pg/mL) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|-----------------------------------|-----------------|---------------------------------|------------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 640.87 ± 399.31 | 14 | 545.04 ± 629.42 | 0.642 (NS) |
| 14 | 12 | 804.89 ± 605.98 | 14 | 594.22 ± 619.82 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | 164.02 (186.69) (0.398) NS | 14 | 49.17 (31.09) (0.137) NS | - |
| Between group | | | | | |
| LS Mean (SE) | 763.18 (128.31) | | 629.96 (118.75) | | - |
| LS Mean Difference (SE) | 132.22 (175.20) | | | | - |
| 95% CI for LS Mean Difference | (-229.21, 495.65) | | | | |
| p-value | 0.455 (NS) | | | | |

By Student t test

NS = Not Significant

By ANCOVA

- As per this analysis at baseline, mean CXCL9 was **640.87 pg/mL** among PCA Capsule which was insignificantly more as compared to **545.04 pg/mL** among Placebo group.
- After 14 days of treatment, mean CXCL9 showed an insignificant rise of **25.6%** among PCA Capsule and **9.0%** in Placebo group from baseline. If compared, the change was more among PCA Capsule than Placebo group, but the difference was not significant.

Figure 64: Mean change in CXCL9 (pg/mL) from baseline

by treatment group, PP population

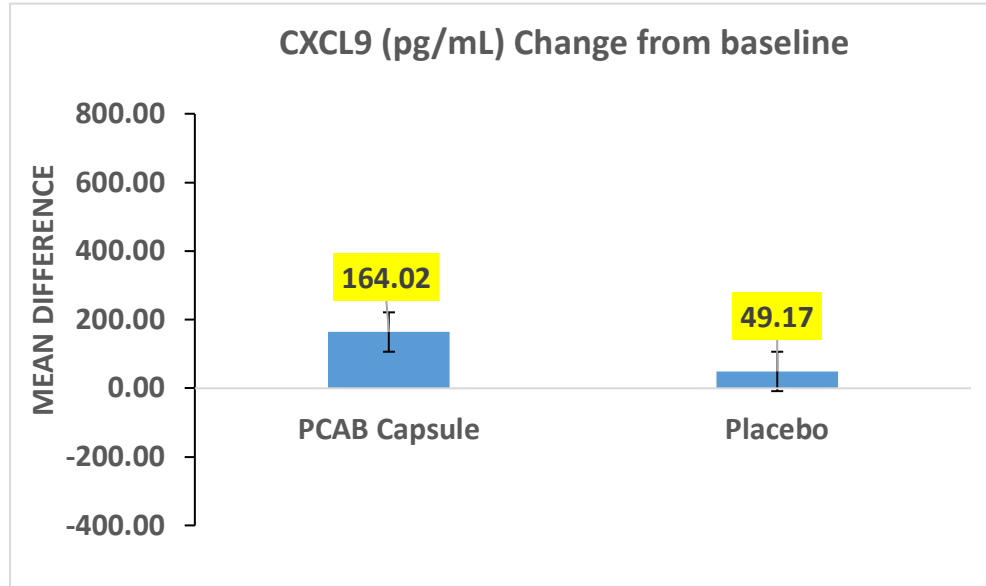


Table 67. Descriptive table for GLP-1 (pmol/mL), PP Population

| Duration (Days) | Mean GLP-1 (pmol/mL) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|--|----------------------------------|---------------|---------------------------------|------------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 0.024 ± 0.004 | 14 | 0.022 ± 0.002 | 0.129 (NS) |
| 14 | 12 | 0.023 ± 0.003 | 14 | 0.023 ± 0.003 | - |
| Change from baseline within group | | | | | |
| Mean (SE) (p value) | 12 | -0.001 (0.001) (1.000) NS | 14 | 0.002 (0.001) (1.000) NS | - |
| Between group | | | | | |
| LS Mean (SE) | 0.023 (0.001) | | 0.024 (0.001) | | - |
| LS Mean Difference (SE) | 0.001 (0.001) | | | | - |
| 95% CI for LS Mean Difference | (-0.002, 0.004) | | | | |
| p-value | 0.695 (NS) | | | | |

By Student t test

NS = Not Significant

By ANCOVA

- According to this study at baseline, mean GLP-1 was **0.02 pmol/mL** which was same among both the group and the difference was not significant.
- After 14 days of treatment, mean GLP-1 showed an insignificant fall of **4.2%** among PCA Capsule and insignificant rise of **9.1%** in Placebo group from baseline. If compared, the change was less among PCA Capsule than Placebo group, but the difference was not significant.

Figure 65: Mean change in GLP-1 (pmol/mL) from baseline

by treatment group, PP population

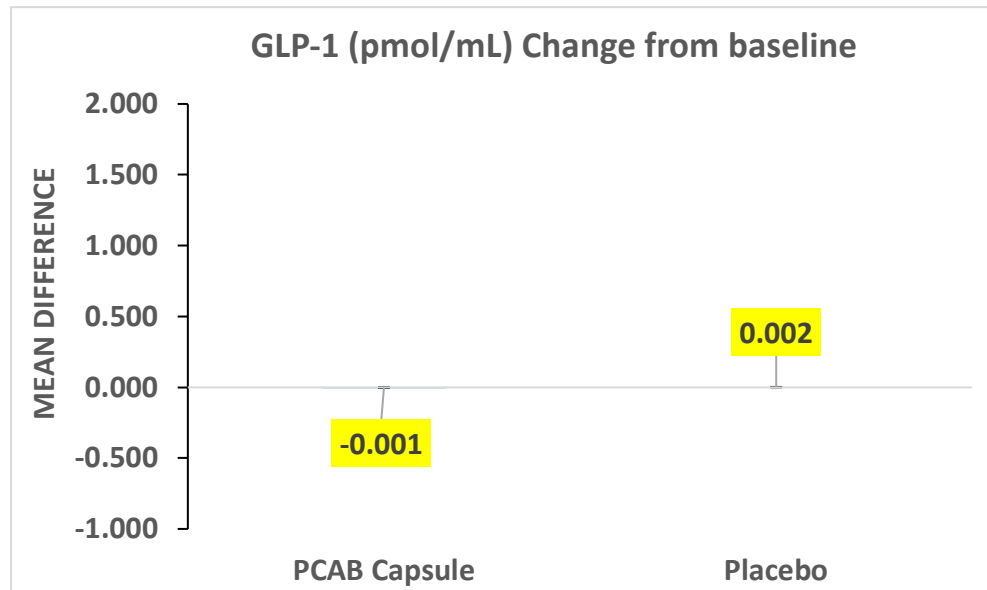


Table 68. Descriptive table for Prothrombin

Time (Sec), PP Population

| Duration (Days) | Mean Prothrombin Time (Sec) ($\bar{X} \pm SD$) | | | | Between Groups (P value) |
|-----------------------------------|---|--------------|----|--------------|--------------------------------|
| | N | PCA Capsule | N | Placebo | |
| Baseline | 12 | 11.97 ± 1.00 | 14 | 12.20 ± 0.90 | 0.546 (NS) |
| 14 | 12 | 12.49 ± 0.81 | 14 | 12.60 ± 1.24 | - |
| Change from baseline within group | | | | | |

| | | | | | |
|-------------------------------|---------------|-------------|--------------|-------------|---|
| Mean (SE) | 12 | 0.53 (0.32) | 14 | 0.40 (0.29) | - |
| (p value) | | (0.120) NS | | (0.192) NS | |
| Between group | | | | | |
| LS Mean (SE) | 12.55 (0.29) | | 12.55 (0.27) | | - |
| LS Mean Difference (SE) | 0.001 (0.39) | | | | - |
| 95% CI for LS Mean Difference | (-0.81, 0.81) | | | | |
| p-value | 0.998 (NS) | | | | |

By Student t test

NS = Not Significant

By ANCOVA

- According to this study at baseline, mean Prothrombin Time was **11.97 sec** among PCA Capsule which was comparable to **12.20 sec** among Placebo group and the difference was not significant.
- After 14 days of treatment, mean Prothrombin Time showed an insignificant rise of **4.4%** among PCA Capsule and **3.3%** in Placebo group from baseline. If compared, the change was comparable between the groups and the difference was not significant.

Figure 66: Mean change in Prothrombin Time (Sec) from baseline by treatment group, PP population

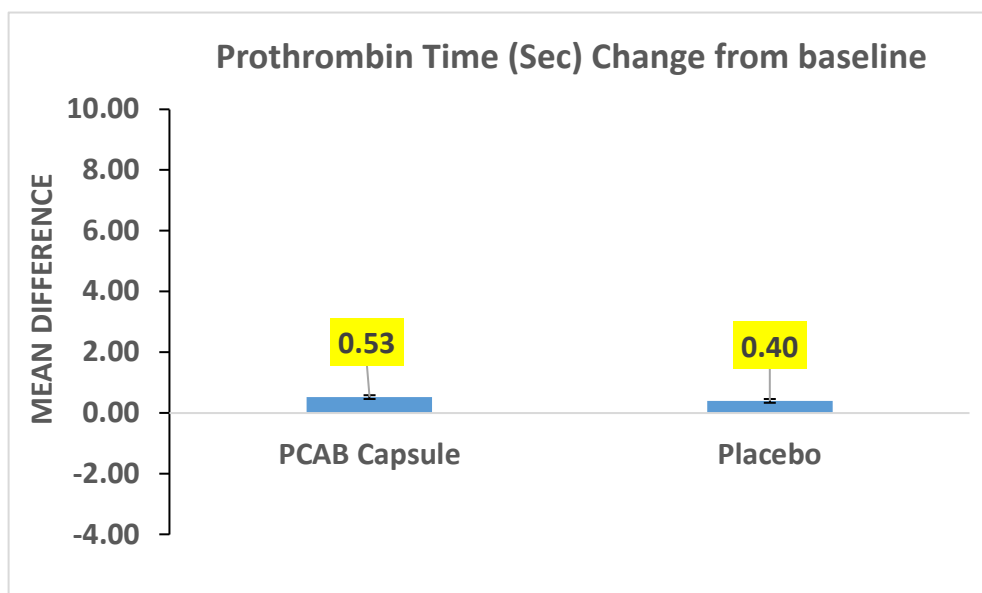


Table 69. Physical examination, ITT Population (Baseline)

| Physical Examination | | PCA Capsule (N =12) | | Placebo (N =14) | | p value |
|----------------------|--------------|------------------------|-------|--------------------|-------|------------|
| | | No. | % | No. | % | |
| General appearance | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Head | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Eye | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Nose | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Throat | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Nails | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |

| | | | | | | |
|--|--------------|----|-------|----|-------|------------|
| Skin | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Heart | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Teeth | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Tongue | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Lungs | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Abdomen | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Extremities & Musculoskeletal | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| CNS | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |

By Chi square Test

NS = Not significant

In this study at Baseline, **100.0%** of the cases had Normal physical examinations among both the groups which was same, and the difference was not significant.

Table 69. Physical examination, ITT Population (Day 14)

| Physical Examination | | PCA Capsule (N =12) | | Placebo (N =14) | | p value |
|---------------------------|--------------|------------------------|-------|--------------------|-------|------------|
| | | No. | % | No. | % | |
| General appearance | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Head | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Eye | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Nose | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |

| | | | | | | |
|--|--------------|----|-------|----|-------|------------|
| | Not examined | - | - | - | - | - |
| Throat | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Nails | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Skin | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Heart | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Teeth | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Tongue | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Lungs | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Abdomen | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| Extremities & Musculoskeletal | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |
| CNS | Normal | 12 | 100.0 | 14 | 100.0 | 1.000 (NS) |
| | Abnormal | - | - | - | - | - |
| | Not examined | - | - | - | - | - |

By Chi square Test

NS = Not significant

At the end of study, **100.0%** of cases had Normal physical examinations among both the groups which was same, and the difference was not significant.

Table 70. Concomitant medication, ITT Population

| Concomitant Medication | PCA Capsule (N = 12) | | Placebo (N = 14) | | Overall (N = 26) | |
|---|---------------------------------|----------|-----------------------------|----------|-----------------------------|----------|
| | No. | % | No. | % | No. | % |
| Subjects with any concomitant medications | 04 | 33.3 | 10 | 71.4 | 14 | 53.8 |
| By Drug Generic Name | | | | | | |
| Metformin | 03 | 25.0 | 05 | 35.7 | 08 | 30.8 |
| Acetylsalicylic acid | 01 | 08.3 | 03 | 21.4 | 04 | 15.4 |

| | | | | | | |
|-----------------------|----|------|----|------|----|------|
| Telmisartan | 02 | 16.7 | 02 | 14.3 | 04 | 15.4 |
| Vildagliptin | - | - | 03 | 21.4 | 03 | 11.5 |
| Amlodipine | 01 | 08.3 | 02 | 14.3 | 03 | 11.5 |
| Glimepiride | 02 | 16.7 | 01 | 07.1 | 03 | 11.5 |
| Atorvastatin | 01 | 08.3 | 01 | 07.1 | 02 | 07.7 |
| Dapagliflozin | 01 | 08.3 | 01 | 07.1 | 02 | 07.7 |
| Rosuvastatin | 01 | 08.3 | 01 | 07.1 | 02 | 07.7 |
| Sitagliptin | 01 | 08.3 | 01 | 07.1 | 02 | 07.7 |
| Thyroxine | - | - | 02 | 14.3 | 02 | 07.7 |
| Vitamin D3 | - | - | 01 | 07.1 | 01 | 03.8 |
| Methylprednisolone | - | - | 01 | 07.1 | 01 | 03.8 |
| Atenolol | - | - | 01 | 07.1 | 01 | 03.8 |
| Calcium | - | - | 01 | 07.1 | 01 | 03.8 |
| Chlorthalidone | - | - | 01 | 07.1 | 01 | 03.8 |
| Deflazacort | - | - | 01 | 07.1 | 01 | 03.8 |
| Gliclazide | - | - | 01 | 07.1 | 01 | 03.8 |
| Indapamide | - | - | 01 | 07.1 | 01 | 03.8 |
| Inj. Cyanocobalamin | - | - | 01 | 07.1 | 01 | 03.8 |
| Levo-carnitine | - | - | 01 | 07.1 | 01 | 03.8 |
| Metoprolol Succinate | - | - | 01 | 07.1 | 01 | 03.8 |
| Perindopril erbumine | - | - | 01 | 07.1 | 01 | 03.8 |
| Pioglitazone | - | - | 01 | 07.1 | 01 | 03.8 |
| Teneligliptin | - | - | 01 | 07.1 | 01 | 03.8 |
| Ticagrelor | - | - | 01 | 07.1 | 01 | 03.8 |
| Torsemide | - | - | 01 | 07.1 | 01 | 03.8 |
| Vitamin E | - | - | 01 | 07.1 | 01 | 03.8 |
| Thiamine (Vitamin B1) | 01 | 08.3 | - | - | 01 | 03.8 |
| Arimumoulth ulcer gel | 01 | 08.3 | - | - | 01 | 03.8 |
| Benidipine | 01 | 08.3 | - | - | 01 | 03.8 |
| Fenofibrate | 01 | 08.3 | - | - | 01 | 03.8 |
| Gabapentin | 01 | 08.3 | - | - | 01 | 03.8 |
| Human insulin | 01 | 08.3 | - | - | 01 | 03.8 |
| Hydrochlorothiazide | 01 | 08.3 | - | - | 01 | 03.8 |
| Imeglimin | 01 | 08.3 | - | - | 01 | 03.8 |
| Levothyroxine Sodium | 01 | 08.3 | - | - | 01 | 03.8 |
| Nortriptyline | 01 | 08.3 | - | - | 01 | 03.8 |
| Olmesartan Medoxomil | 01 | 08.3 | - | - | 01 | 03.8 |
| Repaglinide | 01 | 08.3 | - | - | 01 | 03.8 |
| Voglibose | 01 | 08.3 | - | - | 01 | 03.8 |

Table 71. Percentage of Study Treatment Compliance
at Day 14, ITT Population

| | PCA Capsule (N = 12) | Placebo (N = 14) | Overall (N = 26) |
|-------------------|---------------------------------|-----------------------------|-----------------------------|
| Compliance | | | |
| N | 12 | 14 | 26 |
| Mean | 86.78 | 93.07 | 90.17 |
| SD | 11.07 | 5.80 | 9.03 |
| Median | 87.00 | 92.00 | 92.00 |
| Min | 57.00 | 85.00 | 57.00 |
| Max | 100.0 | 103.0 | 103.0 |
| | | | |
| <80% [n (%)] | 01 (08.3) | - | 01 (03.8) |
| 80-120% [n (%)] | 11 (91.7) | 14 (100.0) | 25 (96.2) |
| >120% [n (%)] | - | - | - |

At Day 14, **96.2%** of total study cases had 80-120% of compliance.
100.0% of the cases had 80-120% compliance in placebo group which
was more as compared to **91.7%** of cases in PCA Capsule group.