IN VITRO BINDING BIOEQUIVALENCE STUDY SUMMARY TABLES AND SAS TRANSPORT FORMATTED TABLES FOR DATASET SUBMISSION

I. For Calcium Acetate Drug Products

Table I.1 Submission Summary*

Drug Product Name	
Strength(s)	
Applicant Name	
Address	
Point of Contact **Name** **Address** **Telephone Number** **Fax Number**	

Or, please provide an electronic copy of Form 356H.

* This information is needed for a complete Bioequivalence review and, although required for the archival copy submitted to the Agency, it is frequently not readily available in the Bioequivalence Submission. The Division of Bioequivalence prefers that this information be submitted as a electronic Form 356H. If this is not possible, then please complete Table 1.

Table I.2. Summary of In Vitro Binding Study

Calcium Acetate Capsules/Tablets/Oral Solution Dose: Maximum Phosphate Binding Capacity (at saturated phosphate concentration (xxx mmole)) Arithmetic Data				
In-Vitro Phosphate Binding Study (Study No.) Phosphate				
Parameter	Mean		Ratio	
	Test (n=)	Reference (n=)	Point Estimate	90%CI
Maximum Binding (mmole)				
%CV			-	-

Table I.3. Pre-Study Analytical Method Validation

Information Requested	Calcium	Phosphate
Analytical method validation report location		
Analyte		
Internal standard (IS)		
Method description		
Limit of quantitation (mM)		
Average recovery (%)		
Linearity		
Intermediate precision range (%)		
Standard curve concentrations (mM)		
QC concentrations (mM)		
Storage Stability (days)		
Stock Stability (days)		
Bench-Top Stability (days)		
Filter Evaluation		
Dilution integrity		
Selectivity		

All SOPs for analytical method validation and in vitro binding test method should be submitted.

Table I.4. Summary of In Vitro Dissolution Studies, if applicable

Dissolution Conditions	**Apparatus:**	
	Speed of Rotation:	
	Medium:	
	Volume:	
	Temperature:	
Firm's Proposed Specifications		
Dissolution Testing Site (Name, Address)		

Study Ref No.	**Testing Date**	**Product ID \ Batch No. (Test - Manufacture Date) (Reference – Expiration Date)**	**Dosage Strength & Form**	**No. of Dosage Units**		**Collection Times (minutes or hours)**					**Study Report Location**
Study Report #:		Test Product	mg Tablet Capsule	12	Mean						
					Range						
					% CV						
Study Report #:		Reference Product	mg Tablet Capsule	12	Mean						
					Range						
					% CV						

Table I.5. Formulation Data

Ingredient	Function	Amount (mg) / Unit*	Amount (% w/w) / Unit*
		Strength 1	Strength 1
Total			**100.00**

- For tablet or capsule. If it is solution, please provide 'Amount (mg)/5 mL' and 'Amount (% w/w)' or 'Amount (% w/v)'.
- Please include the formulations of all strengths.

Table I.6. Reanalysis of Study Samples

In-Vitro Binding Study, Study No. Additional information in Volume(s), Page(s)								
Reason why assay was repeated	**Number of samples reanalyzed**				**Number of recalculated values used in reanalysis**			
	Actual number		**% of total assays**		**Actual number**		**% of total assays**	
	T	**R**	**T**	**R**	**T**	**R**	**T**	**R**
Total								

Please provide a separate table for each analyte.

Table I.7. Study Information

Study Number	
Study Title	
Analytical Site (Name, Address, Phone #)	
Analysis Dates	
Analytical Director	
Storage Period of Study Samples (no. of days from the first day of sample collection to the last day of sample analysis)	

Please provide a separate table for each In Vitro Binding Bioequivalence Study

Table I.8. Product Information

Product	Test	Reference
Treatment ID		
Product Name		
Manufacturer		
Batch/Lot No.		
Manufacture Date		
Expiration Date		
Strength		
Dosage Form		
Batch Size		
Production Batch Size		
Potency Assay		

Table I.9. Assay Validation

1. Phosphate

Phosphate										
Parameter	**Standard Curve Samples**									
Concentration (mM)										
Inter day Precision (%CV)										
Inter day Accuracy (%Actual)										
Linearity	(Range of R2 values)									
Linearity Range (mM)										
Sensitivity/LOQ (mM)										

Parameter	**Quality Control Samples**			
Concentration (mM)				
Inter day Precision (%CV)				
Inter day Accuracy (%Actual)				

2. Calcium

Calcium										
Parameter	**Standard Curve Samples**									
Concentration (mM)										
Inter day Precision (%CV)										
Inter day Accuracy (%Actual)										
Linearity	(Range of R2 values)									
Linearity Range (mM)										
Sensitivity/LOQ (mM)										

Parameter	**Quality Control Samples**			
Concentration (mM)				
Inter day Precision (%CV)				
Inter day Accuracy (%Actual)				

Table I.10. SOP's Dealing with Analytical Repeats

SOP No.	Effective Date of SOP	SOP Title

Please include the complete SOP for Analytical Repeats in your submission.

Table I.11. Calcium Amount in the Supernatant after Binding

Phosphate Spiking Level (mmoles)	Mean (mmol)		Mean Ratio	
	Test	Reference	Point Estimate	90%CI*

* For informational purposes only

Similarity Factor F_2 (Calculated using calcium mean concentrations):

Table I.12. Phosphate Amount in the Supernatant after Binding

Phosphate Spiking Level (mmol)	Mean (mmol) (n=12)		Mean Ratio	
	Test	Reference	Point Estimate	90%CI*

* For informational purposes only

Similarity Factor F_2 (Calculated using phosphate mean concentrations):

II. For a polymer drug that binds to either phosphate (e.g. Sevelamer) or bile acid (e.g., Colesevelam, Cholestyramine or Colestipol)

Table II.1 Submission Summary[†]

Drug Product Name	
Strength(s)	
Applicant Name	
Address	
Point of Contact **Name** **Address** **Telephone Number** **Fax Number**	

Or, please provide an electronic copy of Form 356H.

[†] This information is needed for a complete Bioequivalence review and, although required for the archival copy submitted to the Agency, it is frequently not readily available in the Bioequivalence Submission. The Division of Bioequivalence prefers that this information be submitted as a electronic Form 356H. If this is not possible, then please complete Table 1.

Summaries of In Vitro Binding Studies

II.2. In-Vitro Equilibrium Binding Studies

Table II.2.1. Summary of k_1 and k_2 - Without Acid Pre-Treatment (if applicable)

Condition 1 (e.g., pH 4)							
	Test		**Reference**			**90% CI**	
Parameter	**Mean**	**STD**	**Mean**	**STD**	**Ratio T/R**	**Lower**	**Upper**
k1							
k2							
Condition 2, etc… (e.g., pH 7)							
	Test		**Reference**			**90% CI**	
Parameter	**Mean**	**STD**	**Mean**	**STD**	**Ratio T/R**	**Lower**	**Upper**
k1							
k2							

Note: Please specify testing conditions in the table as appropriate.

Table II.2.2. Summary of k_1 and k_2 - With Acid Pre-Treatment (if applicable)

Condition 1 (e.g., pH 4)							
	Test		**Reference**			**90% CI**	
Parameter	**Mean**	**STD**	**Mean**	**STD**	**Ratio T/R**	**Lower**	**Upper**
k1							
k2							
Condition 2, etc… (e.g., pH 7)							
	Test		**Reference**			**90% CI**	
Parameter	**Mean**	**STD**	**Mean**	**STD**	**Ratio T/R**	**Lower**	**Upper**
k1							
k2							

Note: Please specify the testing conditions in the table as appropriate.

Table II.3. Pre-Study Analytical Method Validation

Information Requested	
Analytical method validation report location	
Analyte	
Internal standard (IS)	
Method description	
Limit of quantitation (mM)	
Average recovery of phosphate (%)	
Linearity	
Intermediate precision range (%)	
Standard curve concentrations (mM)	
QC concentrations (mM)	
Storage Stability (days)	
Stock Stability (days)	
Bench-Top Stability (days)	
Filter Evaluation	
Dilution integrity	
Selectivity	

All SOPs for analytical method validation and in vitro binding test method should be submitted.

Table II.4. Summary of In Vitro Disintegration Studies

Disintegration Conditions	**Apparatus:**	
	Speed of Rotation:	
	Medium:	
	Volume:	
	Temperature:	
Firm's Proposed Specifications		
Disintegration Testing Site (Name, Address)		

Study Ref No.	**Testing Date**	**Product ID \ Batch No. (Test - Manufacture Date) (Reference – Expiration Date)**	**Dosage Strength & Form**	**No. of Dosage Units**		**Disintegration Time (minutes)**	**Study Report Location**
Study Report #:		Test Product	mg Tablet Capsule	12	Mean		
					Range		
					% CV		
Study Report #:		Reference Product	mg Tablet Capsule	12	Mean		
					Range		
					% CV		

Provide disintegration data for all strengths of the test and reference products.

Table II.5. Formulation Data

Ingredient	Function	Amount (mg) / Unit*	Amount (%) / Unit*
		Strength 1	Strength 1
Total			**100.00**

- For tablet or capsule. If it is powder for suspension, please provide ‘amount (mg)/packet’ and ‘amount (% w/w)’.
- Please include the formulations of all strengths

Table II.6. Reanalysis of Study Samples

In-Vitro Binding Study, Study No. Additional information in Volume(s), Page(s)								
Reason why assay was repeated	**Number of samples reanalyzed**				**Number of recalculated values used in reanalysis**			
	Actual number		**% of total assays**		**Actual number**		**% of total assays**	
	T	**R**	**T**	**R**	**T**	**R**	**T**	**R**
Total								

Table II.7. Study Information

Study Number	
Study Title	
Analytical Site (Name, Address, Phone #)	
Analysis Dates	
Analytical Director	
Storage Period of Study Samples (no. of days from the first day of sample collection to the last day of sample analysis)	

Please provide a separate table for each In Vitro Binding Bioequivalence Study

Table II.8. Product Information

Product	Test	Reference
Treatment ID		
Product Name		
Manufacturer		
Batch/Lot No.		
Manufacture Date		
Expiration Date		
Strength		
Dosage Form		
Batch Size		
Production Batch Size		
Binding Capacity Assay and Date of Assay		

Please provide a separate table for each In Vitro Binding Bioequivalence Study

Table II.9.1. Study Design – In Vitro Kinetic Binding Study

Phosphate/Bile Acid Concentration(s)	
Phosphate/Bile Acid Solution Preparation	
Drug Amount	
Final Reaction Volume	
Temperature (^{o}C)	
pH(s) used	
Binding (incubation) Time(s)	
Parameter Determined	
No. of Samples (Replicates)	
Sample Preparation	
Buffer Component(s) and Concentration(s)	

Table II.9.2. Study Design – In Vitro Equilibrium Binding Study

Phosphate/Bile Acid Concentration(s)	
Phosphate/Bile Acid Solution Preparation	
Drug Amount	
Total Volume	
Temperature (^{o}C)	
pH(s) used	
Incubation Time(s)	
Parameter(s) measured (Units of parameters)	
No. of Samples (Replicates)	
Sample Preparation	
Calculation of Langmuir Binding Constants (Linear or Non-linear)	
Buffer Component(s) and Concentration(s)	

Table II.10. Assay Validation

Analyte										
Parameter	**Standard Curve Samples**									
Concentration (mM)										
Inter day Precision (%CV)										
Inter day Accuracy (%Actual)										
Linearity	(Range of R2 values)									
Linearity Range (mM)										
Sensitivity/LOQ (mM)										

Parameter	**Quality Control Samples**			
Concentration (mM)				
Inter day Precision (%CV)				
Inter day Accuracy (%Actual)				

Please provide a separate table for each analyte
Please provide a separate table for each In Vitro Binding Bioequivalence Study

Table II.11. SOP's Dealing with Analytical Repeats

SOP No.	**Effective Date of SOP**	**SOP Title**

Please include the complete SOP for Analytical Repeats in your submission.

In-Vitro Kinetic Binding Study Results

Table II.12.1. T/R Ratios of Mean Phosphate/Bile Acid Binding

Incubation Duration	Mean and %CV of the Test/Reference Ratios (Drug Bound) (n=)			
	T/R Ratio Condition 1	T/R Ratio Condition 2	T/R ratio Condition 3	T/R Ratio Condition 4, etc
Time 1				
Time 2				
Time 3				
Time 4				
Time 5				
Time 6				
Time 7				
Time 8				

Example of conditions: For Sevelamer: pH 4 and 7; For Colesevelam, Cholestyramine and Colestipol: SIF at pH 6.8. Please specify the times and testing conditions in the table as appropriate.

Table II.12.2. With Acid Pre-Treatment (if applicable)

Incubation Duration	Mean and %CV of the Test/Reference Ratios (Drug Bound) (n=)			
	T/R Ratio Condition 1	T/R Ratio Condition 2	T/R ratio Condition 3	T/R Ratio Condition 4, etc
Time 1				
Time 2				
Time 3				
Time 4				
Time 5				
Time 6				
Time 7				
Time 8				

Example of conditions: For Sevelamer: pH 4 and 7; For Colesevelam, Cholestyramine and Colestipol: SIF at pH 6.8. Please specify the times and testing conditions in the table as appropriate.

In-Vitro Equilibrium Binding Study Results

Table II.13.1. Summary of Mean Binding Data

Without Acid-Pretreatment

	Test (n=)		Reference (n=)	
Total Amount of Adsorbate at Start (mM)	**Mean Bound Adsorbate (micromole/gm Adsorbent)**	**%CV**	**Mean Bound Adsorbate (micromole/gm Adsorbent)**	**%CV**
Condition 1 (e.g., pH 4)				
Condition 2 (e.g., pH 7)				

Example of conditions: For Sevelamer: pH 4 and 7; For Colesevelam, Cholestyramine and Colestipol: SIF at pH 6.8. Please specify the testing conditions in the table as appropriate.

Table II.13.1. Summary of Mean Binding Data

With Acid Pre-Treatment (if applicable)

	Test (n=)		Reference (n=)	
Total Amount of Adsorbate at Start (mM)	**Mean Bound Adsorbate (micromole/gm Adsorbent)**	**%CV**	**Mean Bound Adsorbate (micromole/gm Adsorbent)**	**%CV**
Condition 1 (e.g., pH 4)				
Condition 2 (e.g., pH 7)				

Example of conditions: For Sevelamer: pH 4 and 7; For Colesevelam, Cholestyramine and Colestipol: SIF at pH 6.8. Please specify the testing conditions in the table as appropriate.

III. For Lanthanum Drug Products

Table III.1. Submission Summary[‡]

Drug Product Name	
Strength(s)	
Applicant Name	
Address	
Point of Contact **Name** **Address** **Telephone Number** **Fax Number**	

Or, please provide an electronic copy of Form 356H.

[‡] This information is needed for a complete Bioequivalence review and, although required for the archival copy submitted to the Agency, it is frequently not readily available in the Bioequivalence Submission. The Division of Bioequivalence prefers that this information be submitted as a electronic Form 356H. If this is not possible, then please complete Table 1.

Summaries of In Vitro Binding Studies

III.2. Summary of Mean Binding Data

pH 1.2

Condition 1							
	Test		Reference			90% CI	
Parameter	Mean	%CV	Mean	%CV	Ratio T/R	Lower	Upper
k1							
k2							

pH 3

Condition 2							
	Test		Reference			90% CI	
Parameter	Mean	STD	Mean	STD	Ratio T/R	Lower	Upper
k1							
k2							

pH 5

Condition 3,							
	Test		Reference			90% CI	
Parameter	Mean	STD	Mean	STD	Ratio T/R	Lower	Upper
k1							
k2							

Note: Please specify the testing conditions in each table as appropriate.

In Vitro Dissolution Bioequivalence Studies

III.3. Summary of Dissolution Bioequivalence Data

Location	
Medium	
Volume (mL)	
USP Apparatus type	
Rotation (rpm)	
Specifications	

Medium	In vitro study Strength	Other Strength	F2 metric for Test	F2 metric for Test Vs RLD	F2 metric for RLD
0.1 N HCl	1000 mg	500 mg			
		750 mg			
		1000 mg	--		--
pH 3.0 Buffer	1000 mg	500 mg			
		750 mg			
		1000 mg	--		--
pH 5.0 Buffer	1000 mg	500 mg			
		750 mg			
		1000 mg	--		--

Table III.4. Pre-Study Analytical Method Validation (for In Vitro Binding Study Sample Analysis)

Information Requested	
Analytical method validation report location	
Analyte	
Internal standard (IS)	
Method description	
Limit of quantitation (mM)	
Average recovery of phosphate (%)	
Linearity	
Intermediate precision range (%)	
Standard curve concentrations (mM)	
QC concentrations (mM)	
Storage Stability (days)	
Stock Stability (days)	
Bench-Top Stability (days)	
Filter Evaluation	
Dilution integrity	
Selectivity	

All SOPs for analytical method validation and in vitro binding test method should be submitted.

Table III.5. Pre-Study Analytical Method Validation (for In Vitro Dissolution Bioequivalence Study Sample Analysis)

Information Requested	Analyte:
Analytical method validation report location	
Study Report Number	
Analyte	
Method description	
Specificity	
System Precision	
Method precision	
Ruggedness (% difference in dissolution)(state equipment/analysts changed). Intermediate Precision	

Robustness	
Filter Study	
Accuracy (Concentration Levels, percent Recovery, % RSD)	
Linearity (concentration range, r value)	
Stability in analytical solution	
System Suitability Acceptance Criteria; Criteria met? (Yes or No)	
Dilution	

All SOPs for analytical method validation and in vitro dissolution method should be submitted.

Table III.6. Summary of In Vitro Dissolution Studies (for Both In Vitro Dissolution Bioequivalence Studies and Regulatory Dissolution Studies)

Dissolution Conditions	**Apparatus:**	
	Speed of Rotation:	
	Medium:	
	Volume:	
	Temperature:	
Firm's Proposed Specifications		
Dissolution Testing Site (Name, Address)		

Study Ref No.	**Testing Date**	**Product ID \ Batch No. (Test - Manufacture Date) (Reference – Expiration Date)**	**Dosage Strength & Form**	**No. of Dosage Units**		**Collection Times (minutes or hours)**					**Study Report Location**
Study Report #:		Test Product	mg Tablet Capsule	12	Mean						
					Range						
					% CV						
Study Report #:		Reference Product	mg Tablet Capsule	12	Mean						
					Range						
					% CV						

Provide dissolution data for all strengths (test and reference).

Table III.7. Formulation Data

Ingredient	Function	Amount (mg) / Tablet	Amount (% w/w) / Tablet
		Strength 1	Strength 1
Total			**100.00**

Please include the formulations of all strengths.

Table III.8. Reanalysis of Study Samples

In-Vitro Binding Study, Study No. Additional information in Volume(s), Page(s)								
Reason why assay was repeated	**Number of samples reanalyzed**				**Number of recalculated values used in reanalysis**			
	Actual number		**% of total assays**		**Actual number**		**% of total assays**	
	T	**R**	**T**	**R**	**T**	**R**	**T**	**R**
Total								

Table III.9. Study Information

Study Number	
Study Title	
Analytical Site (Name, Address, Phone #)	
Analysis Dates	
Analytical Director	
Storage Period of Study Samples (no. of days from the first day of sample collection to the last day of sample analysis)	

Please provide a separate table for each In Vitro Binding Bioequivalence Study

Table III.10. Product Information

Product	Test	Reference
Treatment ID		
Product Name		
Manufacturer		
Batch/Lot No.		
Manufacture Date		
Expiration Date		
Strength		
Dosage Form		
Batch Size		
Production Batch Size		
Potency Assay		
Uniformity of Dosage Unit		

Please provide a separate table for each In Vitro Binding Bioequivalence Study

Table III.11.1. Study Design – In Vitro Kinetic Binding Study

Phosphate	
Phosphate Preparation	
Drug Amount	
Final Reaction Volume	
Temperature (°C)	
pH(s) used	
Binding (incubation) Time(s)	
Parameter Determined	
No. of Samples (Replicates)	
Sample Preparation	
Buffer Component(s) and Concentration(s)	

Table III.11.2. Study Design – In Vitro Equilibrium Binding Study

Phosphate	
Phosphate Preparation	
Drug Amount	
Total Volume	
Temperature (°C)	
pH(s) used	
Incubation Time(s)	
Parameter(s) measured (Units of parameters)	
No. of Samples (Replicates)	
Sample Preparation	
Calculation of Langmuir Binding Constants (Linear or Non-linear)	
Buffer Component(s) and Concentration(s)	

Table III.12. Assay Validation

Phosphate										
Parameter	**Standard Curve Samples**									
Concentration (mM)										
Inter day Precision (%CV)										
Inter day Accuracy (%Actual)										
Linearity	(Range of R2 values)									
Linearity Range (mM)										
Sensitivity/LOQ (mM)										

Parameter	**Quality Control Samples**			
Concentration (mM)				
Inter day Precision (%CV)				
Inter day Accuracy (%Actual)				

Please provide a separate table for each In Vitro Binding Bioequivalence Study

Table III.13. SOP's Dealing with Analytical Repeats

SOP No.	**Effective Date of SOP**	**SOP Title**

Please include the complete SOP for Analytical Repeats in your submission.

In-Vitro Kinetic Binding Study Results

Table III.14.1 T/R Ratios of Mean Phosphate Binding

pH 1.2

Incubation Duration (minutes)	Test/Reference Ratios (Drug Bound) (n=)		
	Phosphate Concentration 1 (mM)	Phosphate Concentration 2 (mM)	Phosphate Concentration 3 (mM)
	T/R ratio	T/R ratio	T/R ratio
Time 1			
Time 2			
Time 3			
Time 4			
Time 5			
Time 6			
Time 7			
Time 8			

Example of conditions: lowest concentration at pH 1.2, mid concentration at pH 1.2, highest concentration at pH 1.2, etc.
Note: Please specify the times and testing conditions in the table as appropriate.

Table III.14.2 T/R Ratios of Mean Phosphate Binding

pH 3.0

Incubation Duration (minutes)	Test/Reference Ratios (Drug Bound) (n=)		
	Phosphate Concentration 1 (mM)	Phosphate Concentration 2 (mM)	Phosphate Concentration 3 (mM)
	T/R ratio	T/R ratio	T/R ratio
Time 1			
Time 2			
Time 3			
Time 4			
Time 5			
Time 6			
Time 7			
Time 8			

Example of conditions: lowest concentration at pH 3, mid concentration at pH 3, highest concentration at pH 3, etc. Please specify the times and phosphate concentrations as appropriate.

Table 1II.14.3 T/R Ratios of Mean Phosphate Binding

pH 5.0

Incubation Duration (minutes)	Test/Reference Ratios (Drug Bound) (n=)		
	Phosphate Concentration 1 (mM)	Phosphate Concentration 2 (mM)	Phosphate Concentration 3 (mM)
	T/R ratio	T/R ratio	T/R ratio
Time 1			
Time 2			
Time 3			
Time 4			
Time 5			
Time 6			
Time 7			
Time 8			

Example of conditions: lowest concentration at pH 5, mid concentration at pH 5, highest concentration at pH 5, etc. Please specify the times and phosphate concentrations as appropriate.

In-Vitro Equilibrium Binding Study Results

Table III.15. Summary of Mean Binding Data

	Test (n=)		Reference (n=)	
Total Amount of Phosphate at Start (mM)		**%CV**		**%CV**
Condition 1 (e.g., pH 1.2)				
Condition 2 (e.g., pH 3)				
Condition 3 (e.g., pH 5)				

SAS Transport Formatted Tables for Data Submission for In-Vitro Binding Studies (For All But Binding Studies of Calcium Acetate Drug Products)

1. For the Kinetic Binding Study:

Adsorbate = Analyte (Phosphate, Bile salt, etc.) that binds to the drug
Adsorbant = Drug

Variable Name	Variable Label	Variable Type	Notes
PH	pH	Numeric	pH
REP	Replicate number	Numeric	Replicate number
BOUND_K	Bound Adsorbate	Numeric	Amount of Adsorbate Bound /Amount of Drug
PRODUCT	Product name	Character	Identifier for product (TEST or REF)
T1	Incubation Time point 1	Numeric	Incubation Time
T2	Incubation Time point 2	Numeric	Incubation Time
T3	Incubation Time point 3	Numeric	Incubation Time
T4	Incubation Time point 4	Numeric	Incubation Time
T5	Incubation Time point 5	Numeric	Incubation Time
T6	Incubation Time point 6	Numeric	Incubation Time
T7	Incubation Time point 7	Numeric	Incubation Time
T8	Incubation Time point 8	Numeric	Incubation Time

Note: Please provide separate dataset for each binding condition per product-specific guidance, for example, different concentrations of adsorbate, different pH, with/without acid treatment.

2. For the Equilibrium Binding Study:

Adsorbate = Analyte (Phosphate, Bile salt, etc.) that binds to the drug
Adsorbent = Drug

Variable Name	Variable Label	Variable Type	Notes	Terms in Langmuir equation
START	Amount of adsorbate at start	Numeric	Amount of adsorbate at start Units = mg	
REMAIN	Amount of adsorbate at equilibrium (unbound)	Numeric	Amount of adsorbate at equilibrium Units = mg	Ceq
BOUND_E	Amount of adsorbate bound	Numeric	[START – REMAIN] Amount of adsorbate bound Units = mg	x
USED	Amount of adsorbant (Drug) used	Numeric	Amount of adsorbant (Drug) used Units = mg or gram	m
XM	X/M	Numeric	Amount Bound adsorbate / Amount of adsorbant (Drug) Used Units = none	x/m
CEQXM	Ceq/(X/M)	Numeric	Ceq/(X/M) Units = mg	Ceq/(x/m)
PRODUCT	Product name	Character	Identifier for product (TEST or REF)	
REP	Replicate number	Numeric	Replicate number	

Note: Please provide separate dataset for each binding condition per product-specific guidance.