Title: HPLC Technical Information Form

SOP Number. 22720 **Revision Number. 02**

Supersedes: Revision 01 **Effective Date: JUN 28 2019**

Originator/Date: [redacted]

Approval/Date:

Approval/Date:

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1.0 Purpose

This SOP describes the procedure for completing the Technical Information Form for newly developed HPLC (High Pressure Liquid Chromatography) based analytical methods.

This form is designed to document the finalized parameters for HPLC-based analytical methods for new products manufactured under CGMP, GLP, and R&D conditions. It is not necessary to complete this form if PA/QC testing is performed under previously developed methods. An electronic copy of the signed HPLC technical information form will be kept in HPLC Technical Form (SOP 22720) folder on PA drive as well as a designated BOA folder for archiving.

2.0 Scope

This SOP applies to Process Analytics/QC Analysts who perform the testing, Process Analytics, and Quality Assurance reviewers. This procedure applies to the testing of new CGMP, GLP, and R&D materials and products.

3.0 Authority and Responsibility

NOTE: It is the ultimate responsibility of the Requester to ensure that the information provided on this form is accurate, current, and complete.

3.1 The Director, Process Analytics/Quality Control (PA/QC), has the authority to define this procedure.

3.2 Biopharmaceutical Development Program (BDP) production personnel and PA/QC personnel are responsible for performing the procedure.

3.3 PA/QC is responsible for training laboratory personnel and documenting this training to Biopharmaceutical Quality Assurance (BQA).

3.4 PA/QC is responsible for reviewing the data and documenting the results of this Procedure.

3.5 BQA is responsible for quality oversight of this procedure.

4.0 Procedure

The requestor completes **Form 22720-01** when specific parameters of an HPLC-based analytical methods are finalized. Then, the technical form is sent to be reviewed by PA/QC and BQA reviewers. Once all signatures are obtained, an electronic copy of the technical form is kept in HPLC Technical Form (SOP 22720) folder on the PA drive and a designated BQA folder for archiving.

5.0 Attachments

5.1 **Attachment 1** Form 22720-01, HPLC Technical Information Sheet

5.2 **Attachment 2** Example of documentation proof to accompany Form 22720-01

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted].

Attachment 1

HPLC Technical Information Sheet
(Page 1 of 3)

FNLCR, BDP
Form No.: 22720-01
SOP No.: 22720
Revision 02: JUN 28 2019

HPLC Technical Information Sheet	
Revision Number:	
Section A:	
1.0 Method of Chromatography	SEC
2.0 Sample Information	
2.1 Product Name	
2.2 BDP Part Number	
2.3 Lot Number	
2.4 Product Type	Antibody
2.5 Sample Concentration	
2.6 Diluent	
2.7 Molecular Weight/pI Value	
2.8 Amino Acid Sequence (if applicable)	
2.9 Storage Temperature	
2.10 Stability – Related Issues (please specify)	
Section B:	
3.0 Chromatographic Parameters	
3.1 Injection Volume (µl/Inj.)	
3.2 Injection Amount (µg/Inj.)	
3.3 Flow Rate (mL/min)	
3.4 Isocratic	
3.4.1. Mobile Phase	
3.4.2. Run Time (min)	
3.5 Gradient	
3.5.1 Starting % MPB	
3.5.2 Final % MPB	
3.5.3 Run Time (min)	
3.5.4 Mobile Phase A	
3.5.5 Mobile Phase B	
3.5.6 Step Gradient (Please Attach Time Table)	

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Attachment 1 (Continued)
HPLC Technical Information Sheet
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HPLC Technical Information Sheet	
3.6 Detection	
3.7 Autosampler Temperature (default setting is 4°C)	
3.8 Column Temperature (default setting is 21°C to 25°C)	
Section C:	
4.0 Column Information/Resin Information	
4.1 Recommended Column/Resin	
4.1.1 Stationary Phase	
4.1.2 Dimensions	
4.1.3 Particle Size	
4.2 Recommended Manufacturer	
Section D:	
5.0 Sample Preparation	
5.1 Analysis Type	Reduced
5.2 Recommended Reducing Agent	
5.3 Recommended Incubation Temperature	
5.4 Recommended Incubation Time	
5.5 Sample State	Frozen Liquid
5.6 Reconstitution Protocol (Please Attach Protocol)	
Section E:	
6.0 Reference Standard	
6.1 Product Name	
6.2 BDP Part Number	
6.3 Lot Number	
6.4 Diluent	
6.5 Molecular Weight	
6.6 Amino Acid Sequence (if applicable)	
6.7 Storage Temperature	
6.8 Storage Location	

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Attachment 1 (Continued)
HPLC Technical Information Sheet
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HPLC Technical Information Sheet	
Section F:	
7.0 Formulation Buffer Blank	
7.1 Product Name	
7.2 BDP Part Number	
7.3 Lot Number	
Section G:	
8.0 Chromatographic Profile	
8.1 Please Attach Representative Chromatogram	

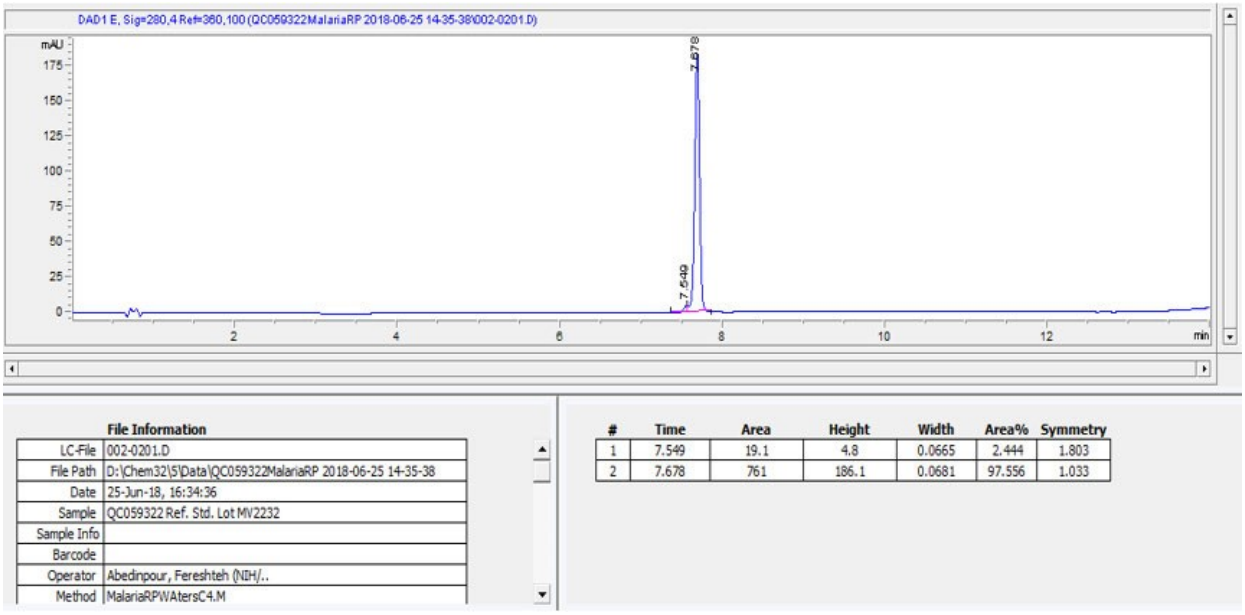
Comments:	

Requestor's Signature/Date:	
[1]Process Analytics/Date:	
[1]Quality Assurance/Date:	

[1]The PA and QA signatures are required only when conditions for HPLC analysis are finalized and used for the release of products manufactured in accordance with CGMPs.

This procedure is made available through federal funds from the National Cancer Institute, NIH, under contract [redacted].

Attachment 2
Example of Document Proof
(To accompany Form 22720-01)



File Information	
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Date	25-Jun-18, 16:34:36
Sample	QC059322 Ref. Std. Lot MV2232
Sample Info	
Barcode	
Operator	Abedinpour, Fereshteh (NIH/..
Method	MalariaRPWAtersC4.M

#	Time	Area	Height	Width	Area%	Symmetry
1	7.549	19.1	4.8	0.0665	2.444	1.803
2	7.678	761	186.1	0.0681	97.556	1.033

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