

Core Competencies – pharm-analyt

Swab/Immersion Samples Cleaning Validation

Analytes with LLOQ in ng/mL (depending on ng/100 cm² surface area criterion of cleaning validation), e.g.:

Cyclosporin A: 4 ng/ml

Testosteron Enanthate: 1 ng/ml

Fulvestrant: 2 ng/ml

Palonosetron: 2 ng/ml

Release Analysis – pharm-analyt

GMP and non-GMP

Analytes:

PEG, Polymers, Detergents (e.g. Triton, Tween/PS, TnBP)

2 Qualified Persons at pharm-analyt

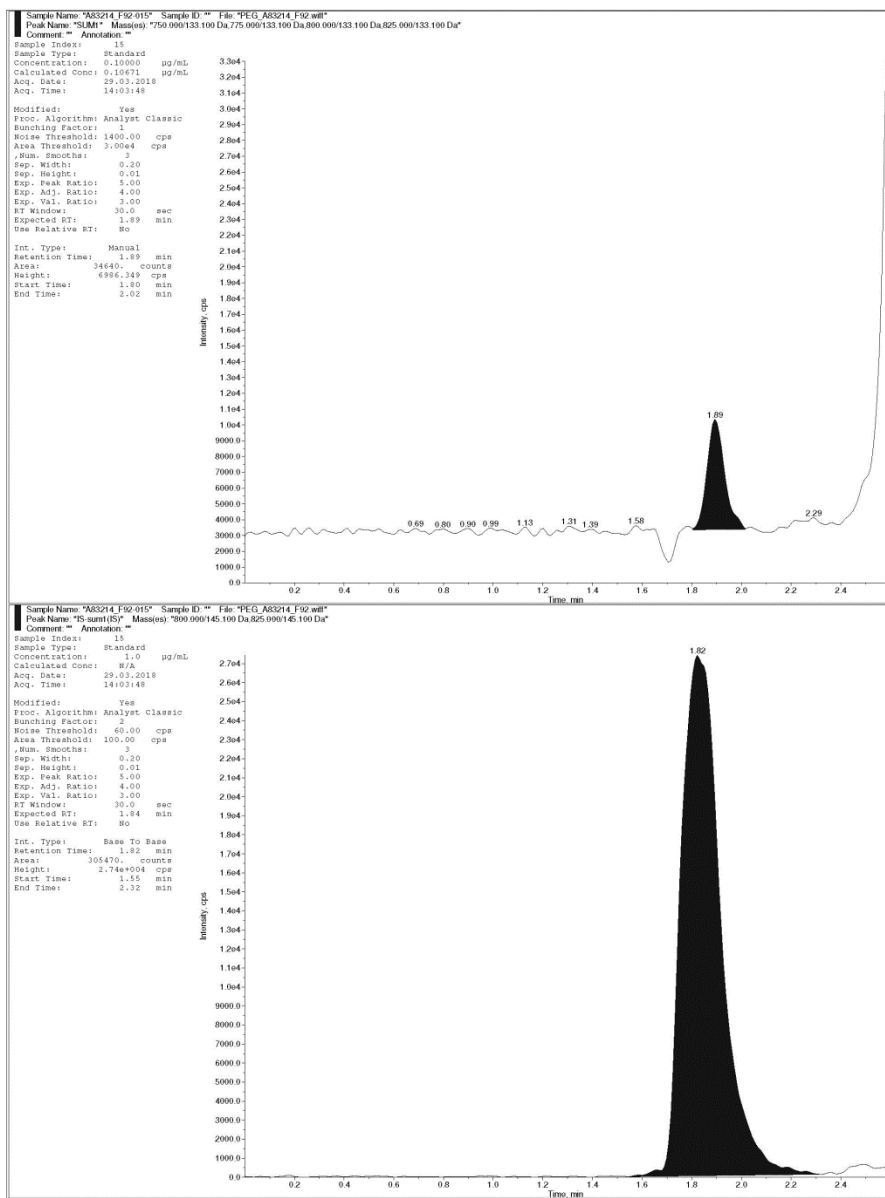
Fast Turnaround Time for Data

Free PEG 20 kDa in FDP

Calibration Range 100 – 10,000 ng/mL

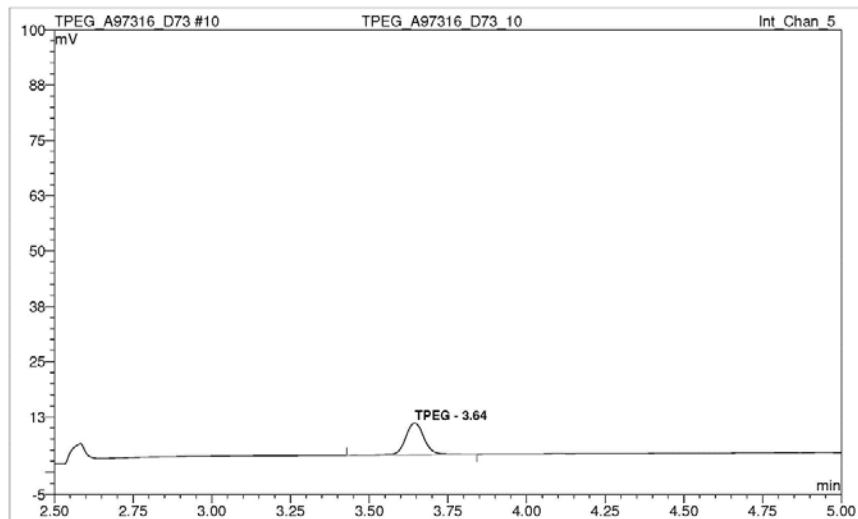
Upper Chrom Std at LLOQ
Lower Chrom Internal Standard

HPLC-MS/MS



TPEG_A97316_D73_10

Sample Name:	TPEG_A97316_D73_10	Injection Volume:	100.0
Project No.	A97316	Channel:	Int_Ch_5
Vial Number:	GA3	Detector:	ELSD
Control Program:	TPEG_ELS_D_2	Wavelength:	n.a
Quantif. Method:	TPEG_1	Dilution Factor:	1.0000
Recording Time:	10.4.2018 12:49	Sample Weight:	1.0000
Run Time (min):	9.10	Sample Amount:	1.0000



No.	Ret.Time	Peak Name	Amount	Area	Height	Peak Width (50%)	Type
Int_Ch_5	Int_Ch_5	Int_Ch_5	Int_Ch_5	Int_Ch_5	Int_Ch_5	Int_Ch_5	Int_Ch_5
	min		µg/mL	mV*min	mV	min	
1	3.64	TPEG	2.7911E+00	4.8187E-01	7.108	0.061	BMB
Total:			2.7911E+00	4.8187E-01	7.108	0.061	

Total PEG 20 kDa in FDP *)

Calibration range 3.00 – 30.0 µg/mL

Chrom Std at LLOQ

HPLC-ELSD

*) after pronase digestion
(PEG minus protein)



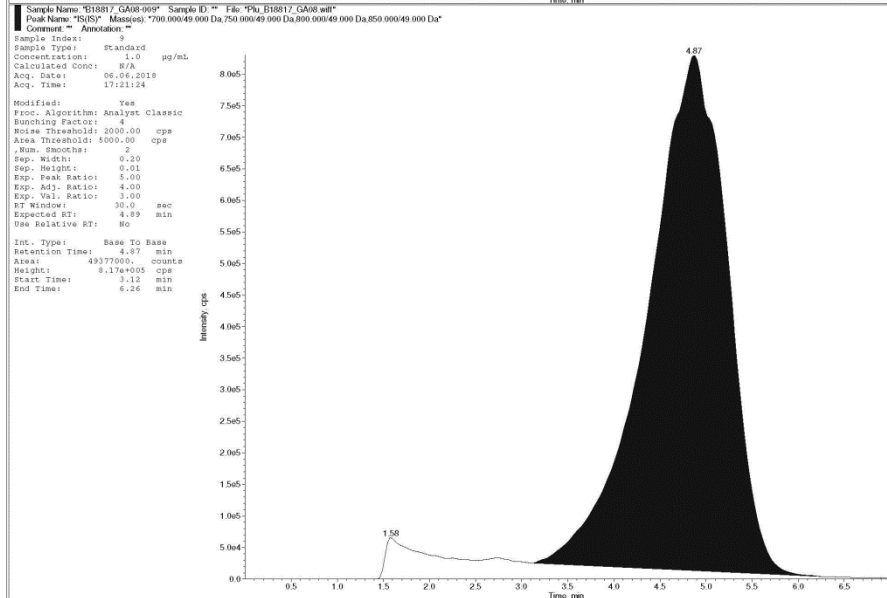
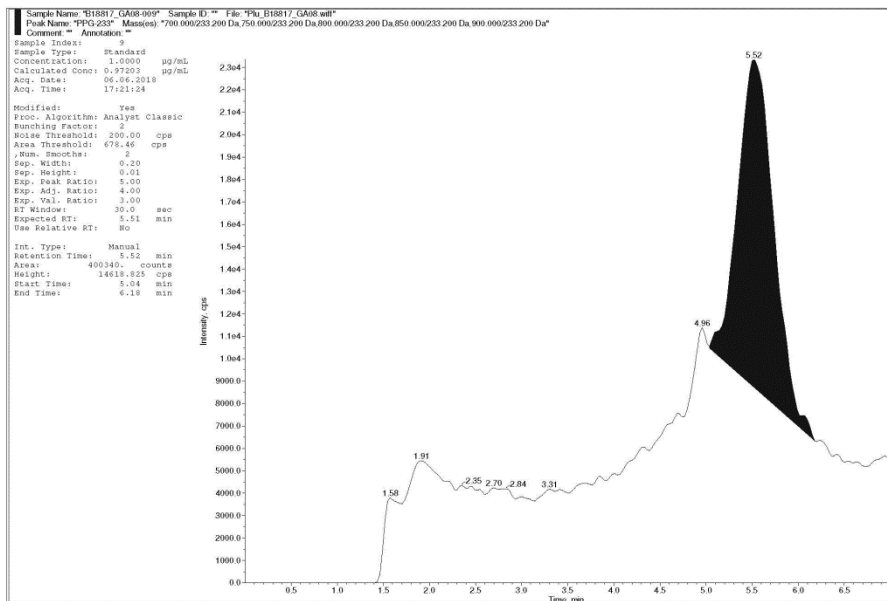
Poloxamer in BDS

Calibration Range 1.00 – 24.0 µg/mL

Upper Chrom Std at LLOQ
Lower Chrom Internal Standard

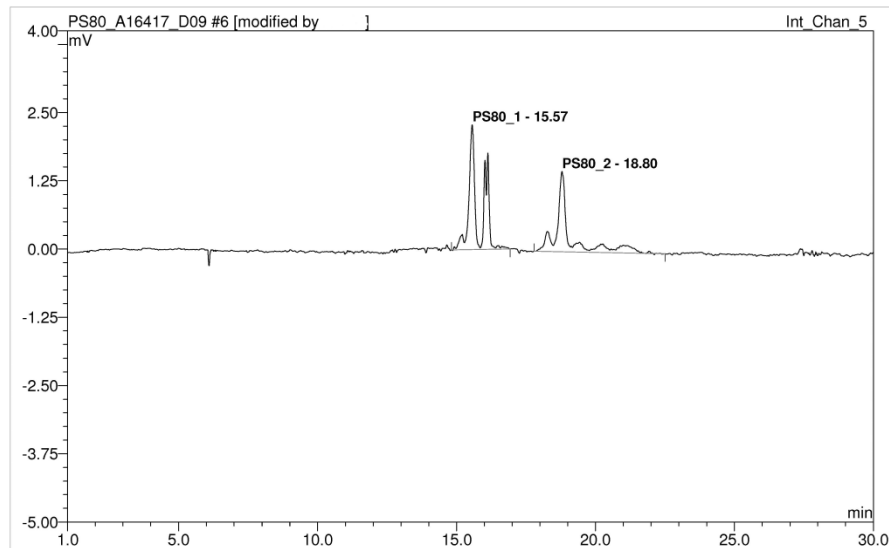
HPLC-MS/MS

*) Polymer
Containing PEG and PPG Units



PS80_B16417_D09_6

Sample Name:	PS80_B16417_D09_6	Injection Volume:	100.0
Project No.	B16417	Channel:	Int_Ch_5
Vial Number:	RA2	Detector	ELSD
Control Program:	ELSD_3	Wavelength:	n.a
Quantif. Method:	PS80_2	Dilution Factor:	1.0000
Recording Time:	6/4/18 14:12	Sample Weight:	1.0000
Run Time (min):	33.10	Sample Amount:	1.0000



No.	Ret.Time	Peak Name	Amount	Group Area	Group Height	Peak Width (50%)	Type
Int_Ch_5	Int_Ch_5	Int_Ch_5	Int_Ch_5	Int_Ch_5	Int_Ch_5	Int_Ch_5	Int_Ch_5
	min		mg/mL	mV*min	mV	min	
1	15.57	PS80_1	9.3390E-03	1.603	3.76	0.184	BMB*
2	18.80	PS80_2	9.4369E-03	1.603	3.76	0.229	BMB
Total:			1.8776E-02	3.21	7.51	0.413	

Tween 80 in FDP/FC

Calibration range 20.0 – 1000 µg/mL

Chrom Std at LLOQ

HPLC-ELSD

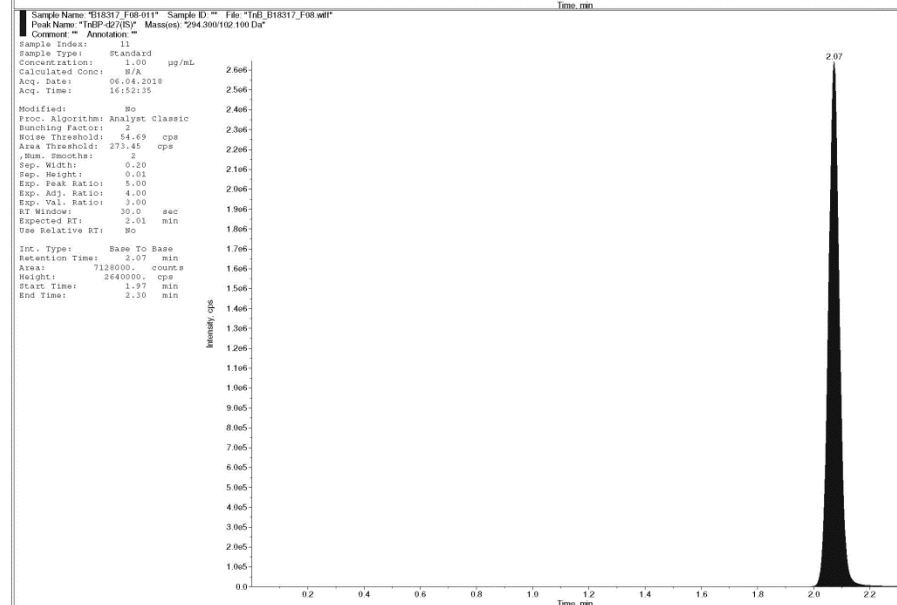
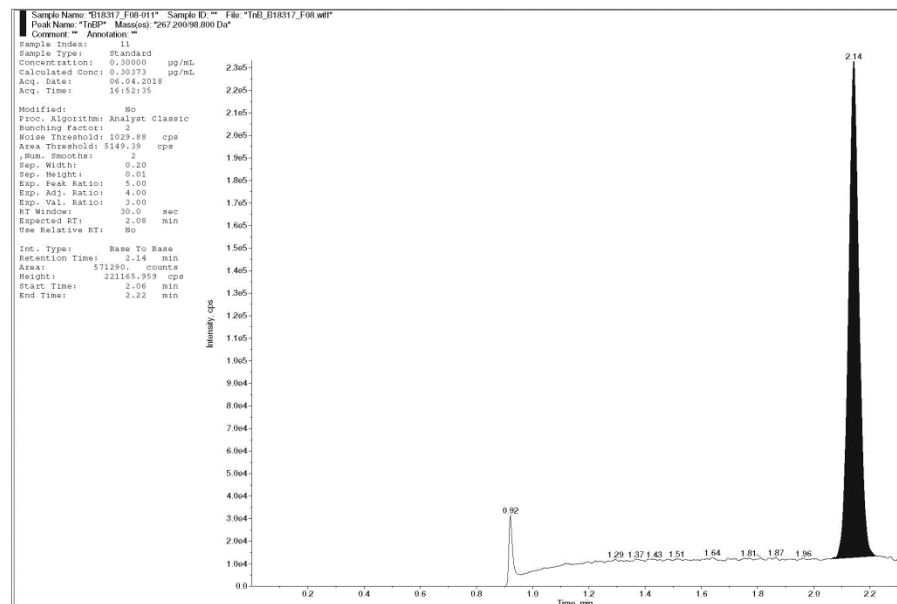


TnBP in FDP/FC

Calibration range 0.300 – 7.50 µg/mL

Upper Chrom Std at LLOQ
Lower Chrom Internal Standard

HPLC-MS/MS



PILLARS – pharm-analyt

