

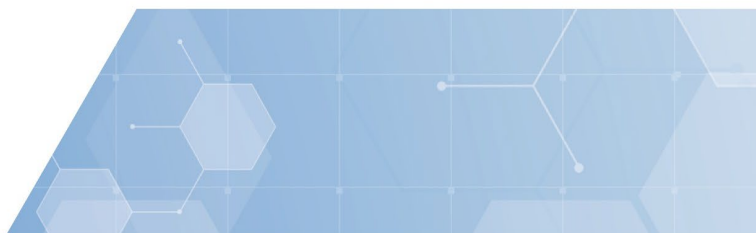
To Whom It May Concern,

September 24, 2021

This letter serves to provide the Loss on Drying Stability Data for Tris API for lots manufactured in 2018. These lots have completed the 36-month stability program. The results for Loss on Drying with a specification of 1.0% max. showed no predictable shelf life as the mean response slope is not significantly different from zero. This is observed as there is negligible degradation of the product shown from these analyses in the 36-month analysis timeframe.

Table 1. 2018 Stability Data for Tris API Loss on Drying

Lot Number	Timepoint	Loss on Drying	Minimum	Maximum	Mean
TR1200-012-0318-PV (2P/P)	0	0.3208	0.0163	0.3314	0.1318
TR1200-012-0318-PV (2P/P)	3	0.0620			
TR1200-012-0318-PV (2P/P)	6	0.1399			
TR1200-012-0318-PV (2P/P)	9	0.0844			
TR1200-012-0318-PV (2P/P)	12	0.0469			
TR1200-012-0318-PV (2P/P)	18	0.3314			
TR1200-012-0318-PV (2P/P)	24	<0.0163			
TR1200-012-0318-PV (2P/P)	36	0.0529			
TR1200-012-0318-PV (Labline)	0	0.3208	<0.0173	0.4352	0.1892
TR1200-012-0318-PV (Labline)	3	0.2319			
TR1200-012-0318-PV (Labline)	6	0.4352			
TR1200-012-0318-PV (Labline)	9	0.0873			
TR1200-012-0318-PV (Labline)	12	0.0850			
TR1200-012-0318-PV (Labline)	18	0.1472			
TR1200-012-0318-PV (Labline)	24	<0.0173			
TR1200-012-0318-PV (Labline)	36	0.0511			
TR1200-013-0318-PV (2P/P)	0	0.0835	0.0512	0.1197	0.0768
TR1200-013-0318-PV (2P/P)	3	0.0555			
TR1200-013-0318-PV (2P/P)	6	0.0686			
TR1200-013-0318-PV (2P/P)	9	0.0873			
TR1200-013-0318-PV (2P/P)	12	0.0729			
TR1200-013-0318-PV (2P/P)	18	0.1197			
TR1200-013-0318-PV (2P/P)	24	0.0512			
TR1200-013-0318-PV (2P/P)	36	0.0760			
TR1200-013-0318-PV (Labline)	0	0.0835	0.0265	0.1263	0.0710
TR1200-013-0318-PV (Labline)	3	0.0480			
TR1200-013-0318-PV (Labline)	6	0.0974			
TR1200-013-0318-PV (Labline)	9	0.0692			
TR1200-013-0318-PV (Labline)	12	0.0763			



Lot Number	Timepoint	Loss on Drying	Minimum	Maximum	Mean
TR1200-013-0318-PV (Labline)	18	0.1263			
TR1200-013-0318-PV (Labline)	24	0.0265			
TR1200-013-0318-PV (Labline)	36	0.0410			
TR1200-014-0318-PV (2P/P)	0	0.0979	0.0407	0.1376	0.0969
TR1200-014-0318-PV (2P/P)	3	0.1376			
TR1200-014-0318-PV (2P/P)	6	0.1128			
TR1200-014-0318-PV (2P/P)	9	0.1118			
TR1200-014-0318-PV (2P/P)	12	0.0407			
TR1200-014-0318-PV (2P/P)	18	0.1063			
TR1200-014-0318-PV (2P/P)	24	0.0805			
TR1200-014-0318-PV (2P/P)	36	0.0878			
TR1200-014-0318-PV (Labline)	0	0.0979			
TR1200-014-0318-PV (Labline)	3	0.0884			
TR1200-014-0318-PV (Labline)	6	0.1098			
TR1200-014-0318-PV (Labline)	9	0.1340			
TR1200-014-0318-PV (Labline)	12	0.0964			
TR1200-014-0318-PV (Labline)	18	0.1145			
TR1200-014-0318-PV (Labline)	24	0.0814			
TR1200-014-0318-PV (Labline)	36	0.1018			
TR1200-015-0318-PV (2P/P)	0	0.0593	0.0150	0.1331	0.0495
TR1200-015-0318-PV (2P/P)	3	<0.0150			
TR1200-015-0318-PV (2P/P)	6	0.0410			
TR1200-015-0318-PV (2P/P)	9	0.0313			
TR1200-015-0318-PV (2P/P)	12	0.1331			
TR1200-015-0318-PV (2P/P)	18	0.0301			
TR1200-015-0318-PV (2P/P)	24	0.0442			
TR1200-015-0318-PV (2P/P)	36	0.0417			

Sincerely,

Crystal Hamelburg
 Associate Director, Compliance
 BioSpectra Inc.