BIOSPECTRA
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TRIS BIO EXCIPIENT GRADE 2015-2018REAL-TIME STABILITY REPORT

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1. OVERVIEW:

The purpose of this report is to analyze and conclude on the data obtained from the real-time stability study of Bio Excipient Grade Tris manufactured at the Stroudsburg PA facility. Testing intervals are designated by T_n, where n = the number of months on stability. Testing is performed every three months for the first year, every six months for the second year, and annually for each subsequent year for a total of three years in order to maintain that the manufactured product remains stable under the specified conditions and for the specified interval of time. The analysis of the compiled data may also aid in a re-evaluation of the retest date for the finished good product.

The data was analyzed utilizing a Shelf-Life Plot, which determines the point in time at which the slope would exceed the acceptance criteria. As long as the slope has a statistically significant difference from zero using a 95% confidence limit, an estimated time in months can be established at which the acceptance criteria will no longer be met, i.e. the Shelf Life. This allows BioSpectra to ensure that the product is stable over the time period in which it is part of the stability program. All quantitative data was analyzed using these methods. The data can be found in the Tris Real Time Stability Program binders.

This Real Time Stability analysis will assess the stability of 8 lots of Tris that were placed on stability in the years 2012-2015 and concluded their stability studies in the years 2015-2018.

2. DEFINITIONS:

CL: Control Limit, the average

UCL: Upper control limit, 3 sigma above the CLLCL: Lower control limit, 3 sigma below the CL

OOT: Out Of Trend, this means that the material still meets control limits but was not in trend with the rest of the material.

OOS: Out of Specification, for the purpose of this stability analysis, OOS will mean that there is a point(s) that fall outside of the UCL or LCL.

3. SAMPLE DESIGNATION:

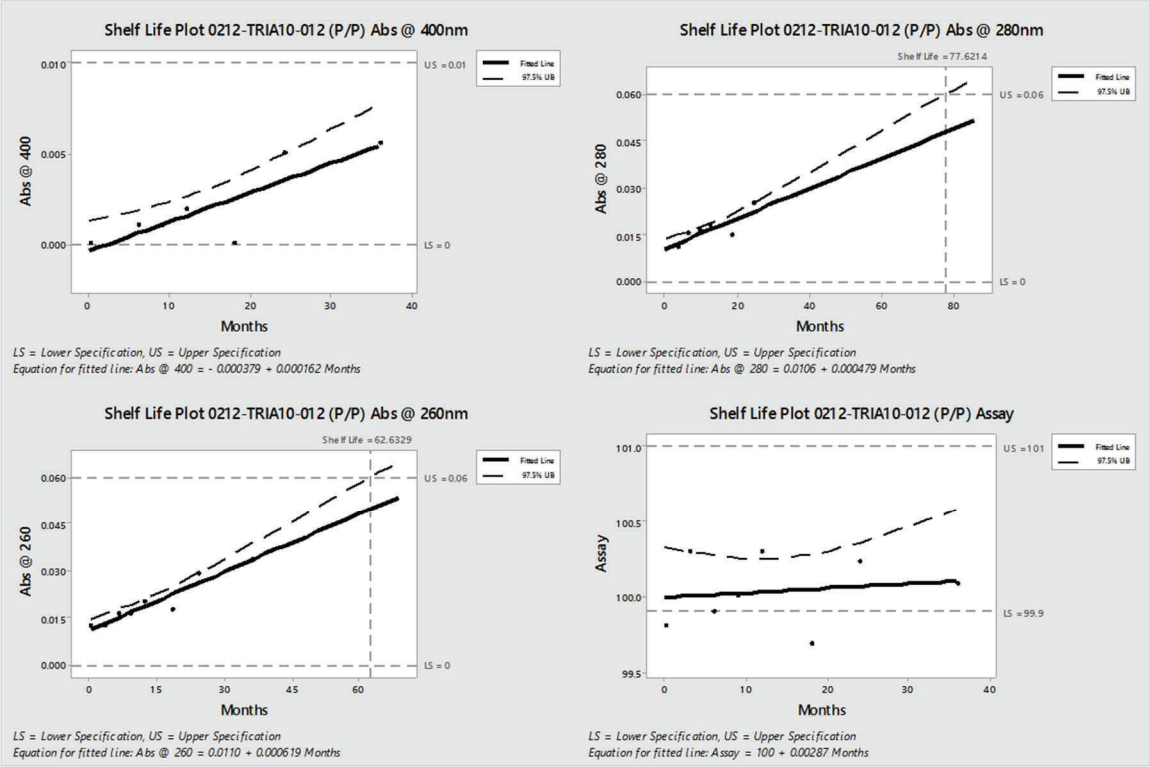
Samples initially placed on the stability program consisted of all process validation batches and one lot per year. Stability samples from each of these batches were put into three different packaging types including Poly/Poly (P/P), Poly/Fiber (P/F), and Poly/ Tyvek (T/P) packaged in accordance with the Sampling Matrix SOP.

4. STORAGE:

Although there are currently no storage conditions for Tris, storage conditions have been continuously measured and recorded. Utilizing MadgeTech data loggers located in the Stroudsburg warehouse with regulated conditions for temperature (15-30°C) and humidity (monitor).

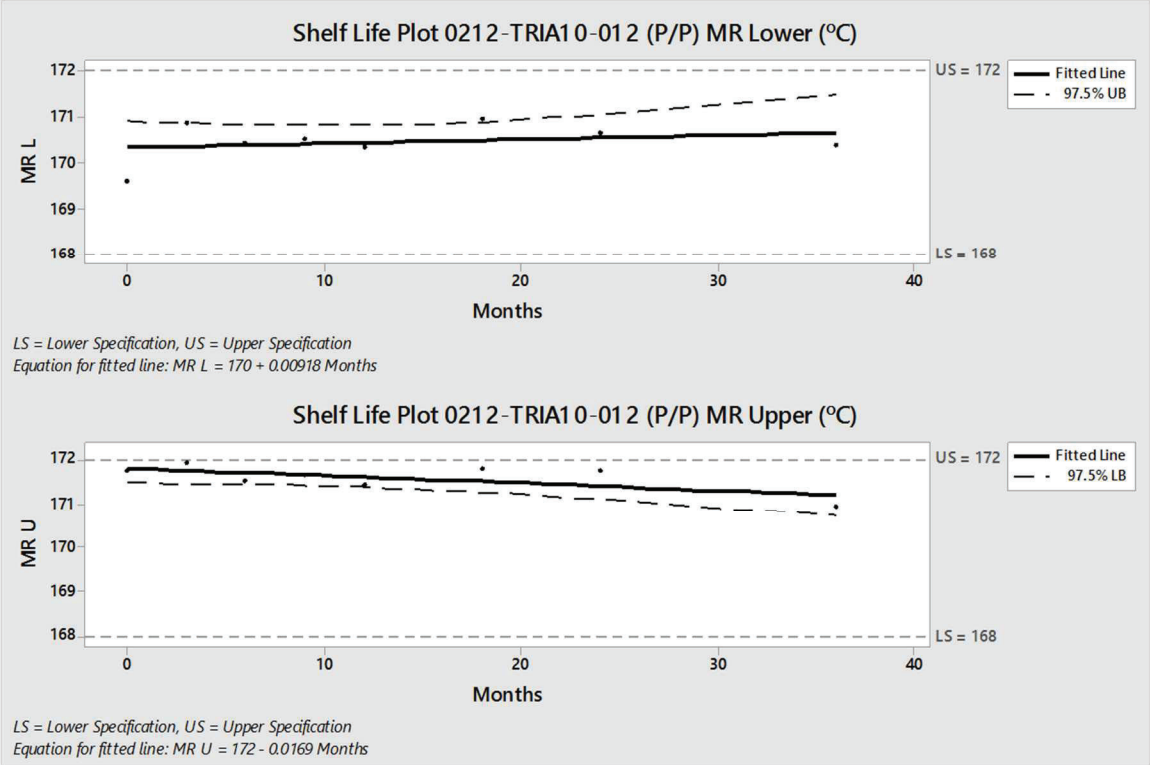
LOT ANALYSIS 0212-TRIA10-012 (P/P):

GRAPH 1. 0212-TRIA10-012 (P/P) ABS @ 400, 280, 260 NM AND ASSAY %



Results for absorbance at 400nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. Shelf lives of 77 and 62 months were predicted based on data for absorbance at 280nm and absorbance at 260nm, respectively. Both predicted shelf lives exceed the current 24 month retest date assigned to this material as well as the 36 month maximum expiration date.

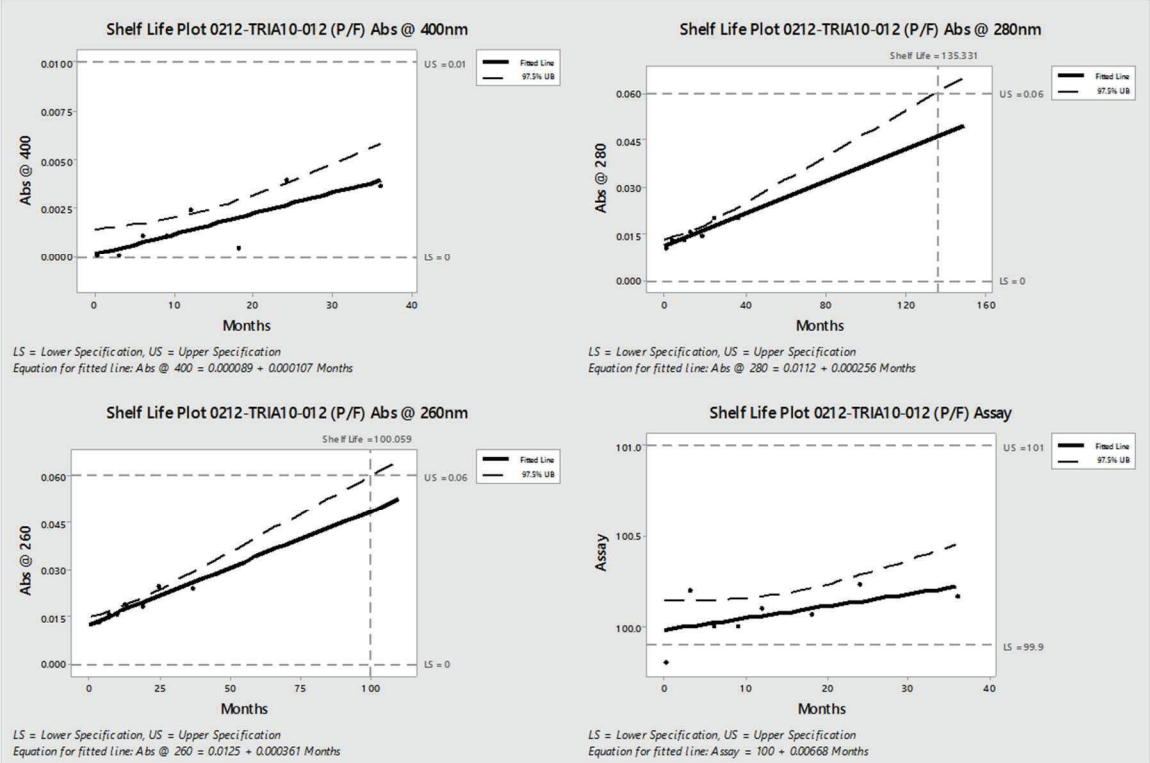
GRAPH 2. 0212-TRIA10-012 (P/P) MELTING RANGE LOWER AND UPPER POINTS



Results for melting range at both the lower and upper points showed no predictable shelf life asthe mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from this analysis.

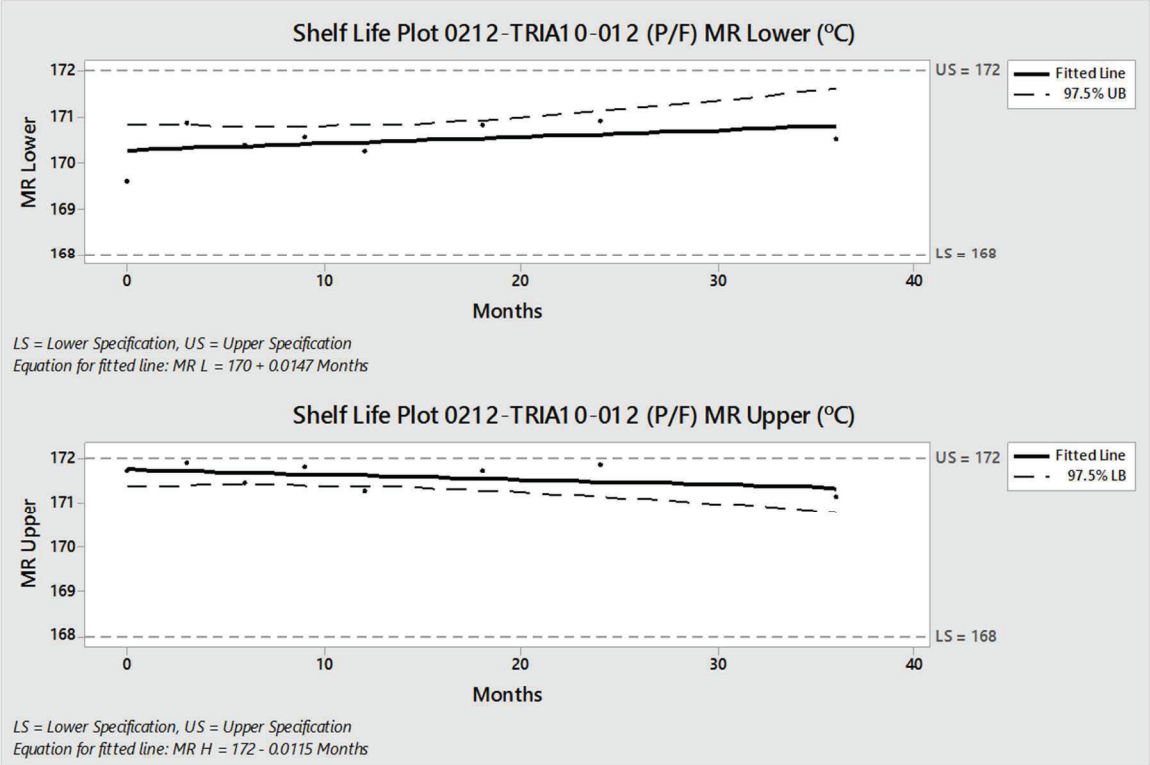
LOT ANALYSIS 0212-TRIA10-012 (P/F):

GRAPH 3. 0212-TRIA10-012 (P/F) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance at 400nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. Shelf lives of 125 and 100 months were predicted based on data for absorbance at 280nm and absorbance at 260nm, respectively. Both predicted shelf lives exceed the current 24 month retest date assigned to this material as well as the 36 month maximum expiration date.

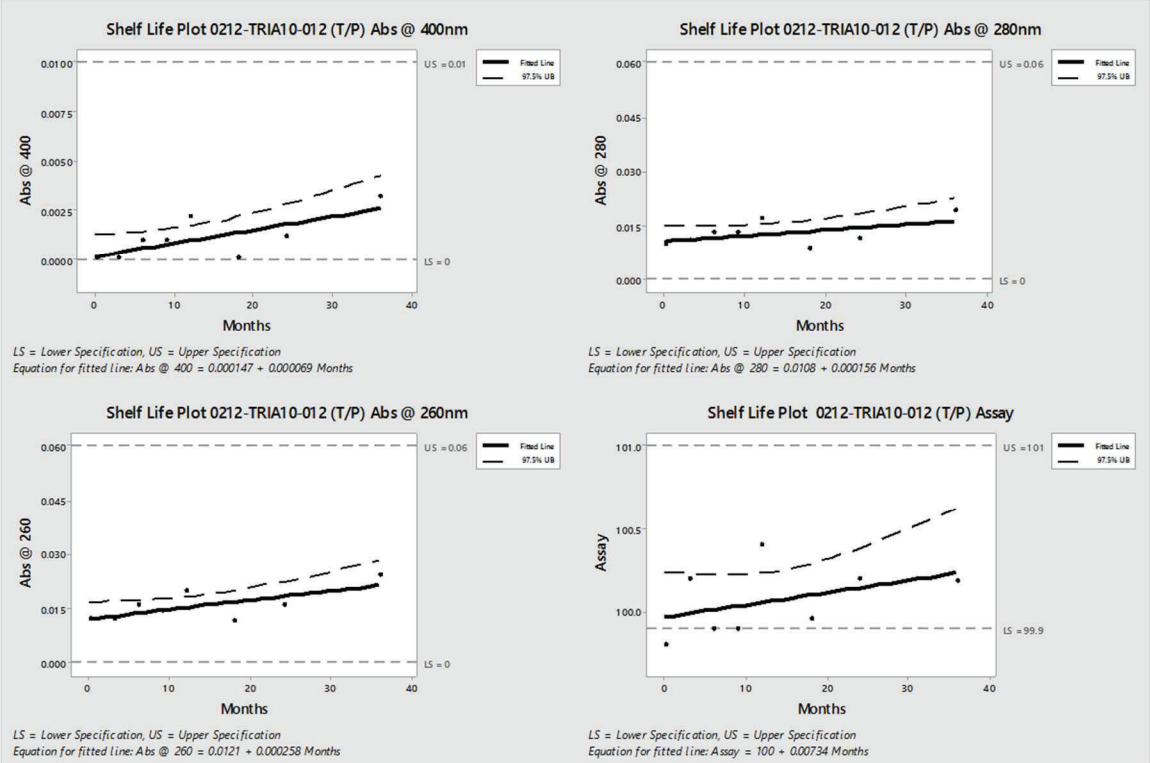
GRAPH 4. 0212-TRIA10-012 (P/F) MELTING RANGE LOWER AND UPPER POINTS



Results for Melting Range at both the Lower and Upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from this analysis.

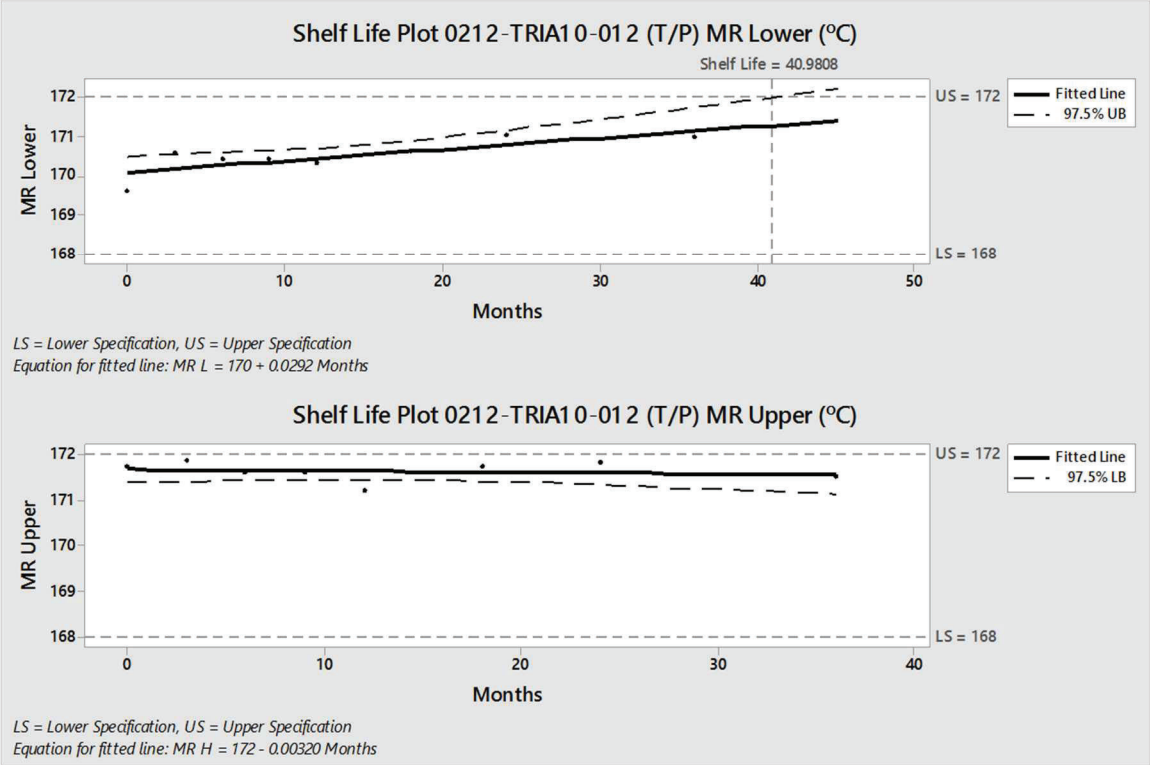
LOT ANALYSIS 0212-TRIA10-012 (T/P):

GRAPH 5. 0212-TRIA10-012 (T/P) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance @ 400nm, 280nm, 260nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

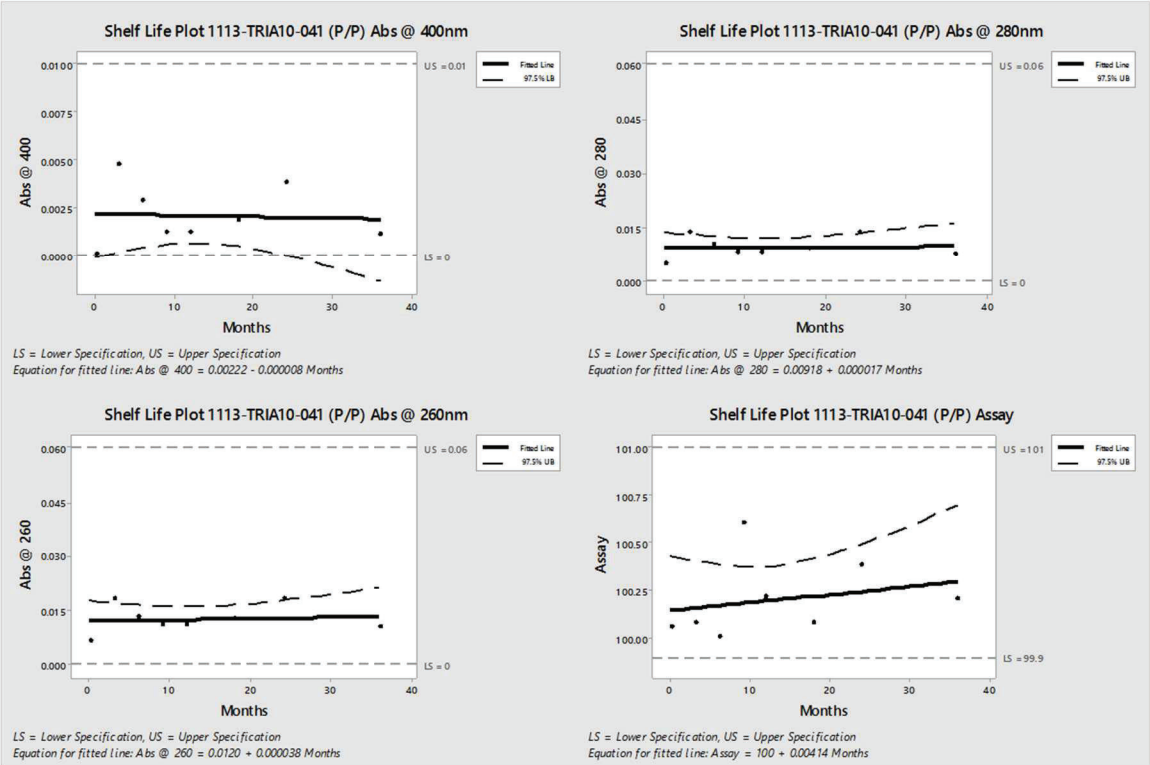
GRAPH 6. 0212-TRIA10-012 (T/P) MELTING RANGE LOWER AND UPPER POINTS



Results for melting range at upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from this analysis. A shelf life of 40.98 months was predicted based on data for melting range at the lower point. The predicted shelf life exceeds the current 24 month retest date assigned to this materialas well as the 36 month maximum expiration date.

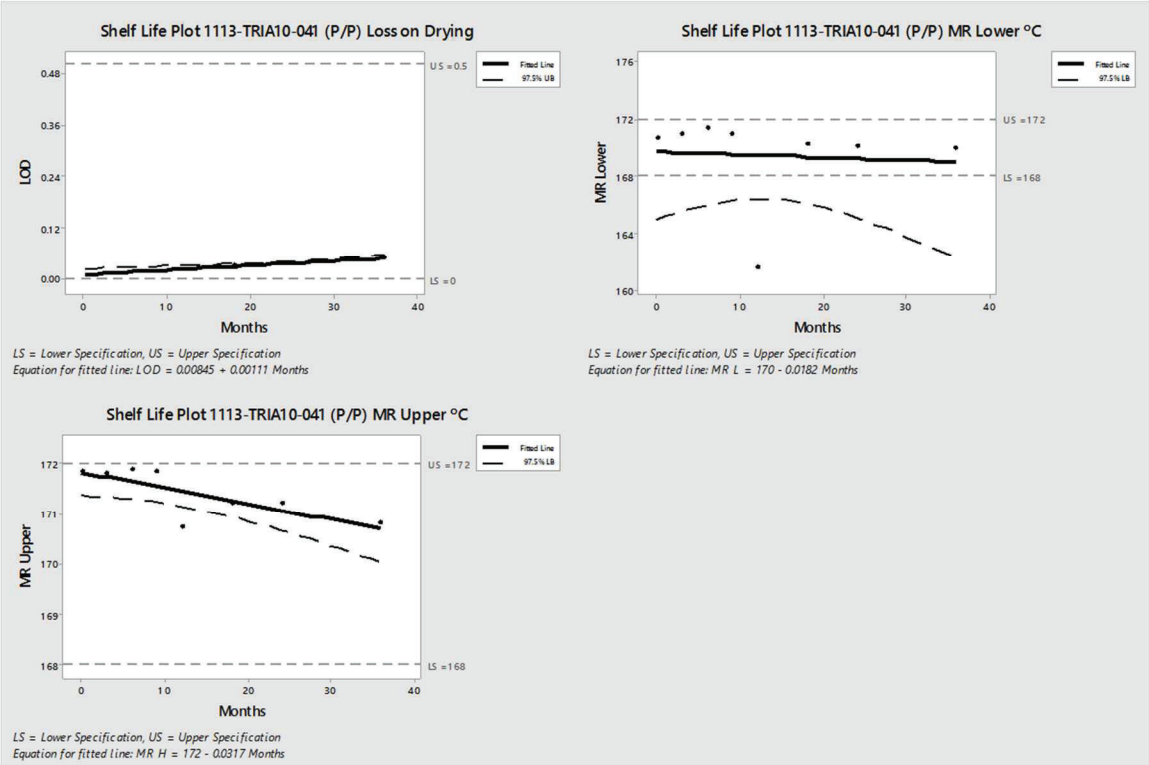
LOT ANALYSIS 1113-TRIA10-041 (P/P):

GRAPH 7. 1113-TRIA10-041 (P/P) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance at 400nm, 280nm, 260nm and Assay showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

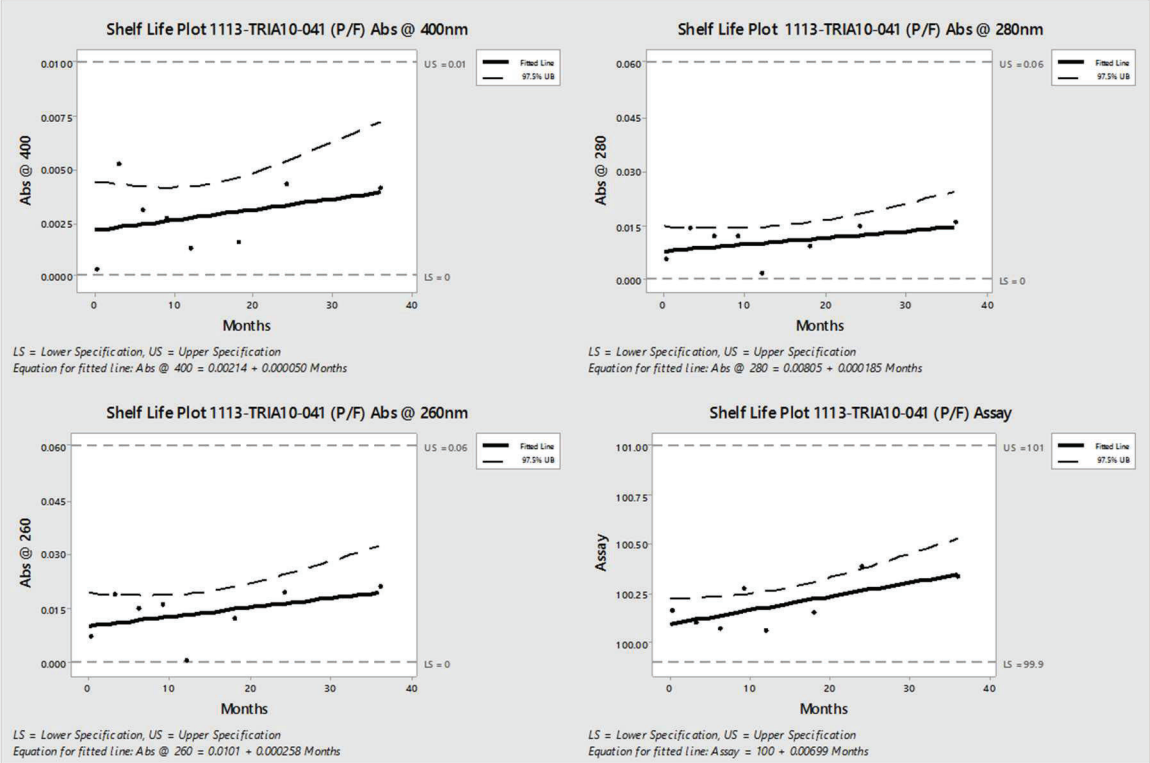
GRAPH 8. 1113-TRIA10-041 (P/P) LOSS ON DRYING %, MELTING RANGE LOWER AND UPPER POINTS



Results for loss on drying and melting range at both the lower and upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

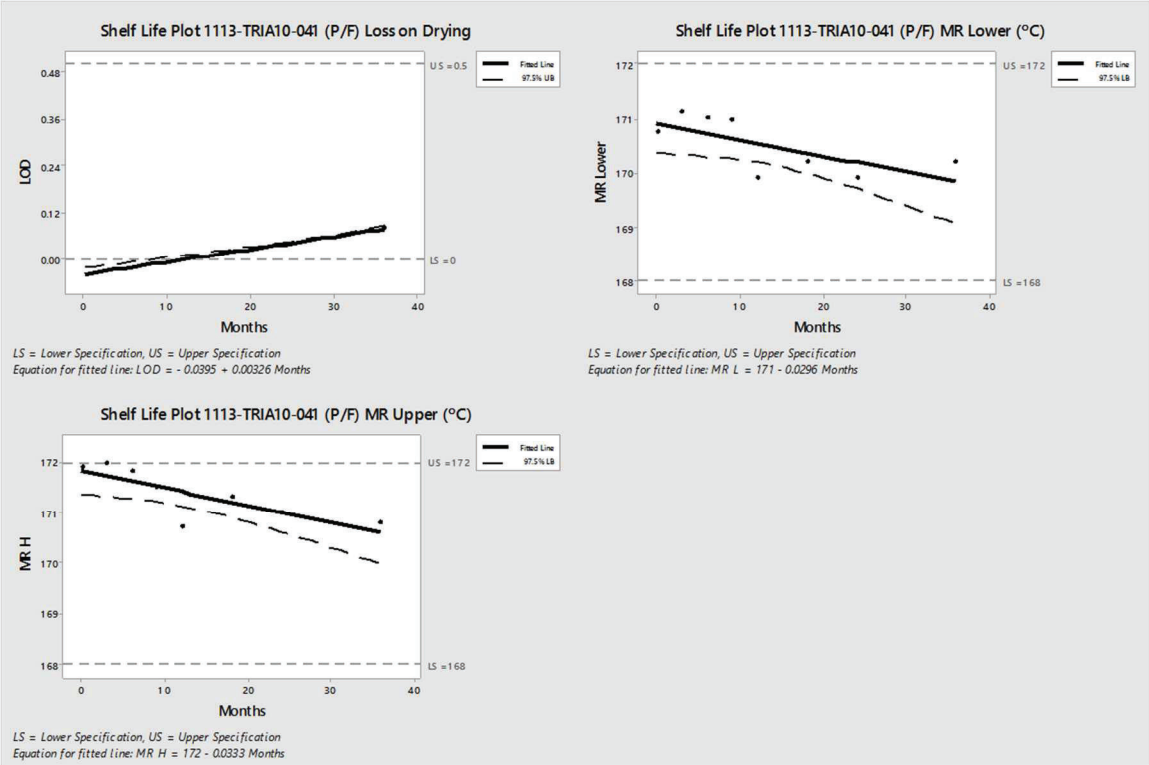
LOT ANALYSIS 1113-TRIA10-041 (P/F):

GRAPH 9. 1113-TRIA10-041 (P/F) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance @ 400nm, 280nm, 260nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

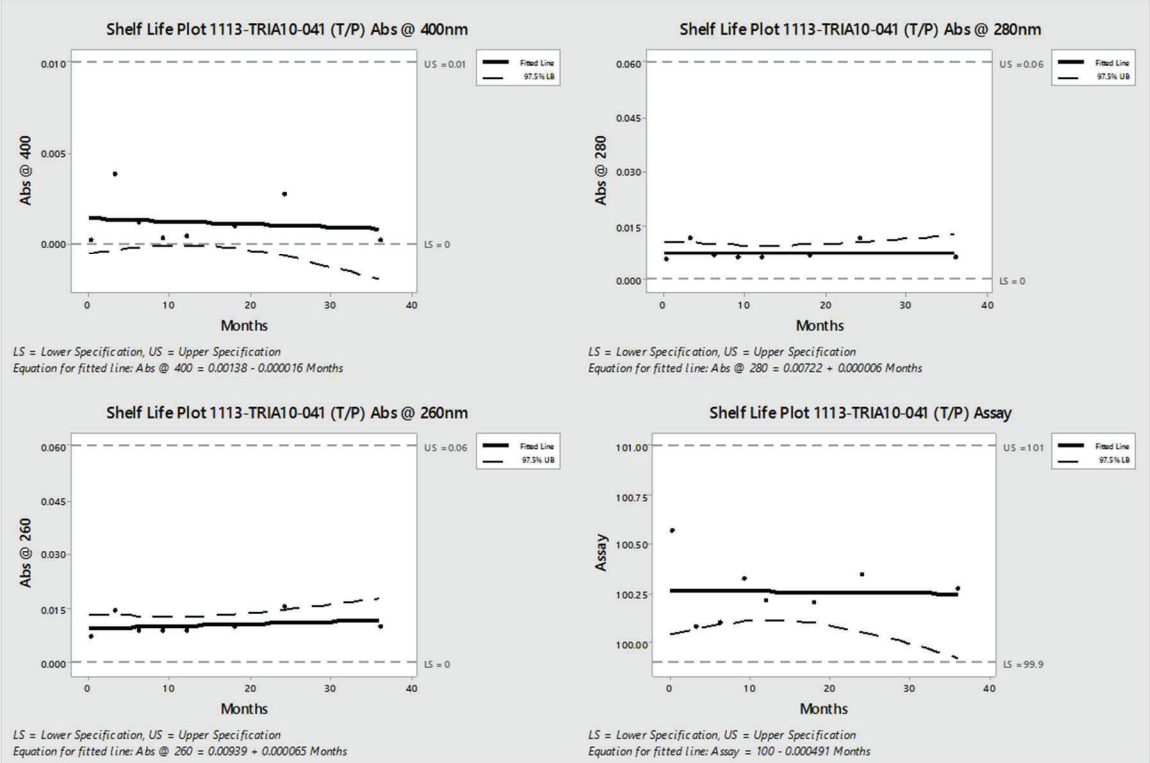
GRAPH 10. 1113-TRIA10-041 (P/F) LOSS ON DRYING %, MELTING RANGE LOWER AND UPPER POINTS



Results for loss on drying and melting range at both the lower and upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

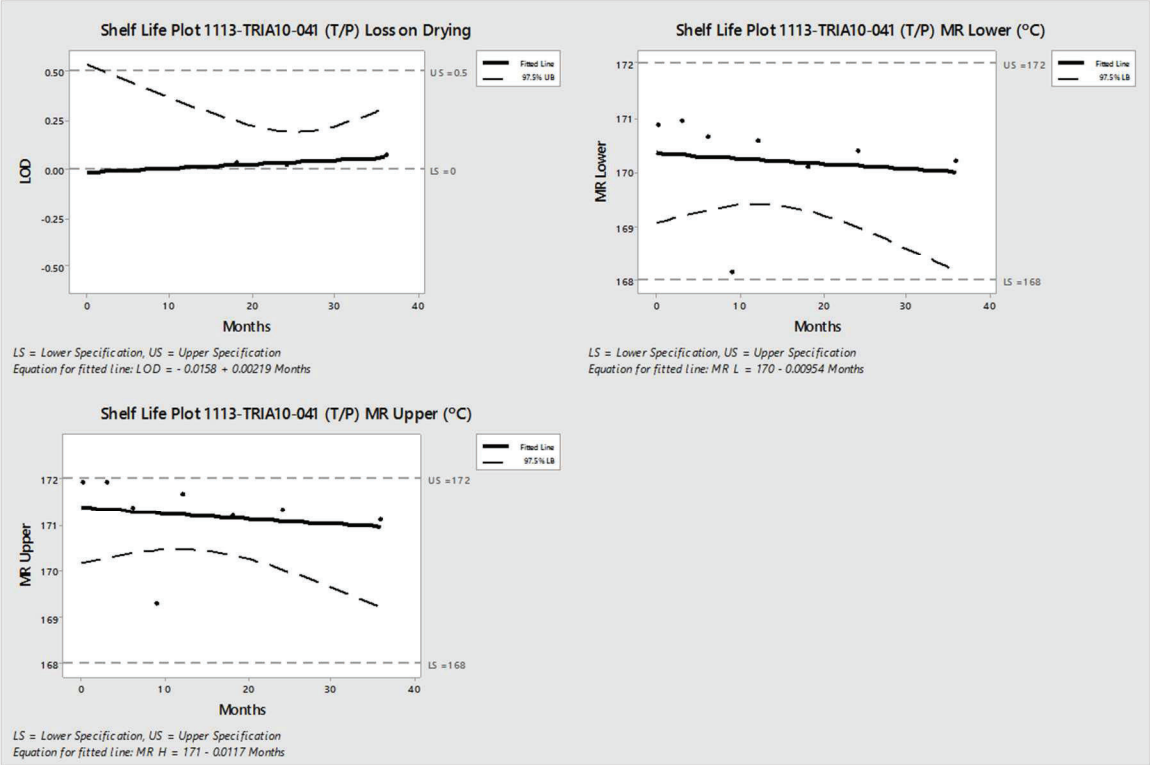
LOT ANALYSIS 1113-TRIA10-041 (T/P):

GRAPH 11. 1113-TRIA10-041 (T/P) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance @ 400nm, 280nm, 260nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

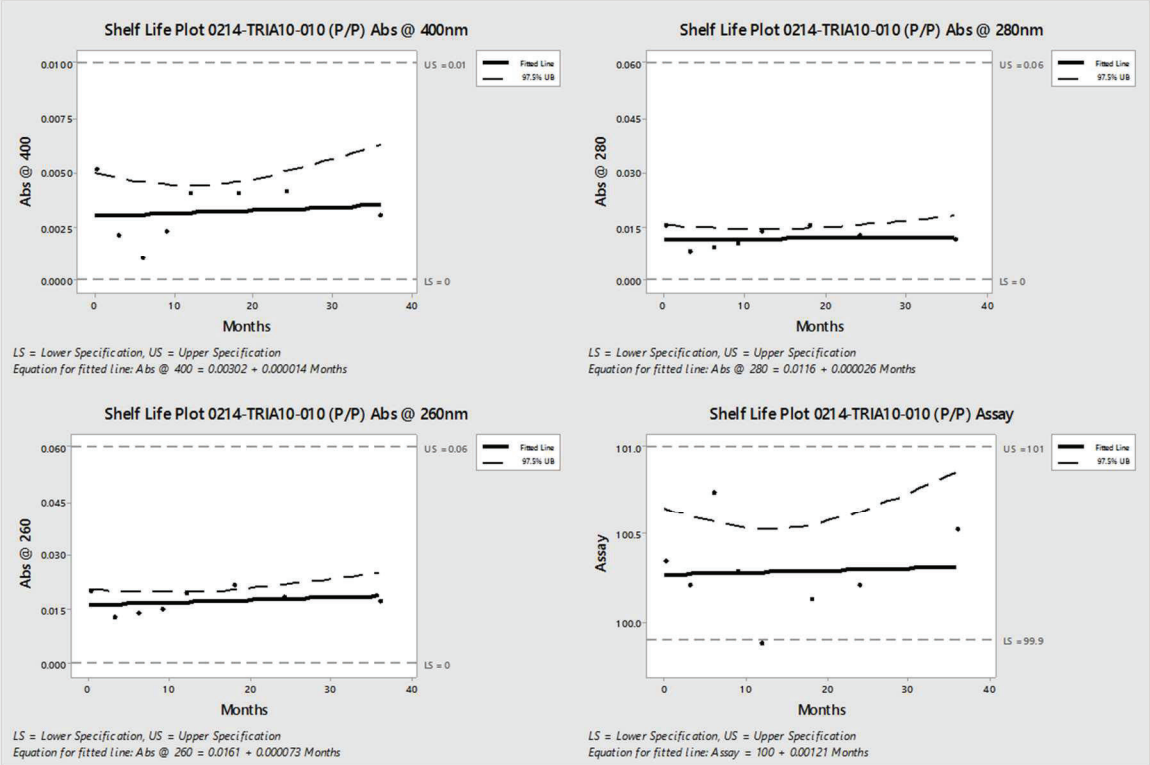
GRAPH 12. 1113-TRIA10-041 (T/P) LOSS ON DRYING %, MELTING RANGE LOWER AND UPPER POINTS



Results for loss on drying and melting range at both the lower and upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

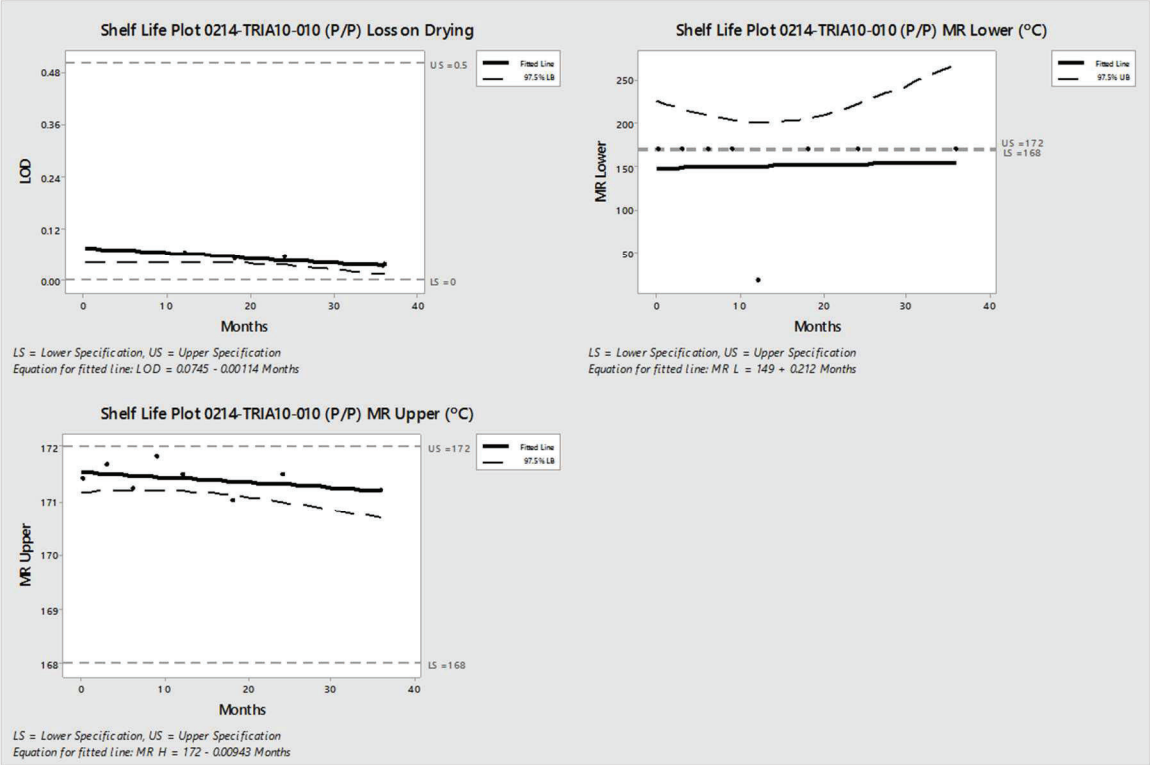
LOT ANALYSIS 0214-TRIA10-010 (P/P):

GRAPH 13. 0214-TRIA10-010 (P/P) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance @ 400nm, 280nm, 260nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

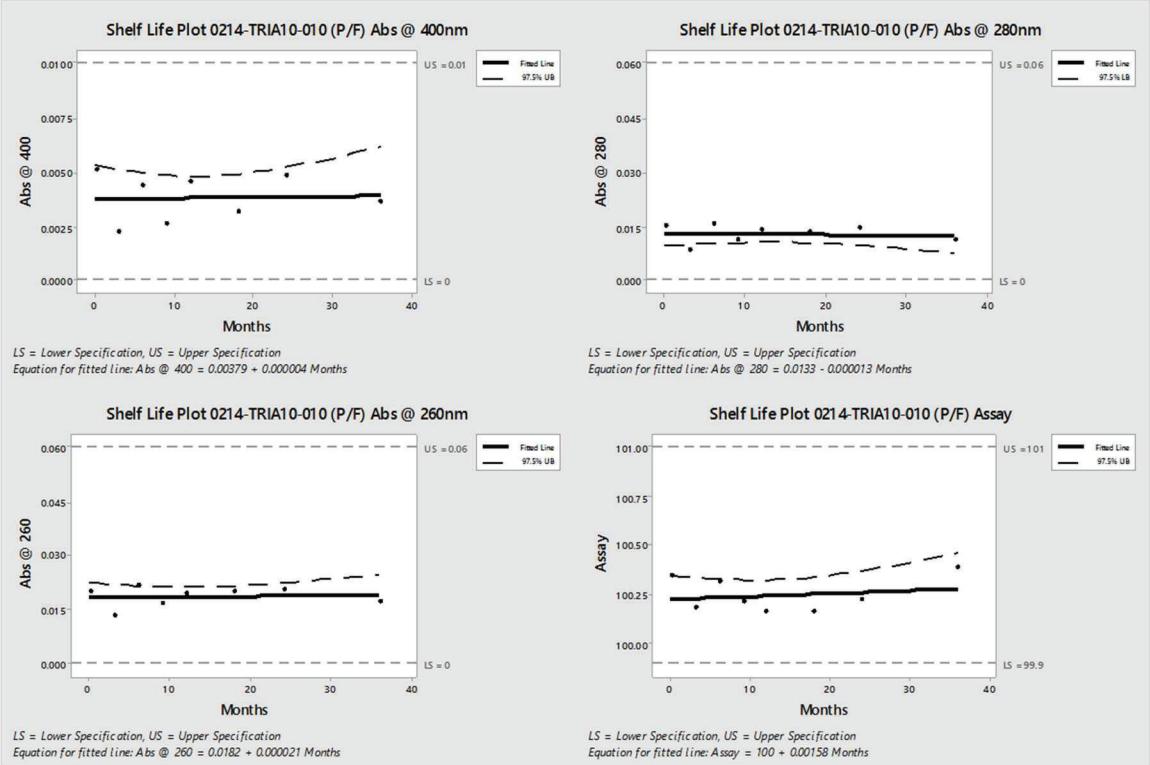
GRAPH 14. 0214-TRIA10-010 (P/P) LOSS ON DRYING %, MELTING RANGE LOWER AND UPPER POINTS



Results for loss on drying and melting range at both the lower and upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

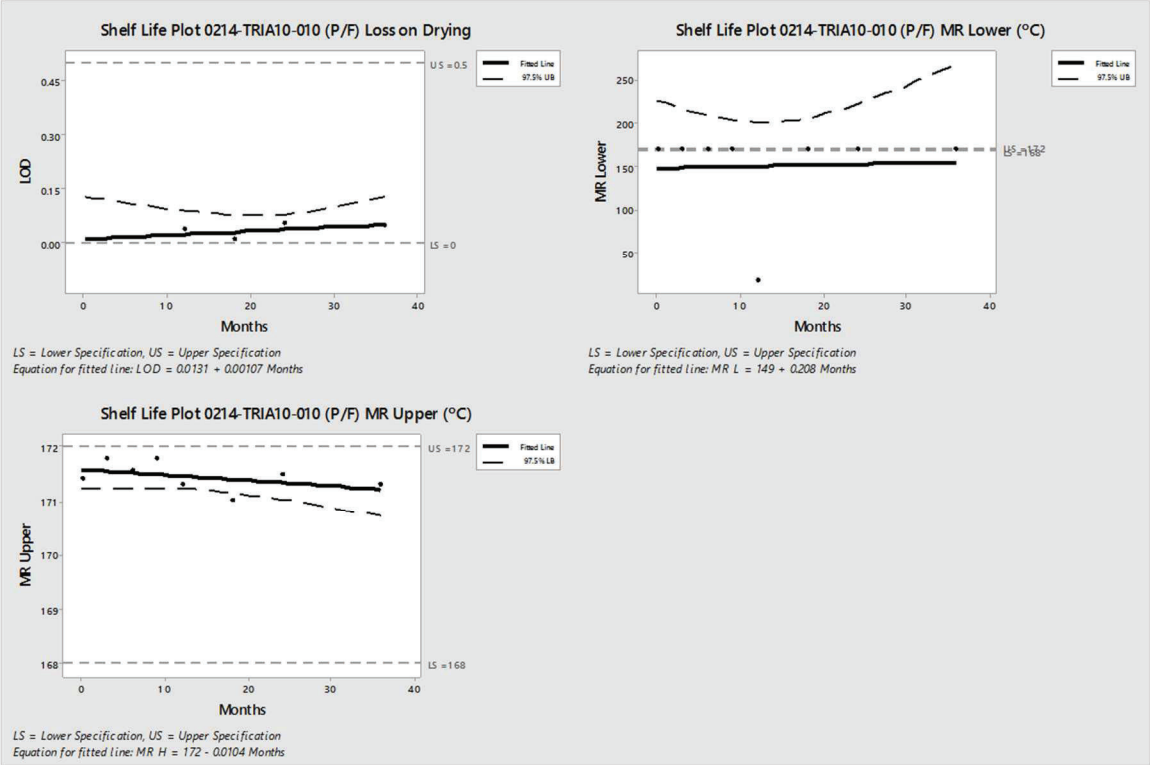
LOT ANALYSIS 0214-TRIA10-010 (P/F):

GRAPH 15. 0214-TRIA10-010 (P/F) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance @ 400nm, 280nm, 260nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

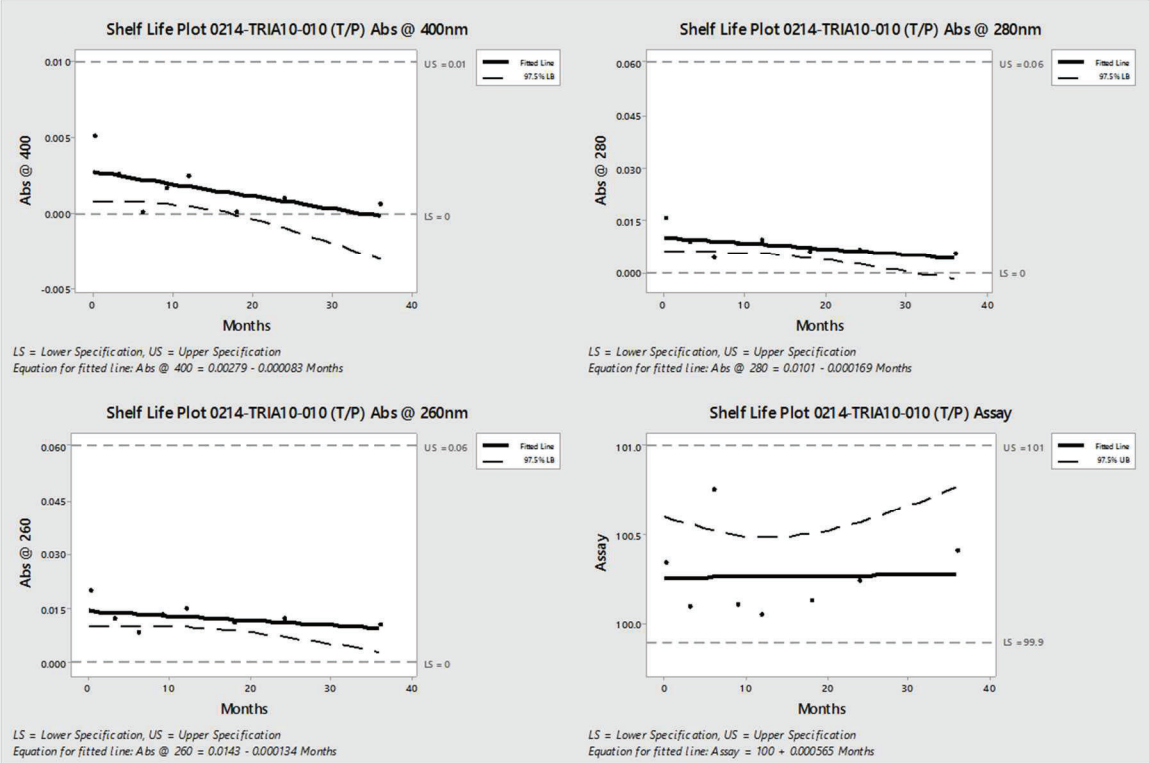
GRAPH 16. 0214-TRIA10-010 (P/F) LOSS ON DRYING %, MELTING RANGE LOWER AND UPPER POINTS



Results for loss on drying and melting range at both the lower and upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from this these analyses.

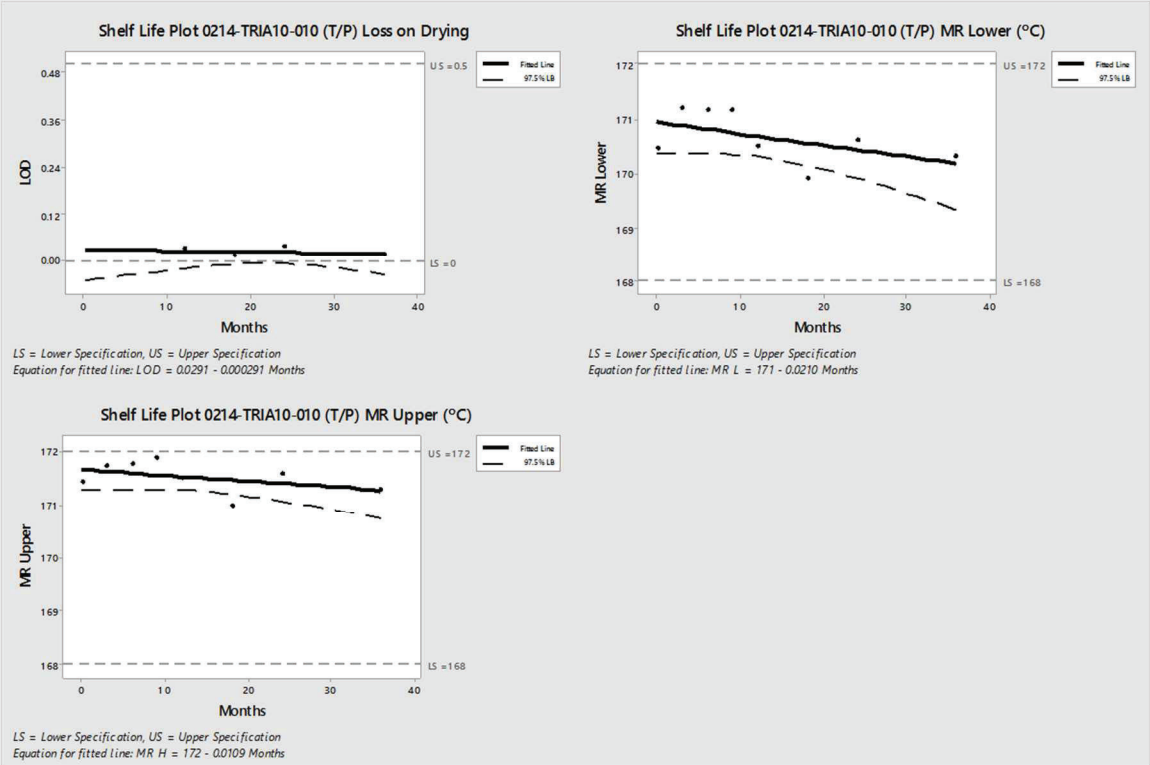
LOT ANALYSIS 0214-TRIA10-010 (T/P):

GRAPH 17. 0214-TRIA10-010 (T/P) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance @ 400nm, 280nm, 260nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

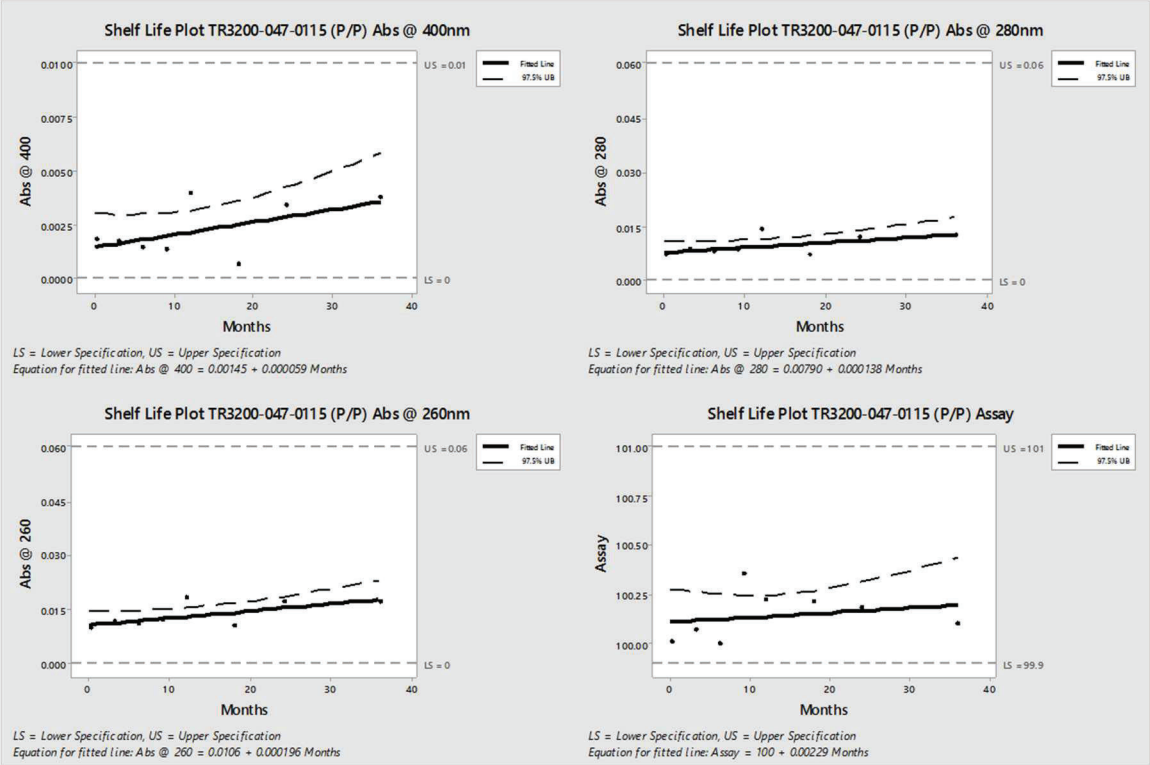
GRAPH 18. 0214-TRIA10-010 (T/P) LOSS ON DRYING %, MELTING RANGE LOWER AND UPPER POINTS



Results for loss on drying and melting range at both the lower and upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

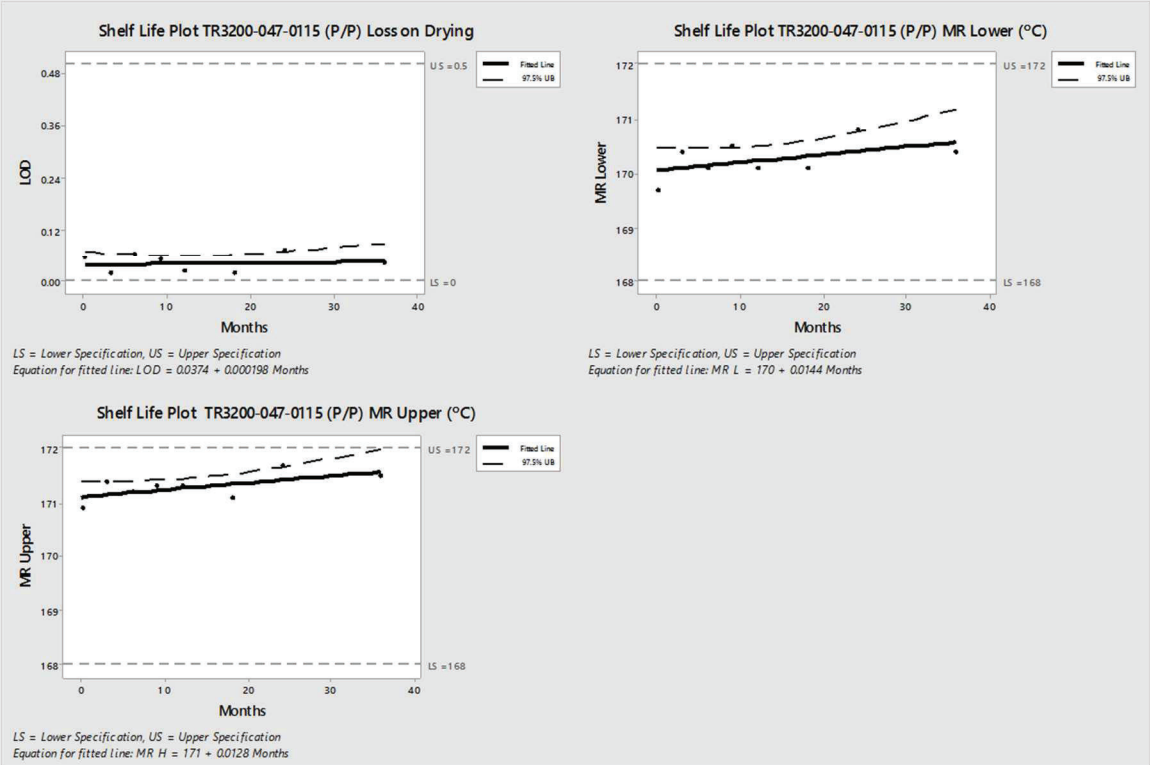
LOT ANALYSIS TR3200-047-0115 (P/P):

GRAPH 19. TR3200-047-0115 (P/P) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance @ 400nm, 280nm, 260nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

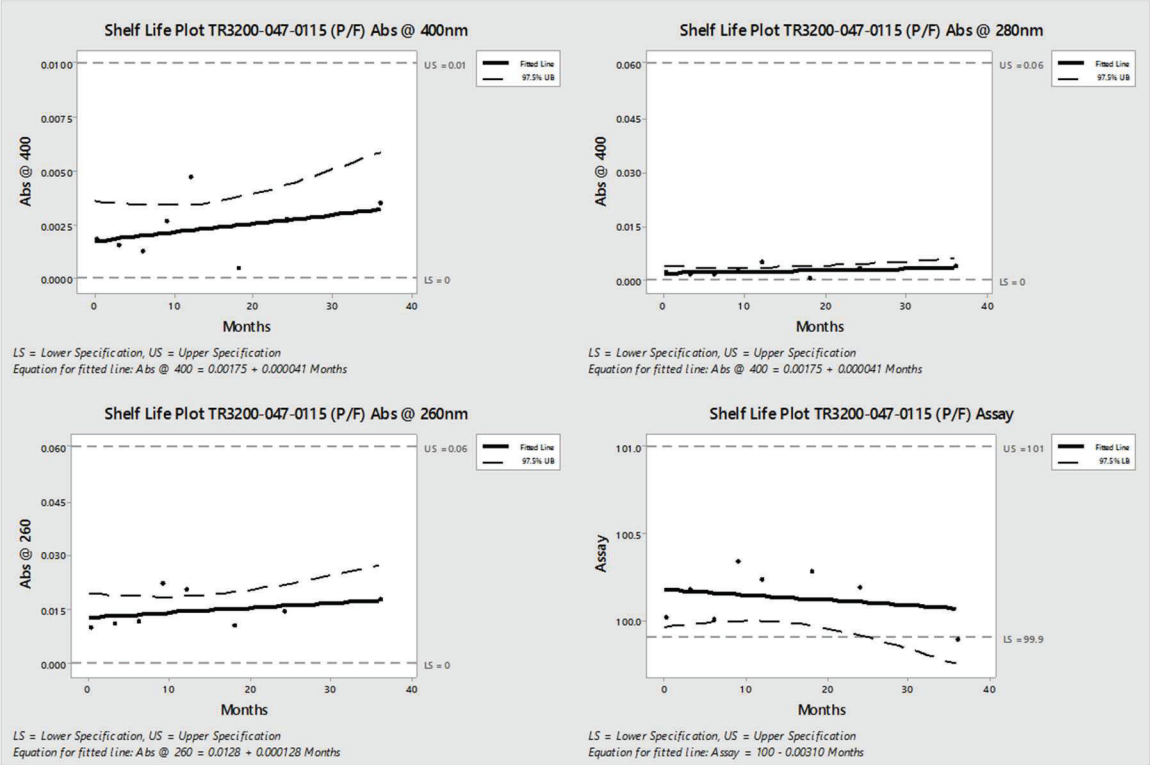
GRAPH 20. TR3200-047-0115 (P/P) LOSS ON DRYING %, MELTING RANGE LOWER AND UPPER POINTS



Results for loss on drying and melting range at both the lower and upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

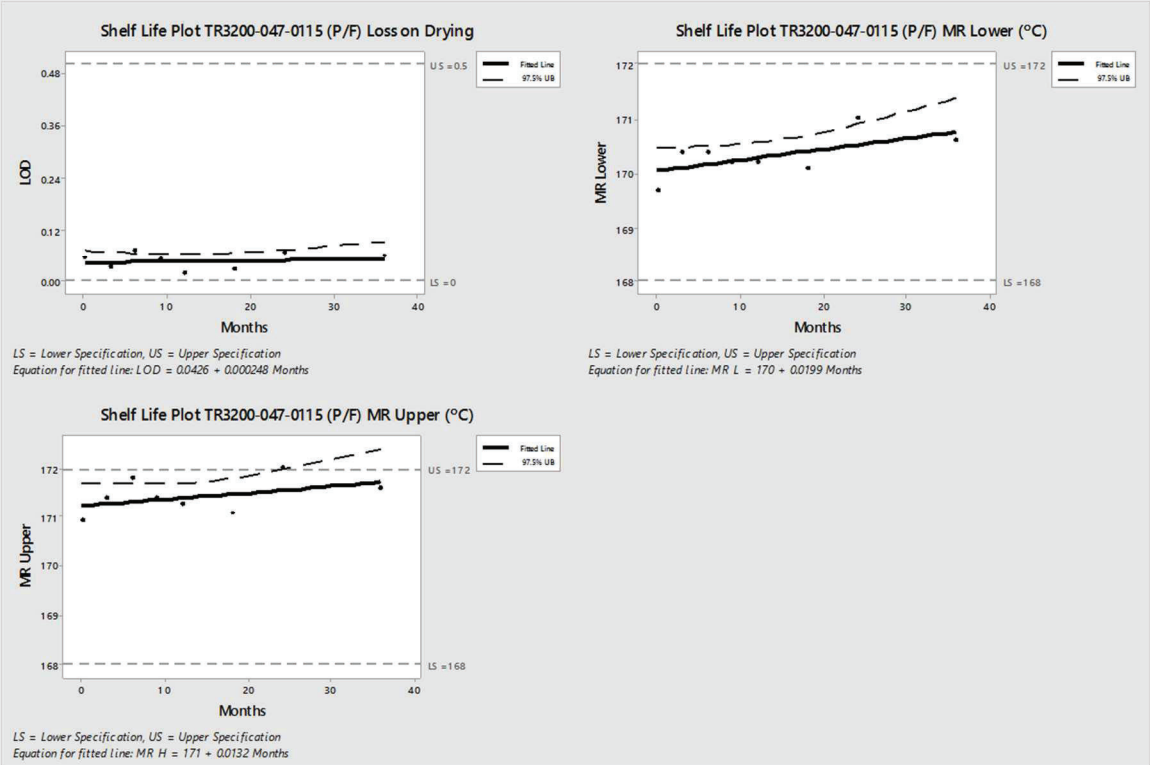
LOT ANALYSIS TR3200-047-0115 (P/F):

GRAPH 21. TR3200-047-0115 (P/F) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance @ 400nm, 280nm, 260nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

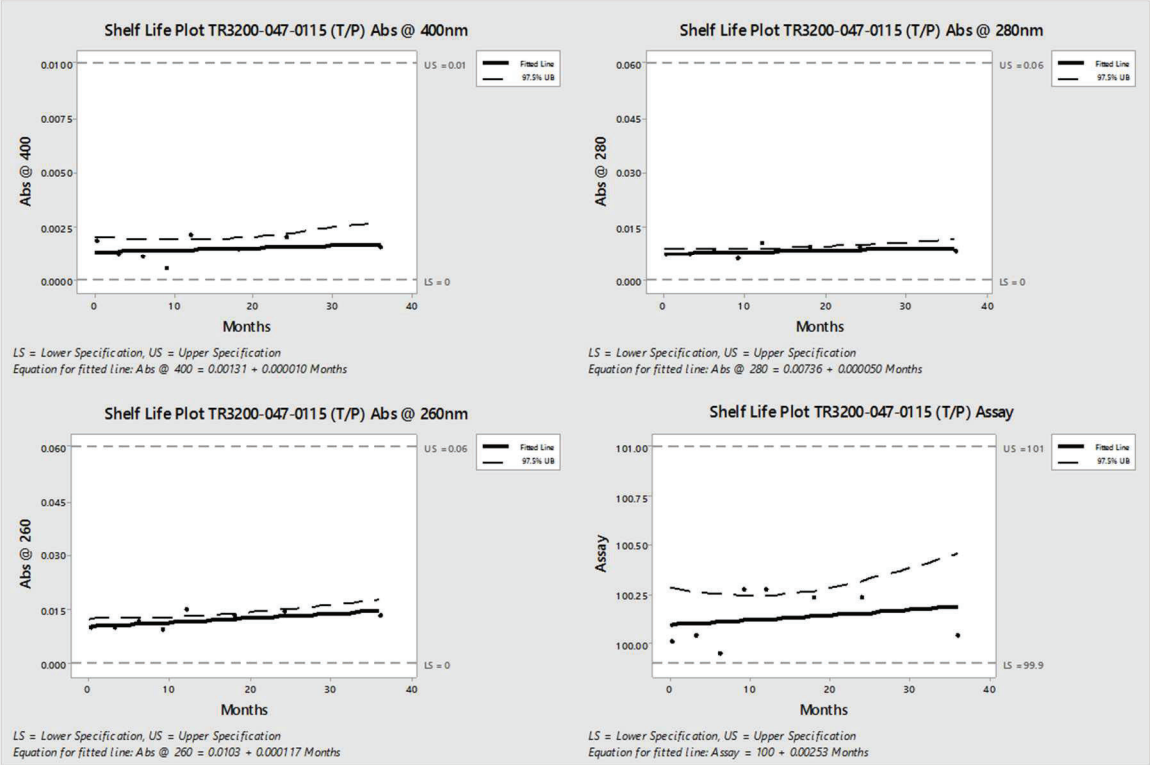
GRAPH 22. TR3200-047-0115 (P/F) LOSS ON DRYING %, MELTING RANGE LOWER AND UPPER POINTS



Results for loss on drying and melting range at both the lower and upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

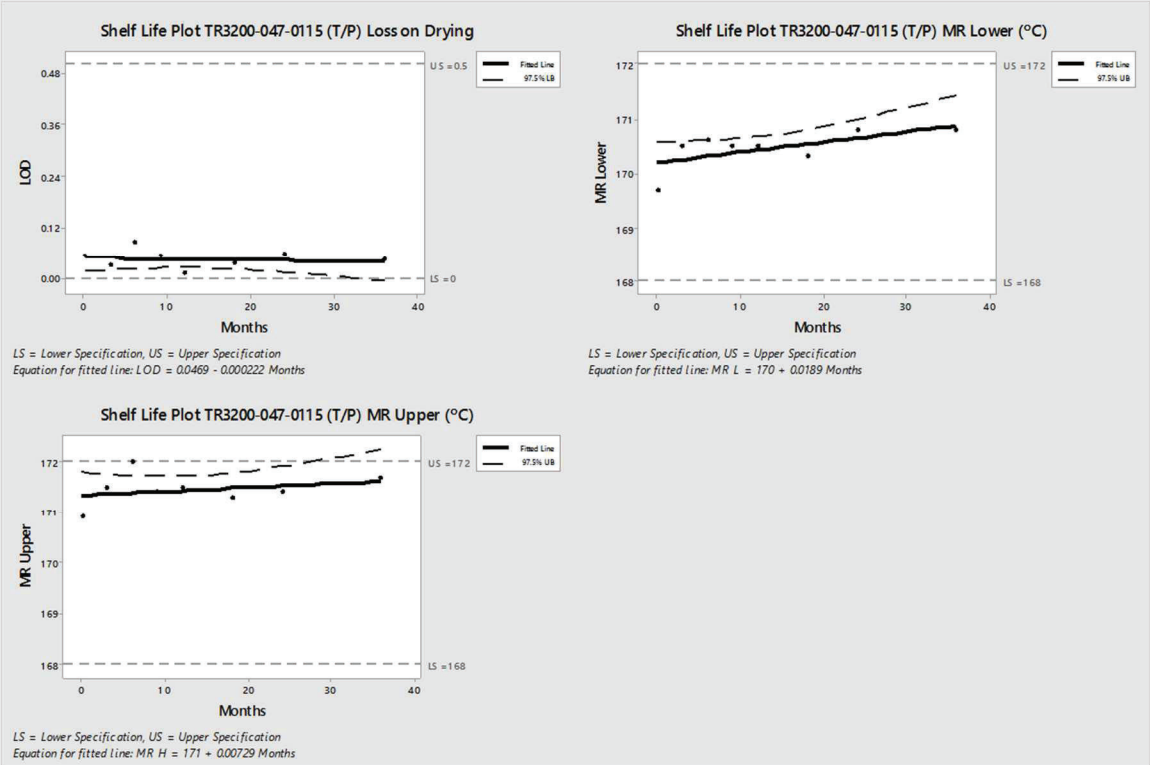
LOT ANALYSIS TR3200-047-0115 (T/P):

GRAPH 23. TR3200-047-0115 (T/P) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance @ 400nm, 280nm, 260nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

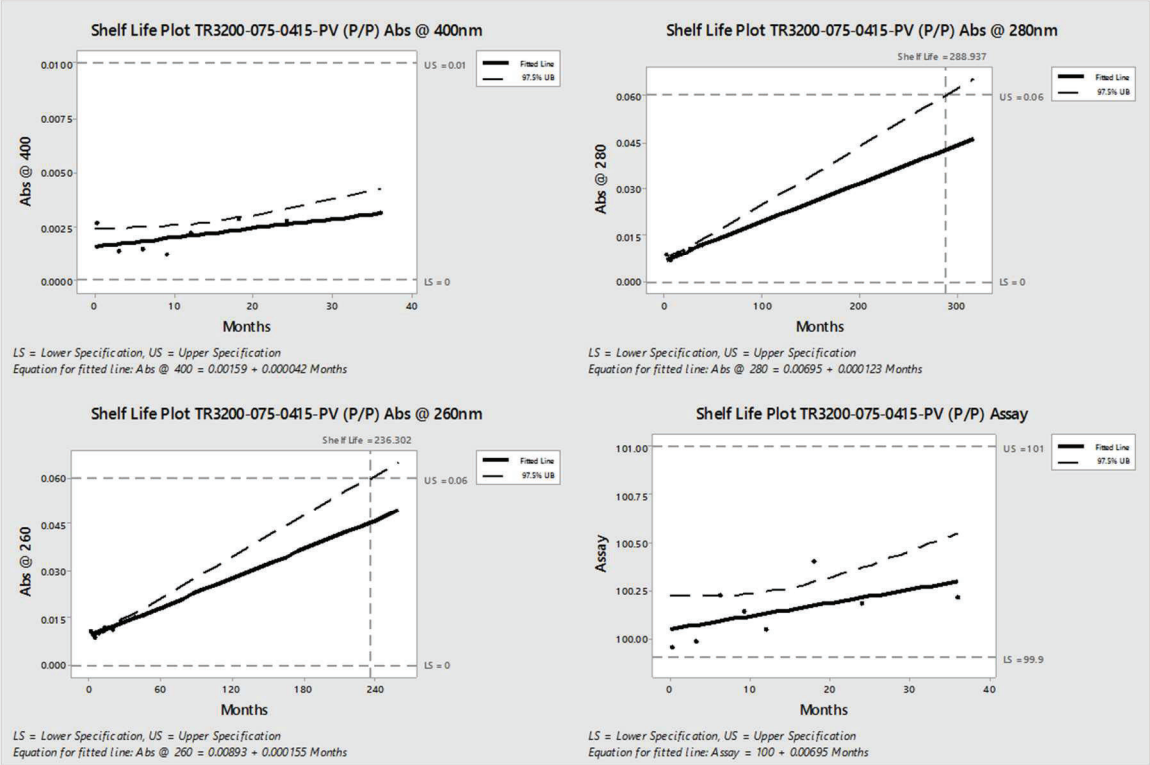
GRAPH 24. TR3200-047-0115 (T/P) LOSS ON DRYING %, MELTING RANGE LOWER AND UPPER POINTS



Results for loss on drying and melting range at both the lower and upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

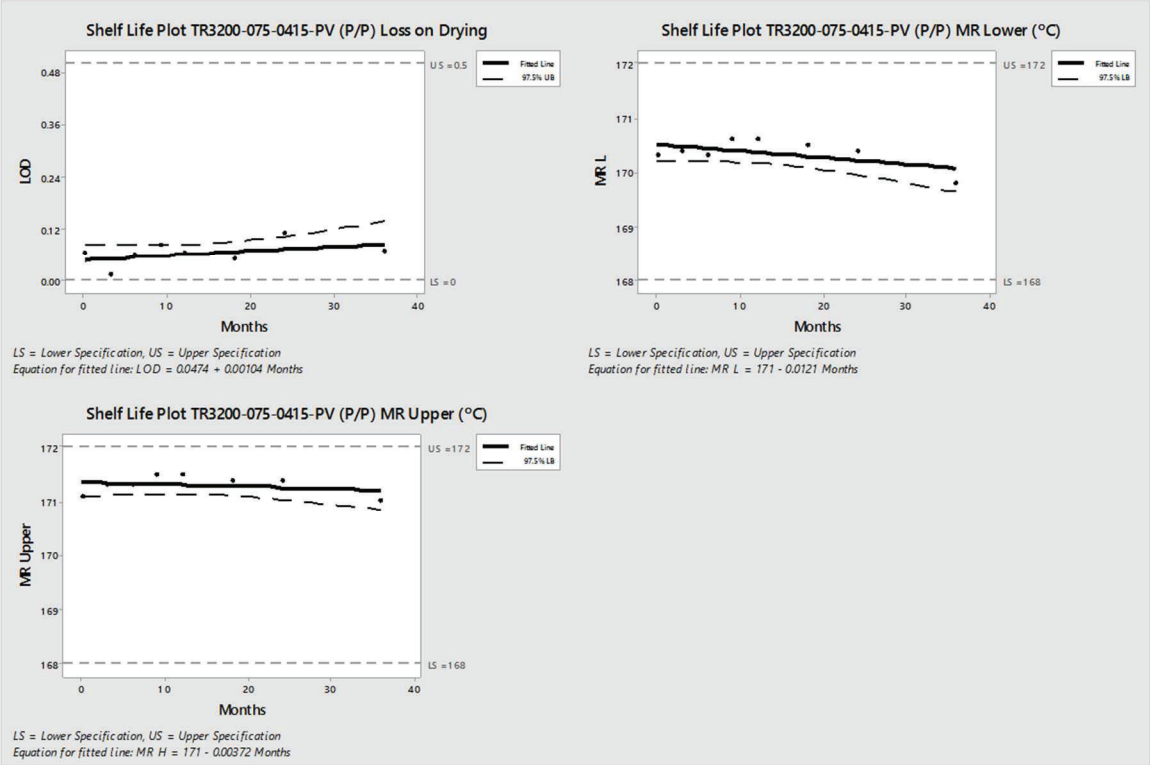
LOT ANALYSIS TR3200-075-0415-PV (P/P):

GRAPH 25. TR3200-075-0415-PV (P/P) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance at 400nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. Shelf lives of 288.9 and 236 months were predicted based on data for absorbance at 280nm and absorbance at 260nm, respectively. Both predicted shelf lives exceed the current 24 month retest date assigned to this material as well as the 36 month maximum expiration date.

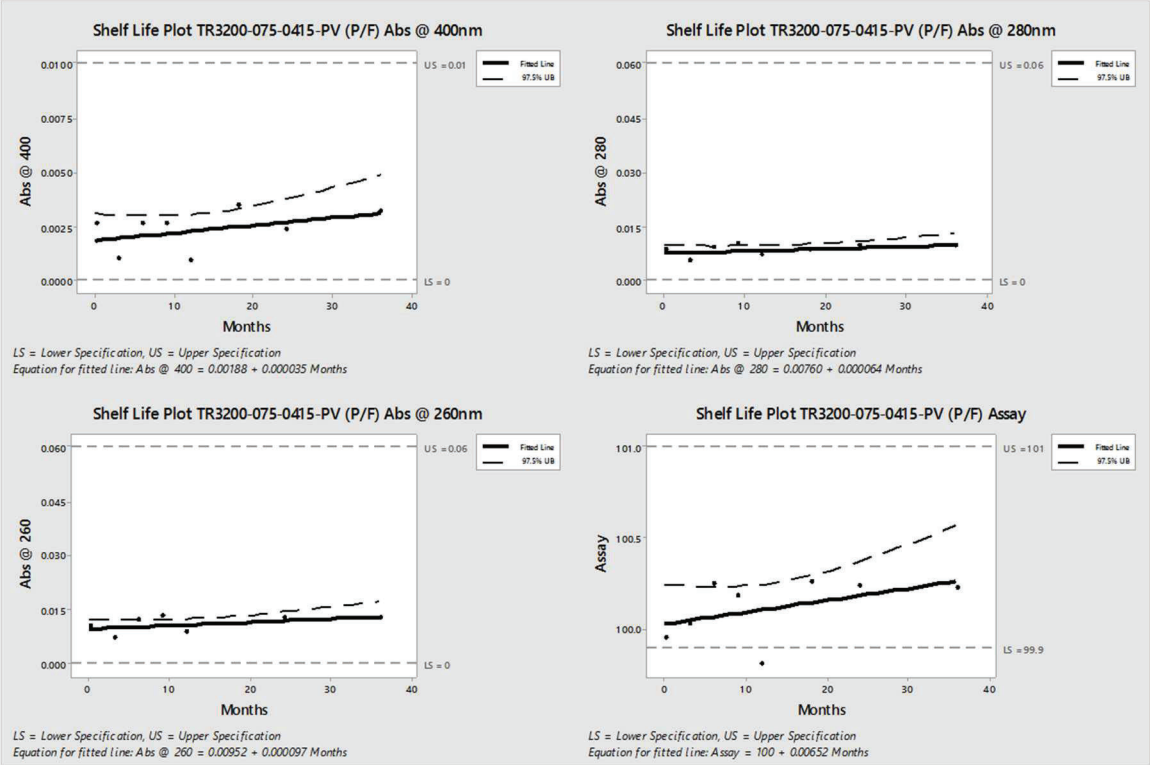
GRAPH 26. TR3200-075-0415-PV (P/P) LOSS ON DRYING %, MELTING RANGE LOWER AND UPPER POINTS



Results for loss on drying and melting range at both the lower and upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

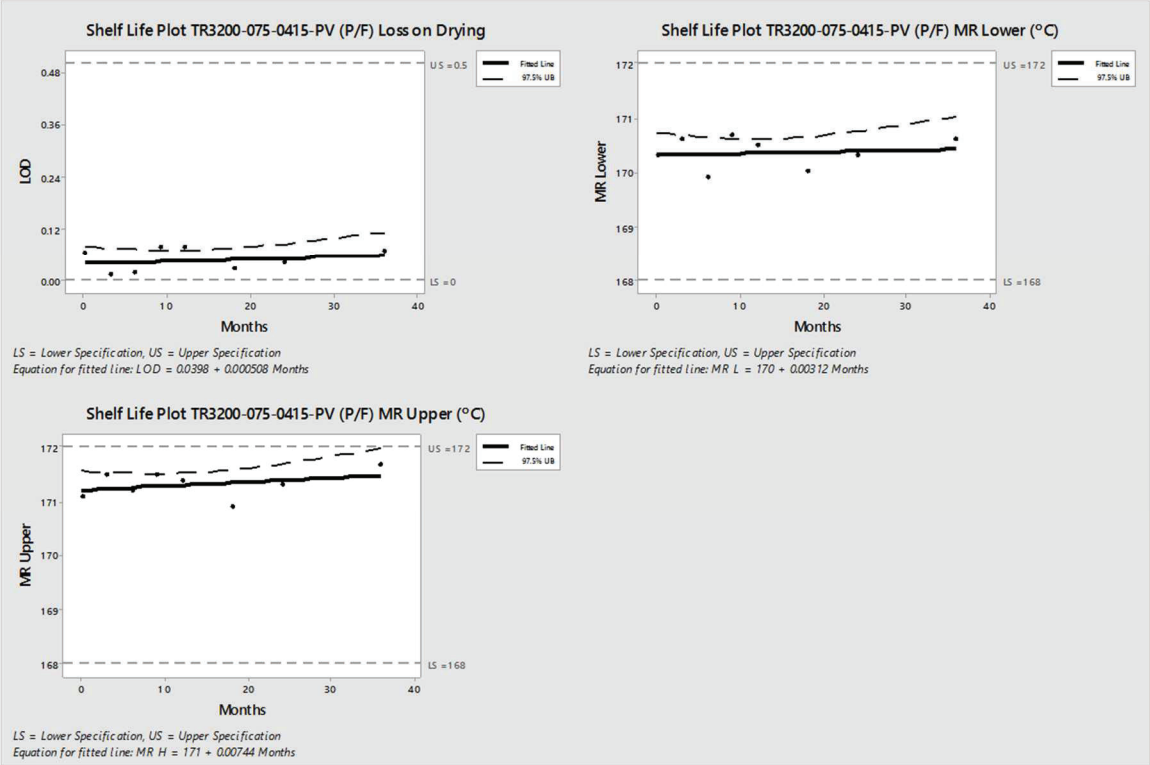
LOT ANALYSIS TR3200-075-0415-PV (P/F):

GRAPH 27. TR3200-075-0415-PV (P/F) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance @ 400nm, 280nm, 260nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

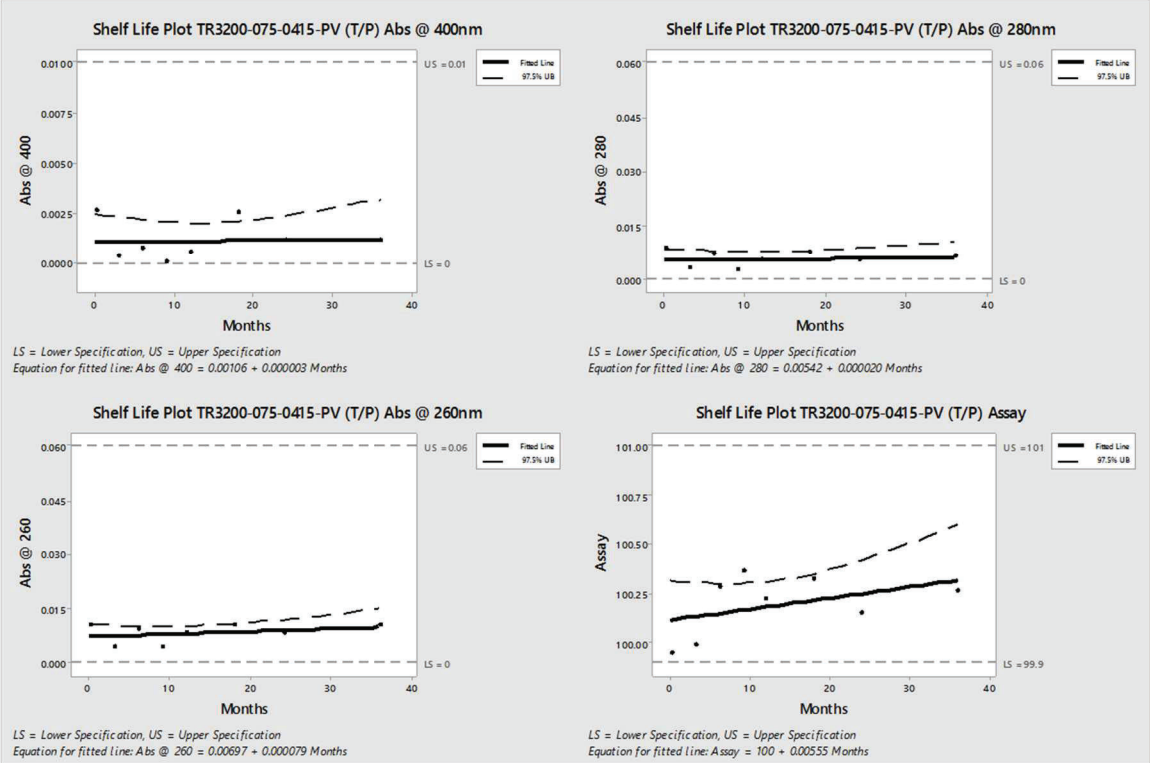
GRAPH 28. TR3200-075-0415-PV (P/F) LOSS ON DRYING %, MELTING RANGE LOWER AND UPPER POINTS



Results for loss on drying and melting range at both the lower and upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

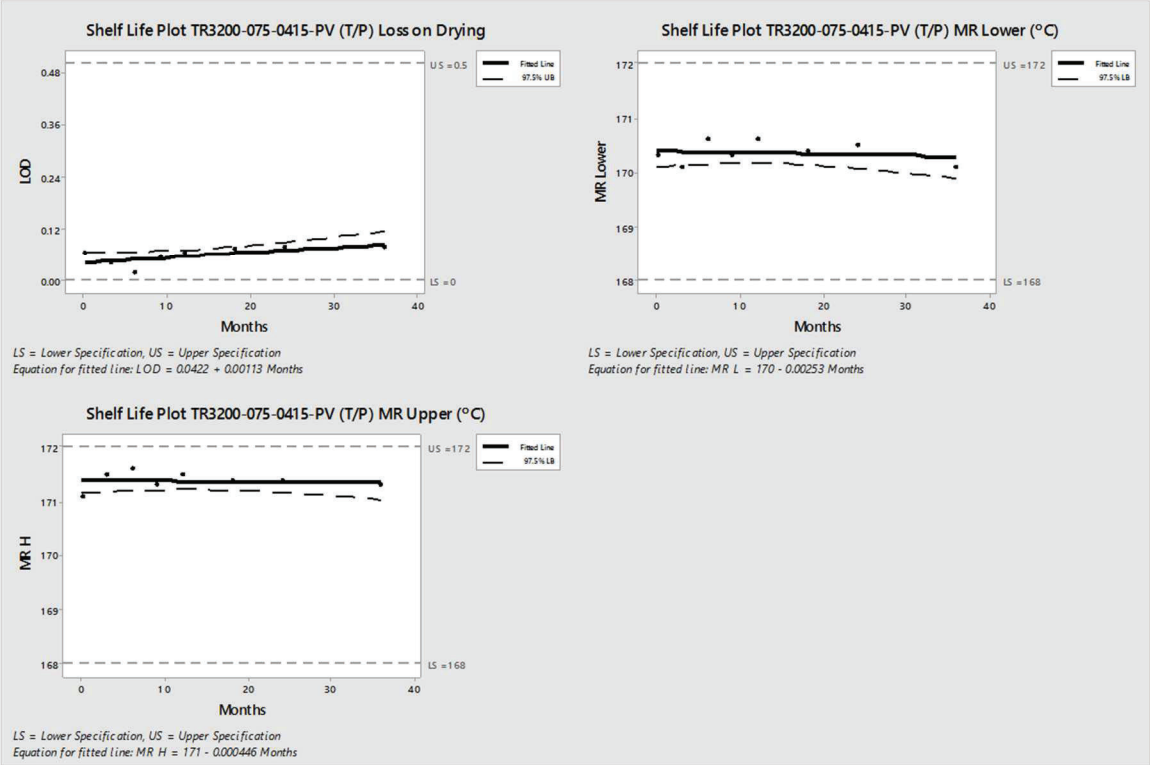
LOT ANALYSIS TR3200-075-0415-PV (T/P):

GRAPH 29. TR3200-075-0415-PV (T/P) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance @ 400nm, 280nm, 260nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

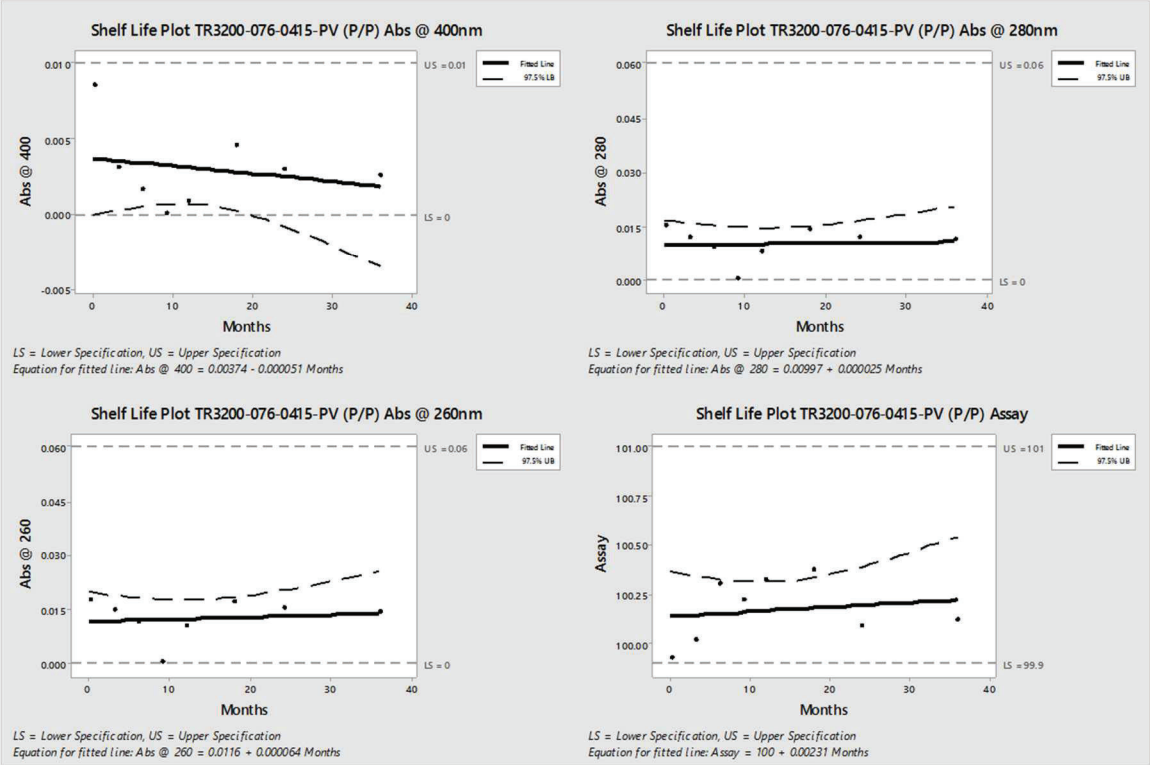
GRAPH 30. TR3200-075-0415-PV (T/P) LOSS ON DRYING %, MELTING RANGE LOWER AND UPPER POINTS



Results for loss on drying and melting range at both the lower and upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

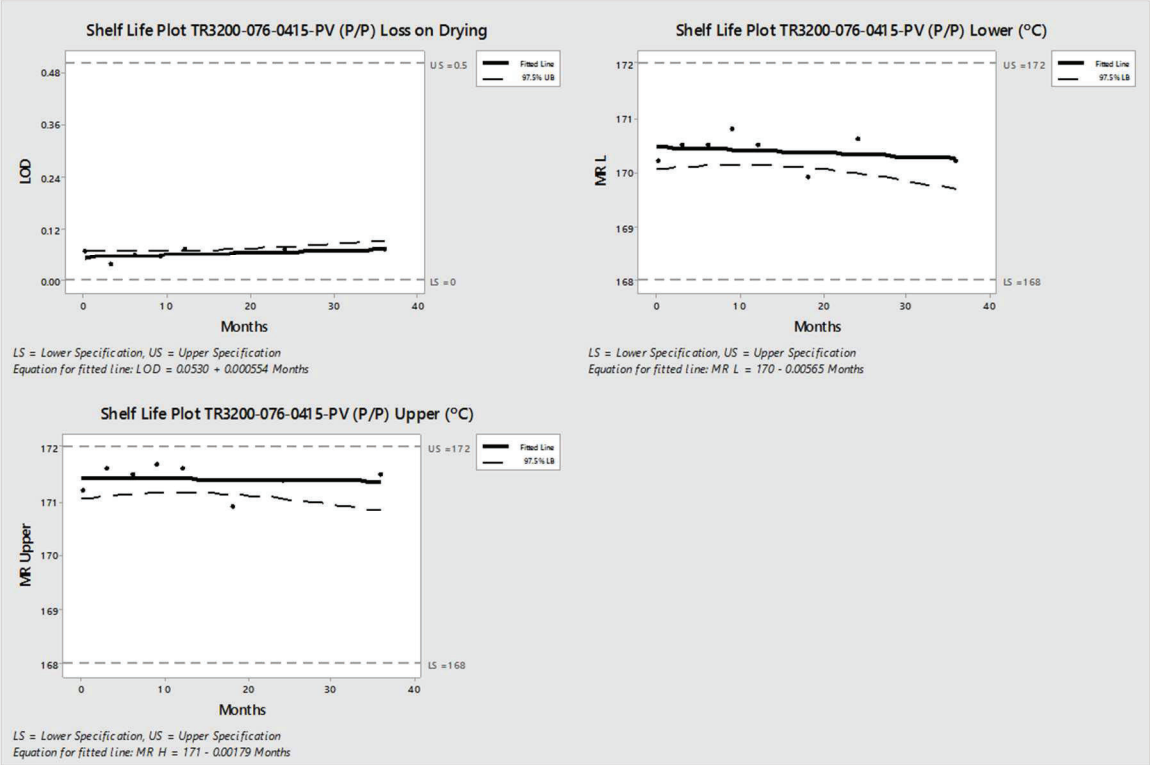
LOT ANALYSIS TR3200-076-0415-PV (P/P):

GRAPH 31. TR3200-076-0415-PV (P/P) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance @ 400nm, 280nm, 260nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

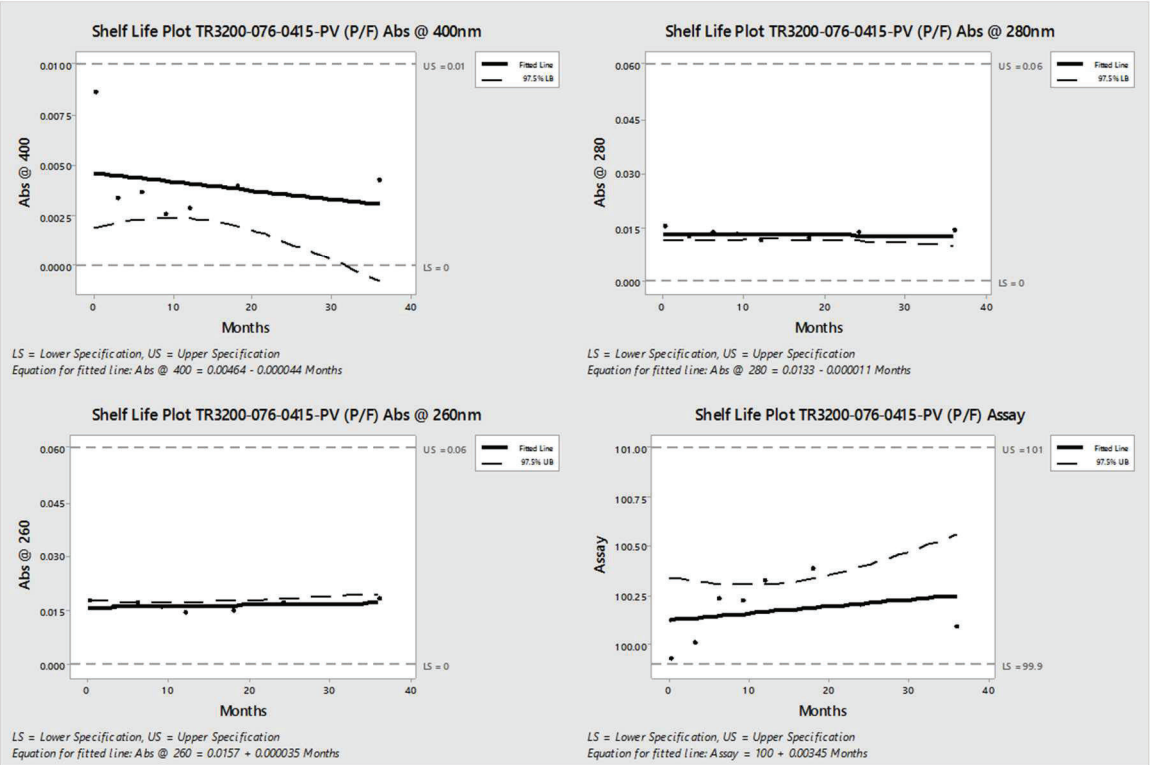
GRAPH 32. TR3200-076-0415-PV (P/P) LOSS ON DRYING %, MELTING RANGE LOWER AND UPPER POINTS



Results for loss on drying and melting range at both the lower and upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

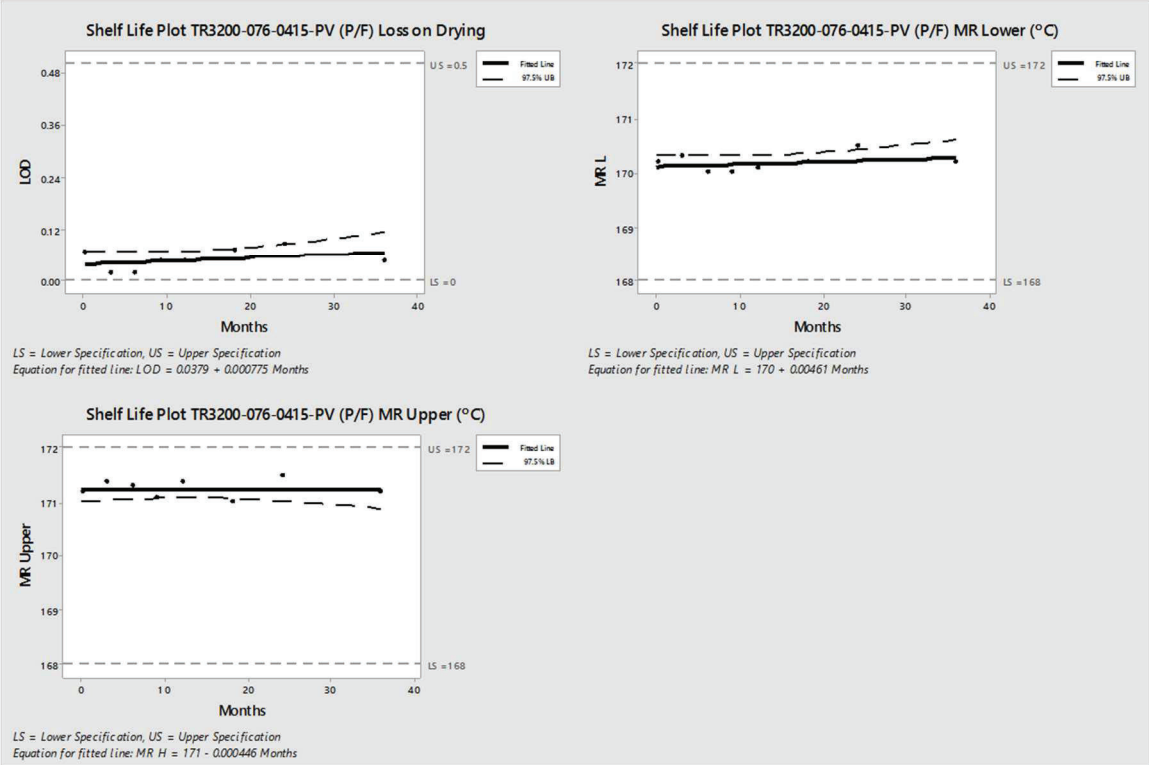
LOT ANALYSIS TR3200-076-0415-PV (P/F):

GRAPH 33. TR3200-076-0415-PV (P/F) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance @ 400nm, 280nm, 260nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

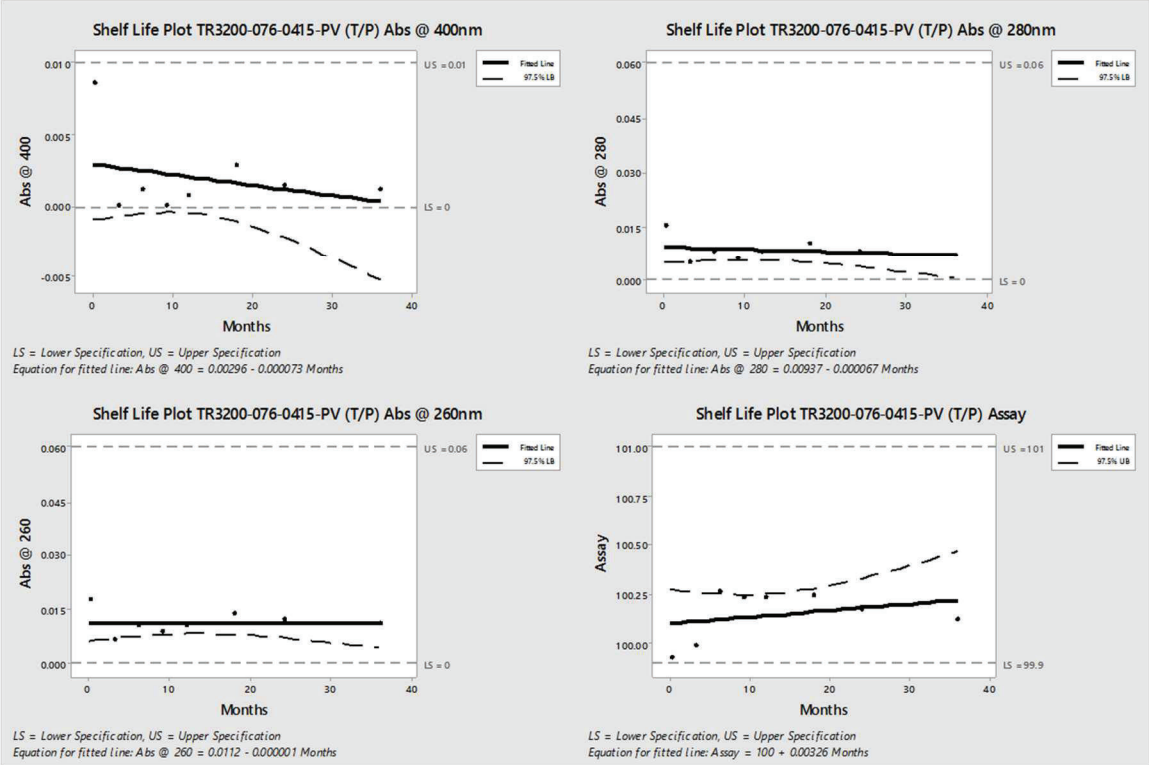
GRAPH 34. TR3200-076-0415-PV (P/F) LOSS ON DRYING %, MELTING RANGE LOWER AND UPPER POINTS



Results for loss on drying and melting range at both the lower and upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

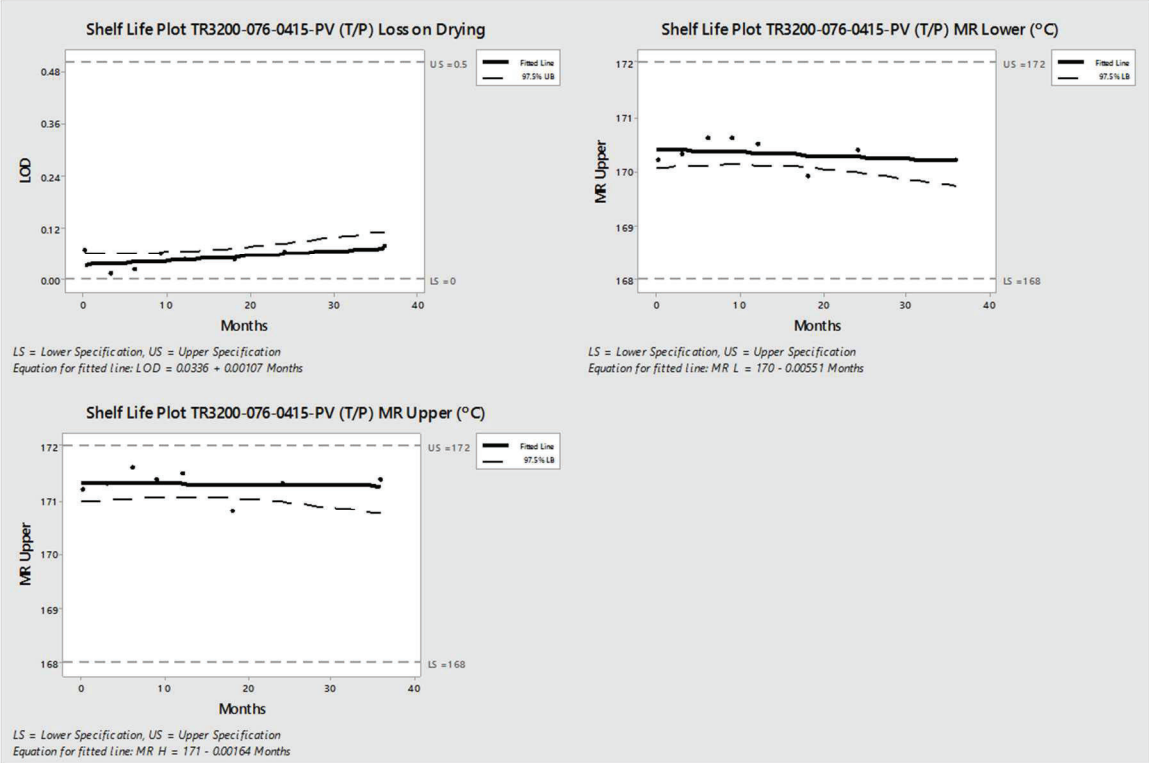
LOT ANALYSIS TR3200-076-0415-PV (T/P):

GRAPH 35. TR3200-076-0415-PV (T/P) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance @ 400nm, 280nm, 260nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

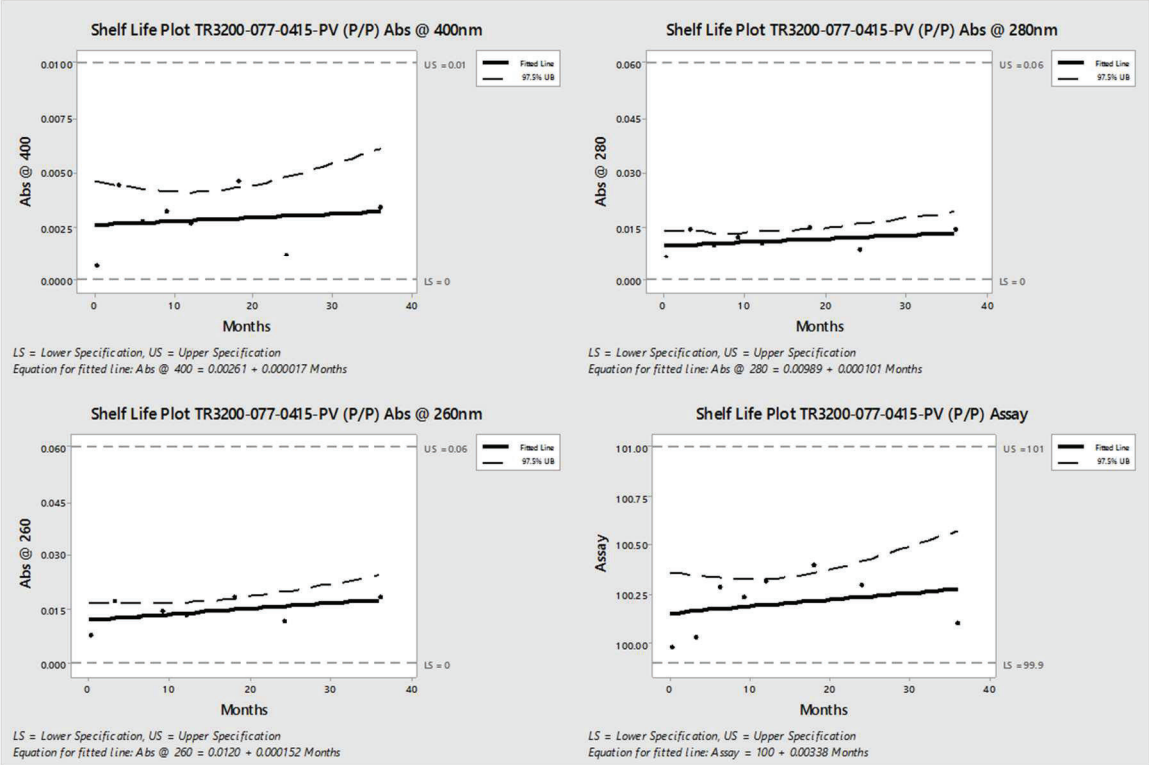
GRAPH 36. TR3200-076-0415-PV (T/P) LOSS ON DRYING %, MELTING RANGE LOWER AND UPPER POINTS



Results for loss on drying and melting range at both the lower and upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

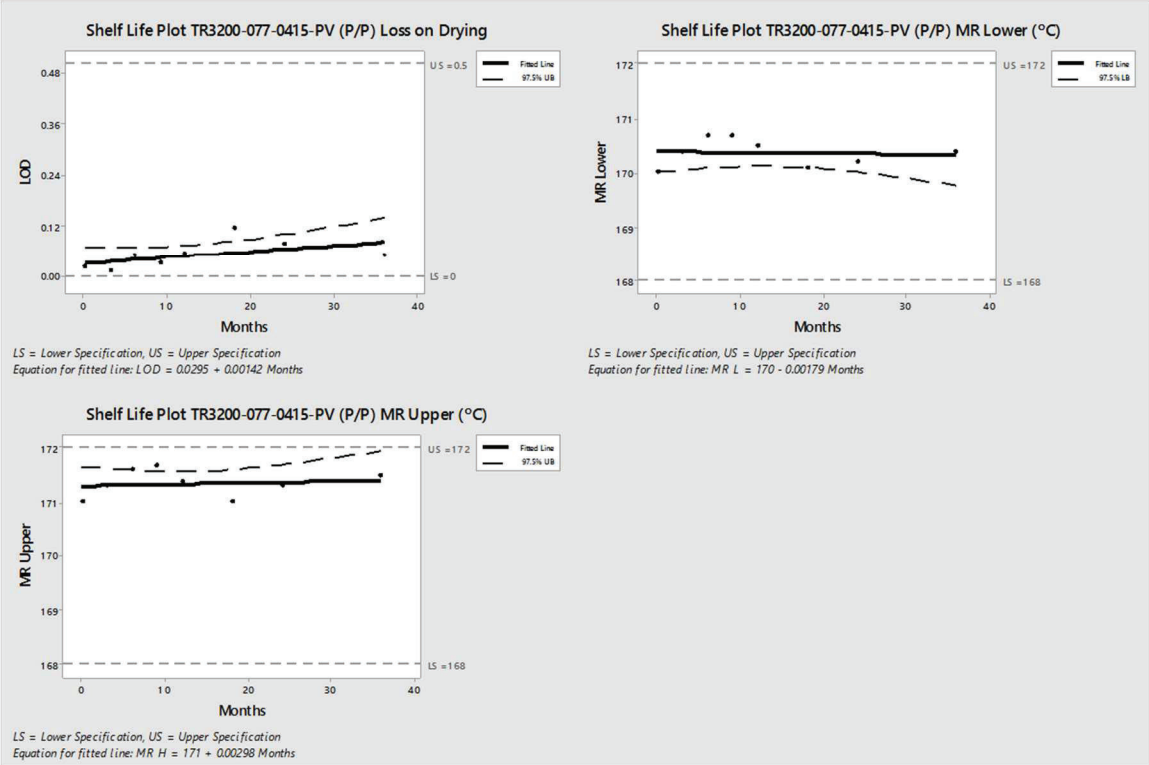
LOT ANALYSIS TR3200-077-0415-PV (P/P):

GRAPH 37. TR3200-077-0415-PV (P/P) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance @ 400nm, 280nm, 260nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

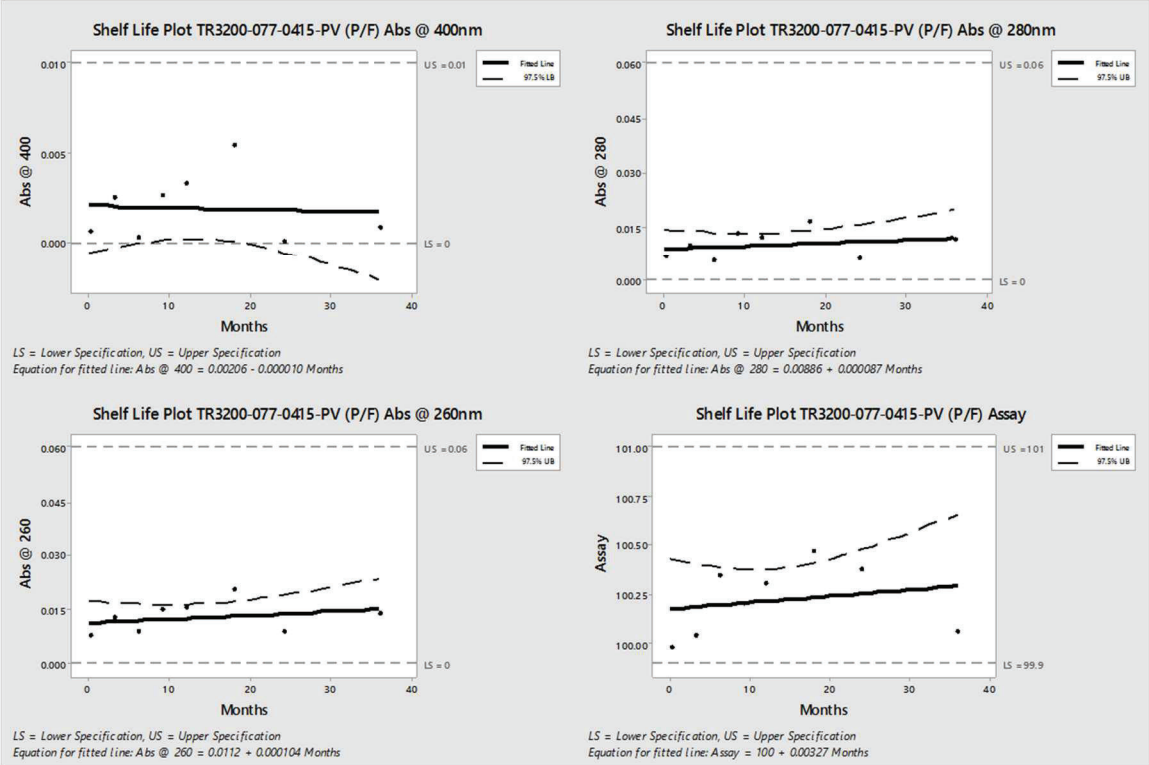
GRAPH 38. TR3200-077-0415-PV (P/P) LOSS ON DRYING %, MELTING RANGE LOWER AND UPPER POINTS



Results for loss on drying and melting range at both the lower and upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

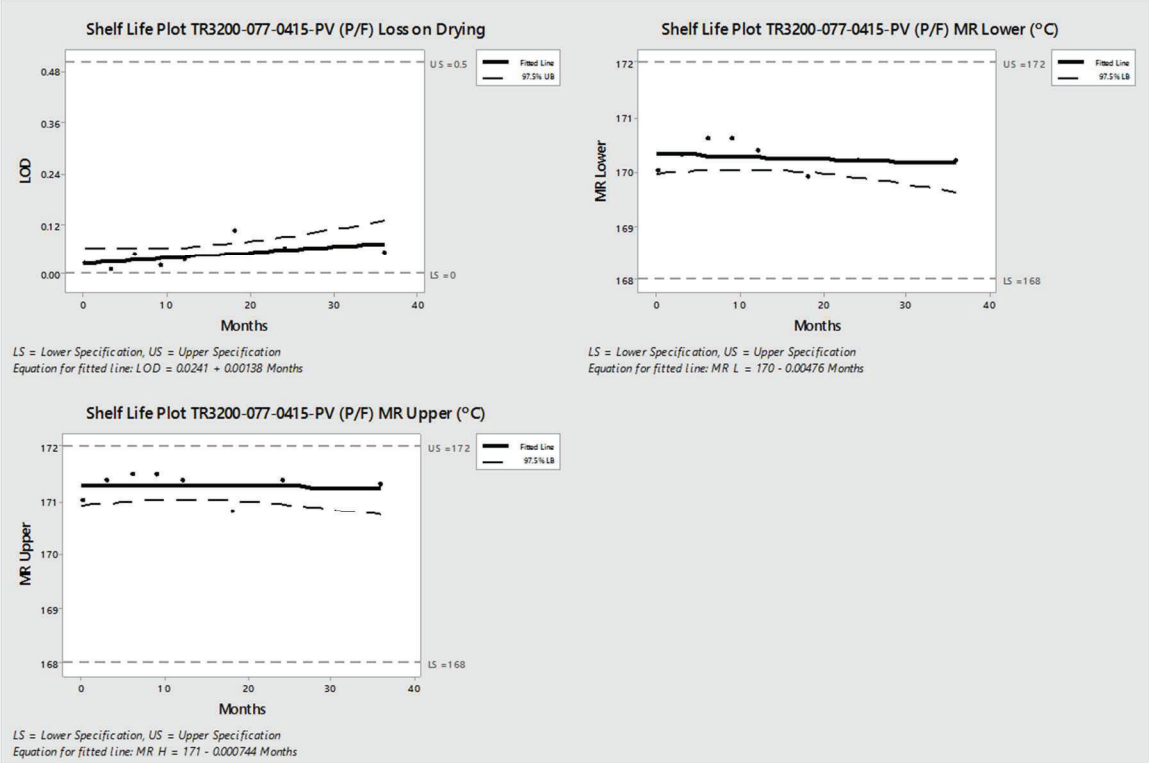
LOT ANALYSIS TR3200-077-0415-PV (P/F):

GRAPH 39. TR3200-077-0415-PV (P/F) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance @ 400nm, 280nm, 260nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

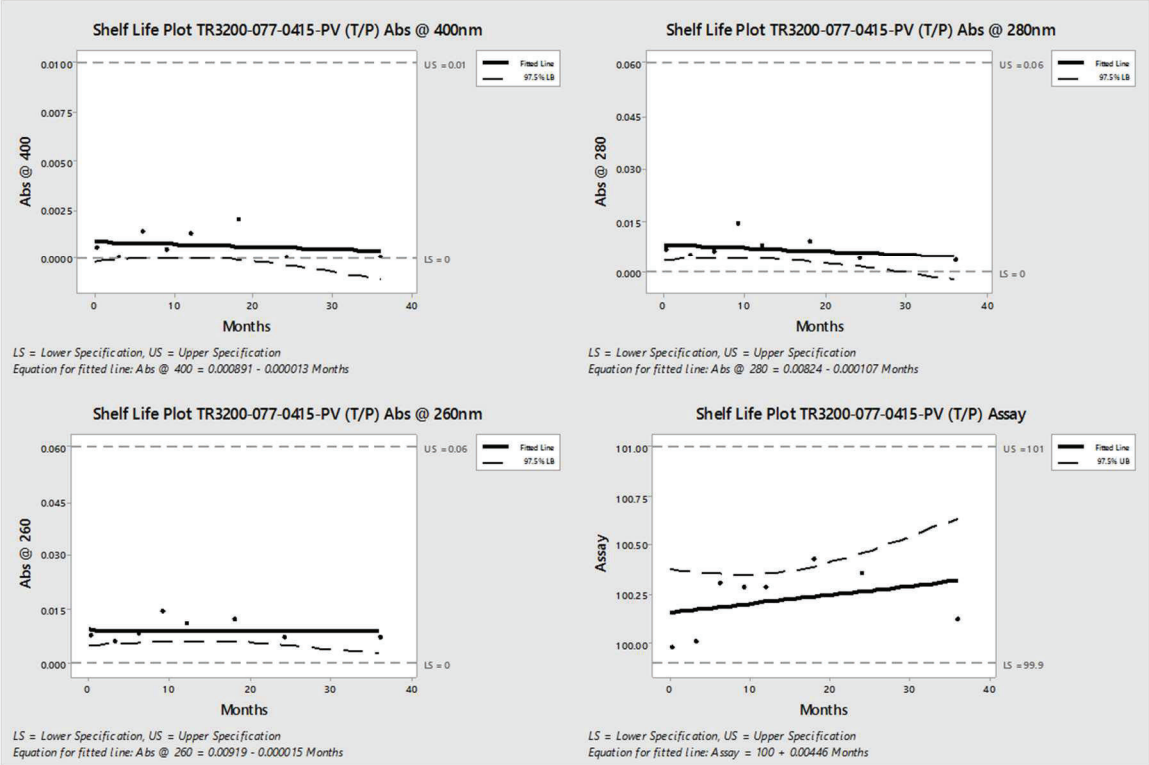
GRAPH 40. TR3200-077-0415-PV (P/F) LOSS ON DRYING %, MELTING RANGE LOWER AND UPPER POINTS



Results for loss on drying and melting range at both the lower and upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

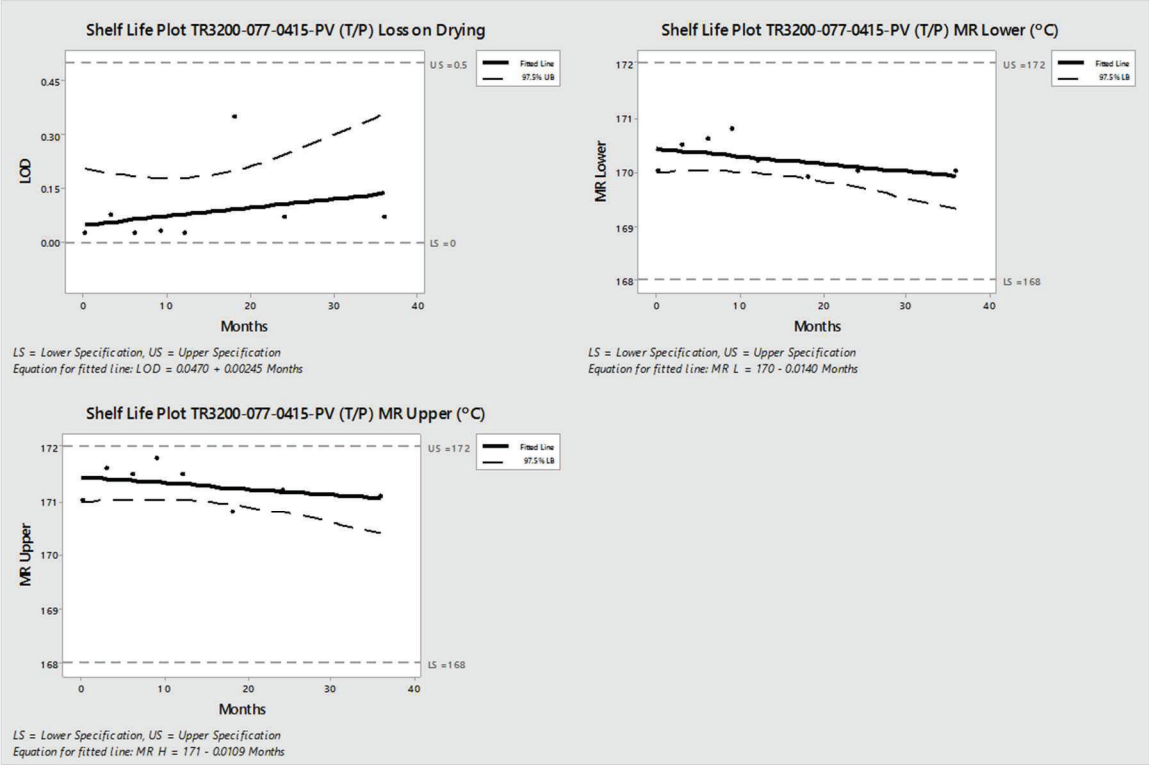
LOT ANALYSIS TR3200-077-0415-PV (T/P):

GRAPH 41. TR3200-077-0415-PV (T/P) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance @ 400nm, 280nm, 260nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

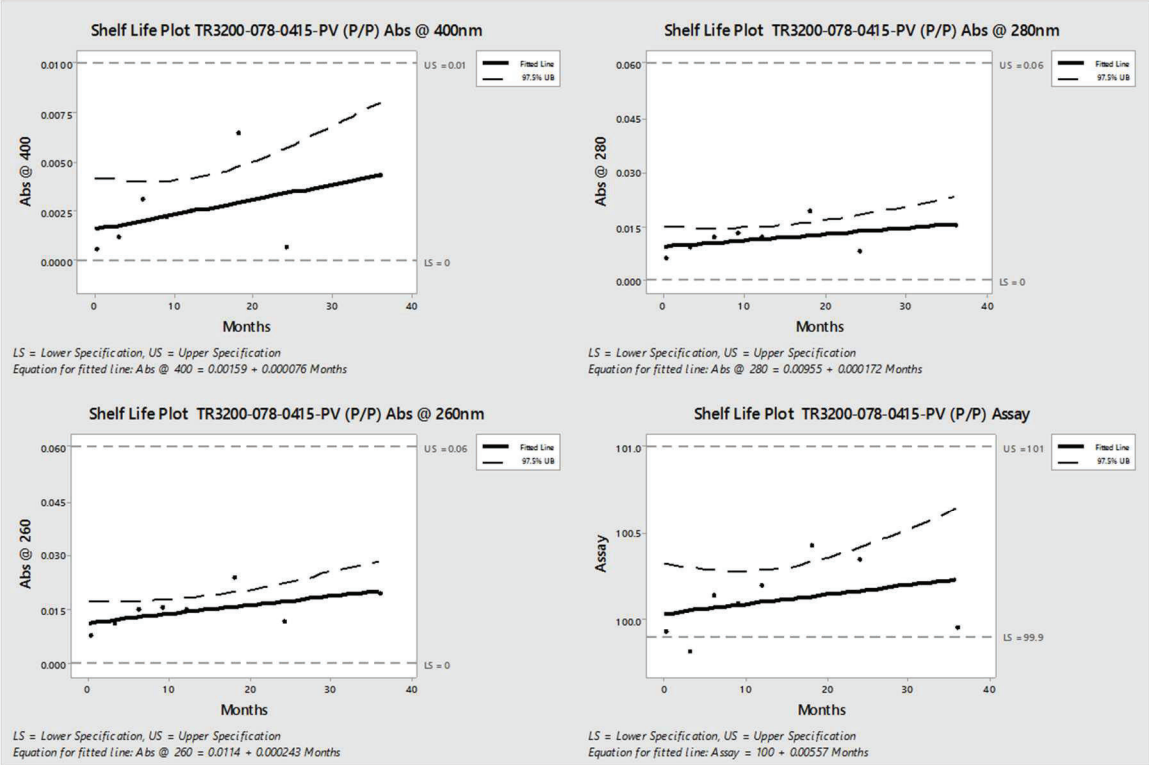
GRAPH 42. TR3200-077-0415-PV (T/P) LOSS ON DRYING %, MELTING RANGE LOWER AND UPPER POINTS



Results for loss on drying and melting range at both the lower and upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

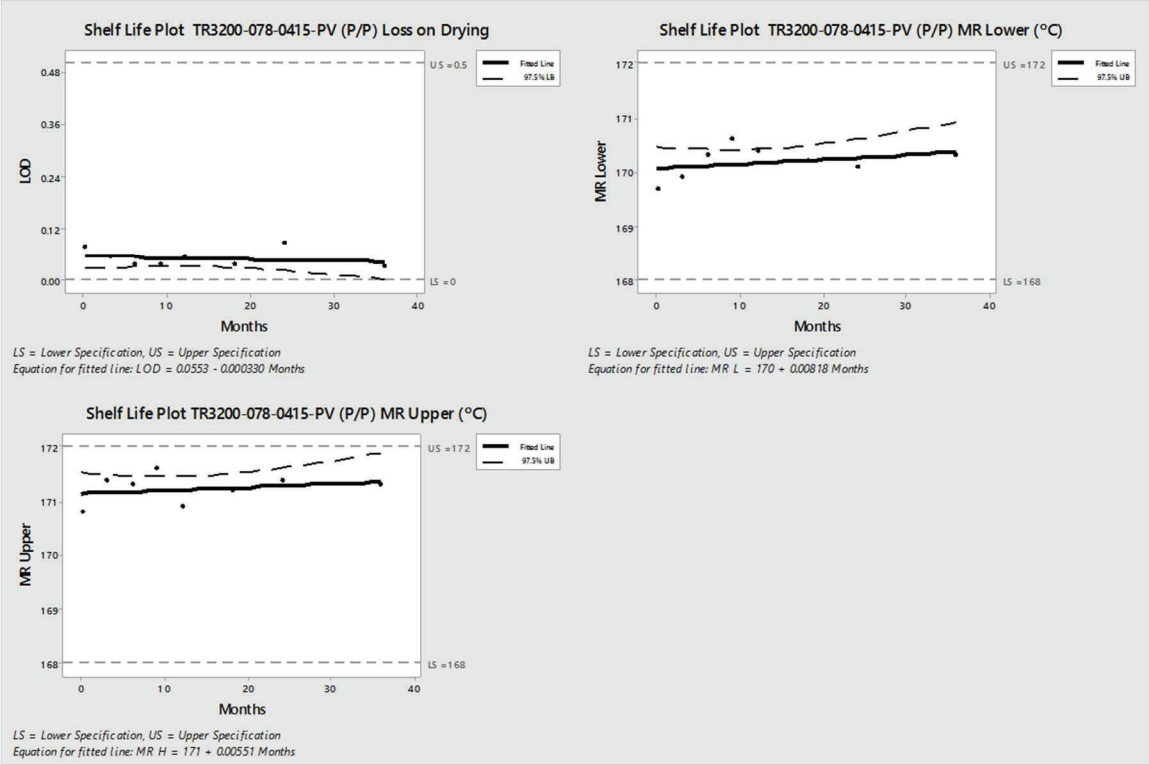
LOT ANALYSIS TR3200-078-0415-PV (P/P):

GRAPH 43. TR3200-078-0415-PV (P/P) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance @ 400nm, 280nm, 260nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

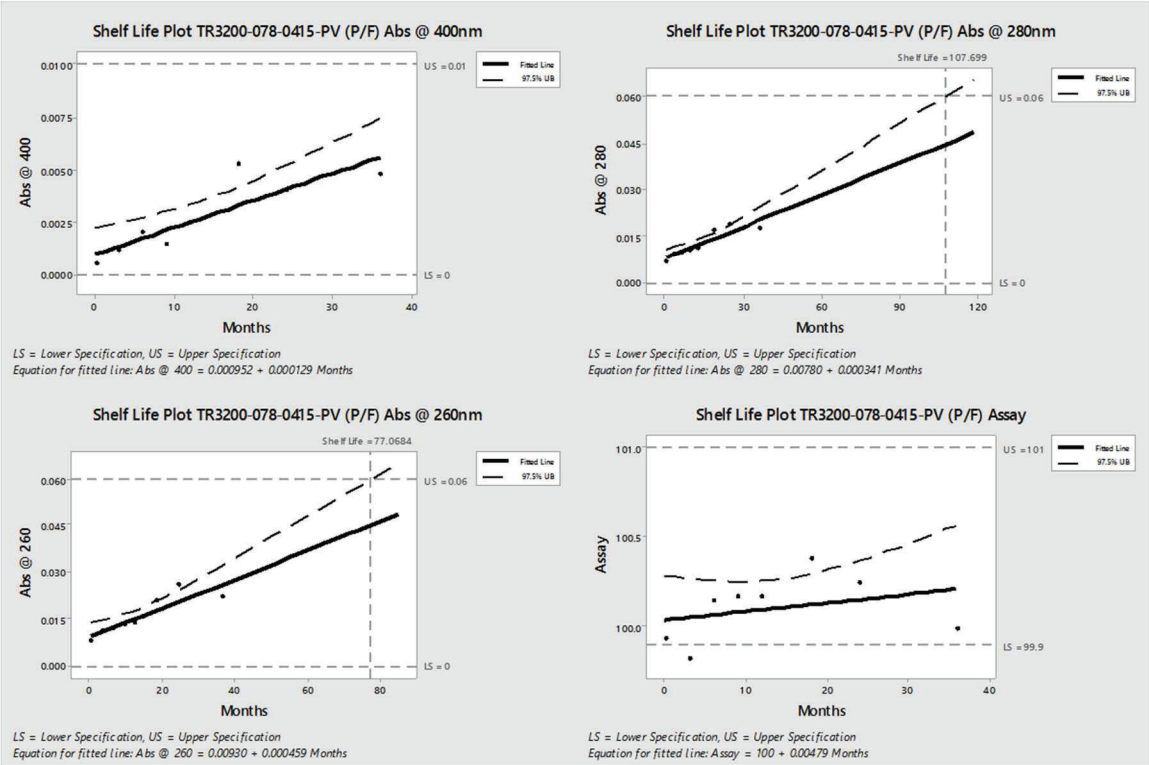
GRAPH 44. TR3200-078-0415-PV (P/P) LOSS ON DRYING %, MELTING RANGE LOWER AND UPPER POINTS



Results for loss on drying and melting range at both the lower and upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

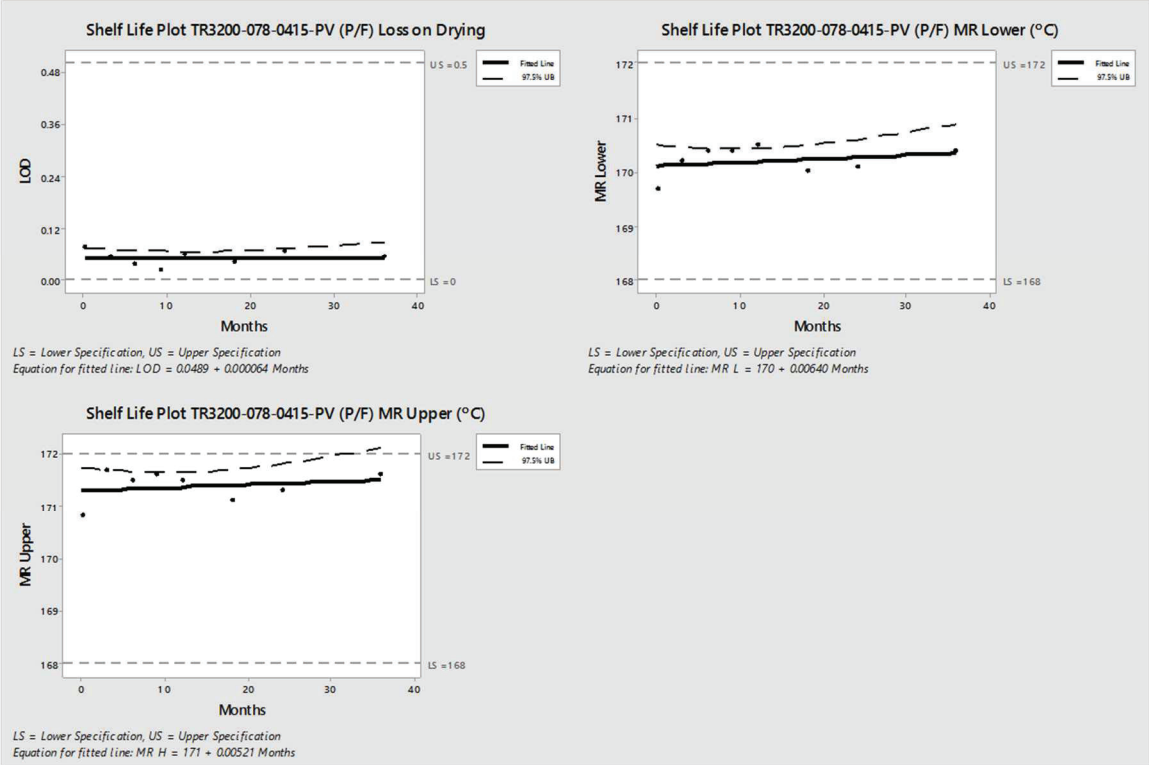
LOT ANALYSIS TR3200-078-0415-PV (P/F):

GRAPH 45. TR3200-078-0415-PV (P/F) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance at 400nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. Shelf lives of 107.69 and 77 months were predicted based on data for absorbance at 280nm and absorbance at 260nm, respectively. Both predicted shelf lives exceed the current 24 month retest date assigned to this material as well as the 36 month maximum expiration date.

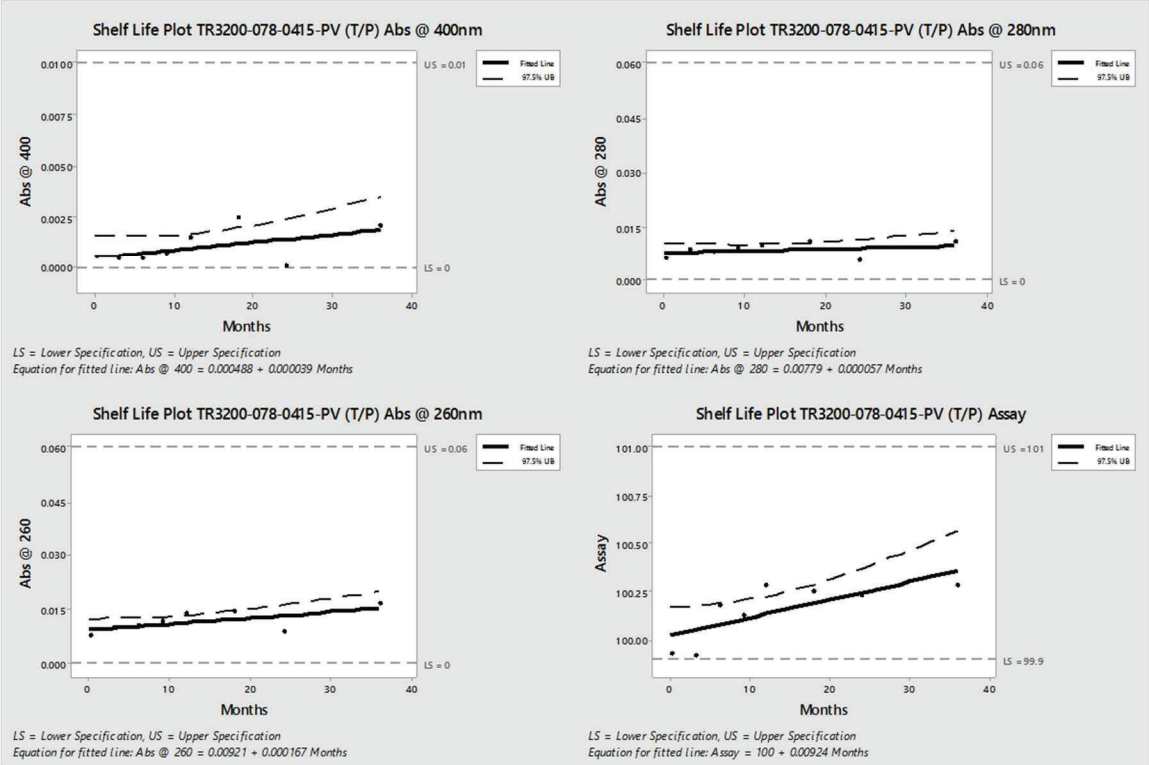
GRAPH 46. TR3200-078-0415-PV (P/F) LOSS ON DRYING %, MELTING RANGE LOWER AND UPPER POINTS



Results for loss on drying and melting range at both the lower and upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

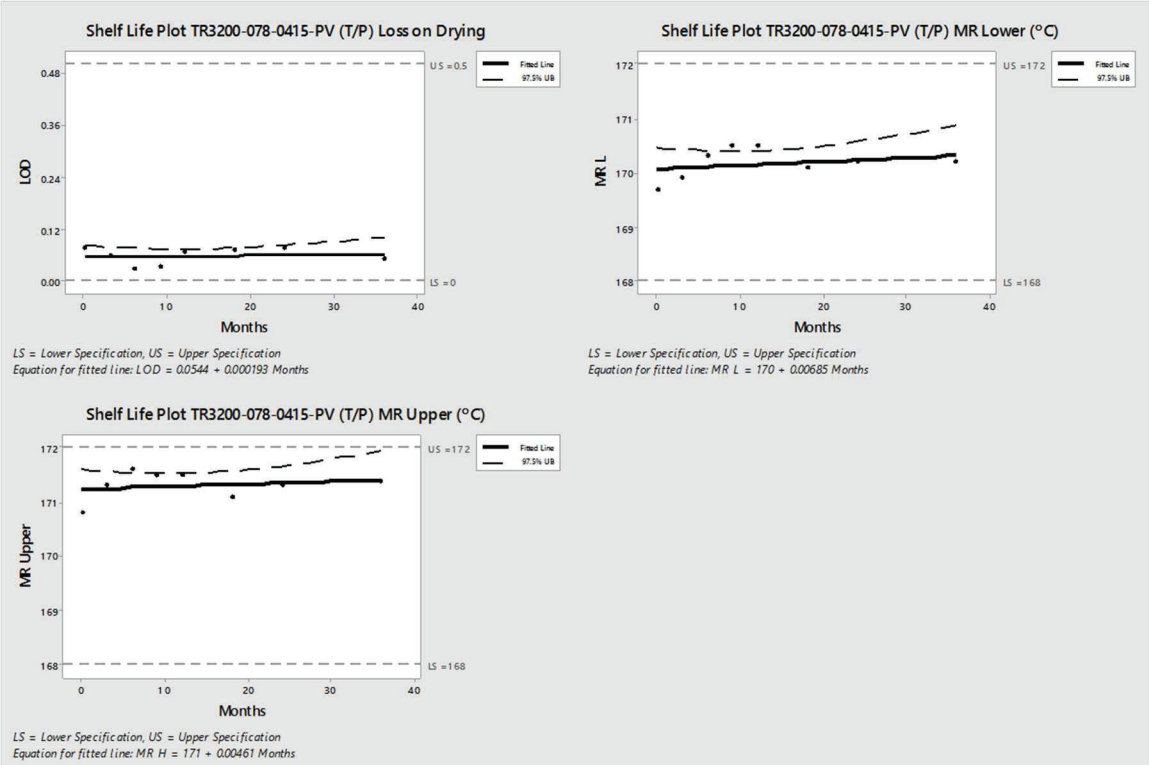
LOT ANALYSIS TR3200-078-0415-PV (T/P):

GRAPH 47. TR3200-078-0415-PV (T/P) ABS @ 400, 280, 260NM AND ASSAY %



Results for absorbance @ 400nm, 280nm, 260nm and assay showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

GRAPH 48. TR3200-078-0415-PV (T/P) LOSS ON DRYING %, MELTING RANGE LOWER AND UPPER POINTS



Results for loss on drying and melting range at both the lower and upper points showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is little degradation of the product shown from these analyses.

5. CONCLUSION:

All Stability data has met the specifications set forth in the Stability Testing Program. The successful completion of this 36 month stability study can confirm that all codes for this material are stable for up to 3 years. A 2-year retest date or 3-year expiry date may be issued for this material.