SOP Title: HPLC Technical Information Form
SOP Number: 22720
Revision: 03

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1. 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 BQA folder for archiving.

2. 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. RESPONSIBILITIES

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

3.1 Director / Process Analytics/Quality Control (PA/QC)

- Defines procedure

3.2 PA/QC Personnel

- Trains lab personnel
- Performs procedure
- Records and reviews data

3.3 Production Personnel

- Performs procedure

3.4 Biopharmaceutical Quality Assurance (BQA)

- Provides quality oversight

4. 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. REFERENCES AND RELATED DOCUMENTS

Document Number	Title
22720-01	HPLC Technical Information Sheet

6. ATTACHMENTS

Attachment 1 Example of documentation proof to accompany Form 22720-01

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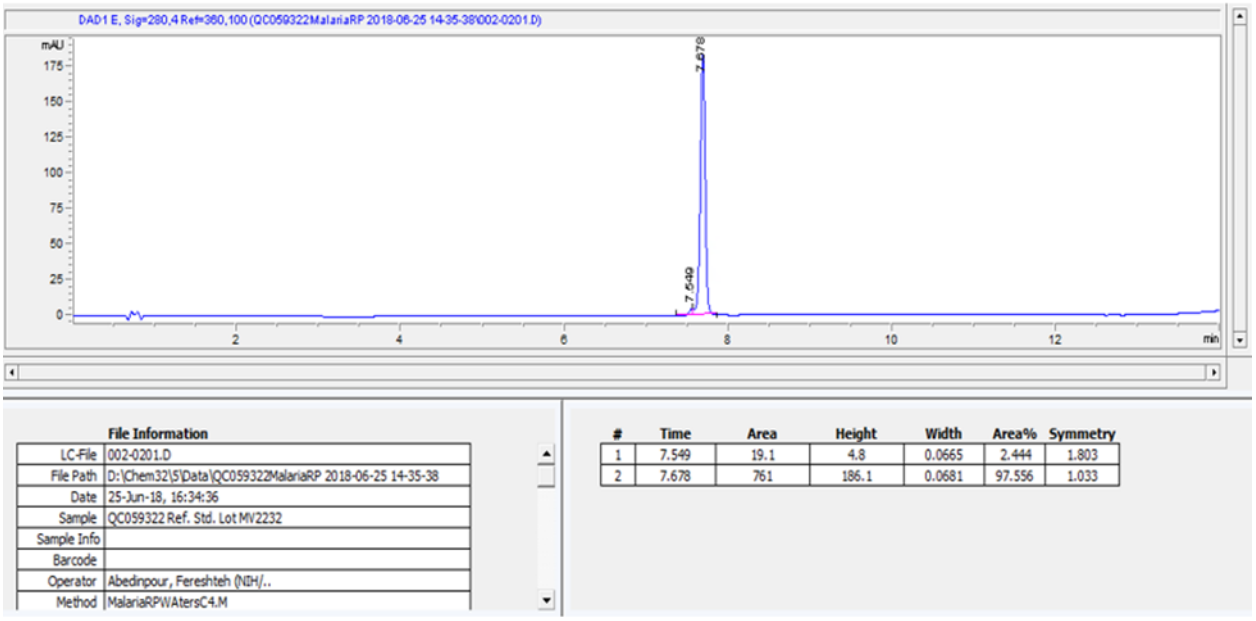
Attachment 1 Example of documentation proof to accompany Form 22720-01



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Method	MalariaRPWAtersC4.M

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