

## Supporting Information

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### Development and validation of a simple HPLC assay method for ibuprofen, pseudoephedrine hydrochloride and chlorpheniramine maleate in syrup form

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| <b>Table of Contents</b>   | <b>Page</b> |
|--|-------------|
| <b>Table S1.</b> Information of standard compounds   | 2           |
| <b>Table S2.</b> Gradient program for chromatographic conditions.                                    | 2           |
| <b>Table S3.</b> Linearity and range – IBU (1)   | 3           |
| <b>Figure S1.</b> Linearity of IBU (1)   | 3           |
| <b>Table S4.</b> Linearity and range – PSEH (2)  | 4           |
| <b>Figure S2.</b> Linearity of PSEH (2)  | 4           |
| <b>Table S5.</b> Linearity and range – CHL (3)   | 5           |
| <b>Figure S3.</b> Linearity of CHL (3)   | 5           |
| <b>Figure S4.</b> HPLC chromatogram of diluent   | 6           |
| <b>Figure S5.</b> HPLC chromatogram of standards   | 7           |
| <b>Table S6.</b> Repeatability (precision of the method) results of IBU, PSEH and CHL                | 9           |
| <b>Table S7.</b> Intermediate precision results of IBU, PSEH and CHL                                 | 9           |
| <b>Table S8.</b> Comparison of repeatability and intermediate precision results of IBU, PSEH and CHL | 10          |
| <b>Table S9.</b> Comparison of robustness and repeatability test results – IBU (1)                   | 11          |
| <b>Table S10.</b> Comparison of robustness and repeatability test results – PSEH (2)                 | 11          |
| <b>Table S11.</b> Comparison of robustness and repeatability test results – CHL (3)                  | 11          |

**Table S1.** Information of standard compounds

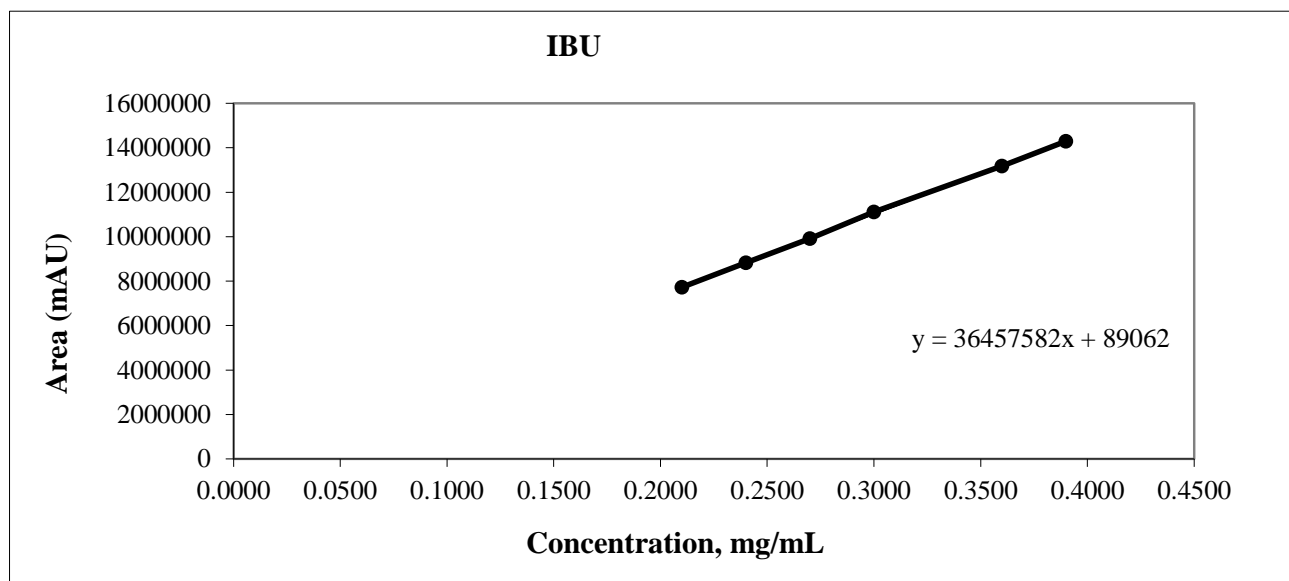
| <b>Standard Name</b> | <b>Lot Number</b> | <b>Source</b>                                     | <b>Potency%<br/>(as is)</b> |
|----------------------|-------------------|---|-----------------------------|
| IBU (1)              | C100-1004161M     | Hubei Biocause Phamaceutical<br>Co., Ltd. (China) | 99.4                        |
| PSEH (2)             | 510111Z02         | Malladi Drugs &<br>Pharmaceuticals Ltd. (India)   | 99.9                        |
| CHL (3)              | SLL/C/0911150     | Supriya Lifescience Ltd. (India)                  | 99.5                        |

**Table S2.** Gradient program for chromatographic conditions

| <b>Time (min.)</b> | <b>Mobile Phase A (%) (%)</b> | <b>Mobile Phase B (%)</b> |
|--------------------|-------------------------------|---------------------------|
| 0-7                | 50                            | 50                        |
| 7-13               | 50→40                         | 50→60                     |
| 13-17              | 40                            | 60                        |
| 17-26              | 40→30                         | 60→70                     |
| 26-28              | 30→50                         | 70→50                     |
| 28-30              | 50                            | 50                        |

**Table S3.** Linearity and range – IBU (1)

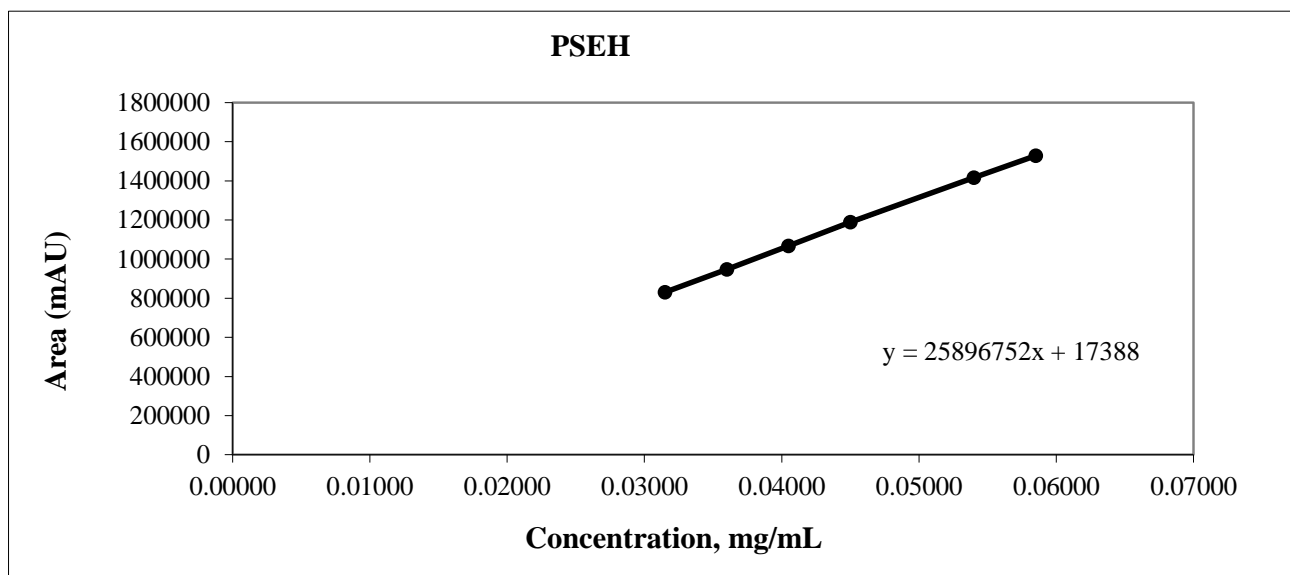
| Linearity Level (%) | Concentration (mg/mL) | Peak Area            | Average Area |
|---------------------|-----------------------|----------------------|--------------|
| 70                  | 0.209997              | 7734457<br>7719301   | 7726879      |
| 80                  | 0.239997              | 8820499<br>8835939   | 8828219      |
| 90                  | 0.269996              | 9919461<br>9917908   | 9918685      |
| 100                 | 0.299996              | 11104898<br>11112805 | 11108852     |
| 120                 | 0.359995              | 13178299<br>13186693 | 13182496     |
| 130                 | 0.389994              | 14281307<br>14315188 | 14298248     |



**Figure S1.** Linearity of IBU (1)

**Table S4.** Linearity and range – PSEH (2)

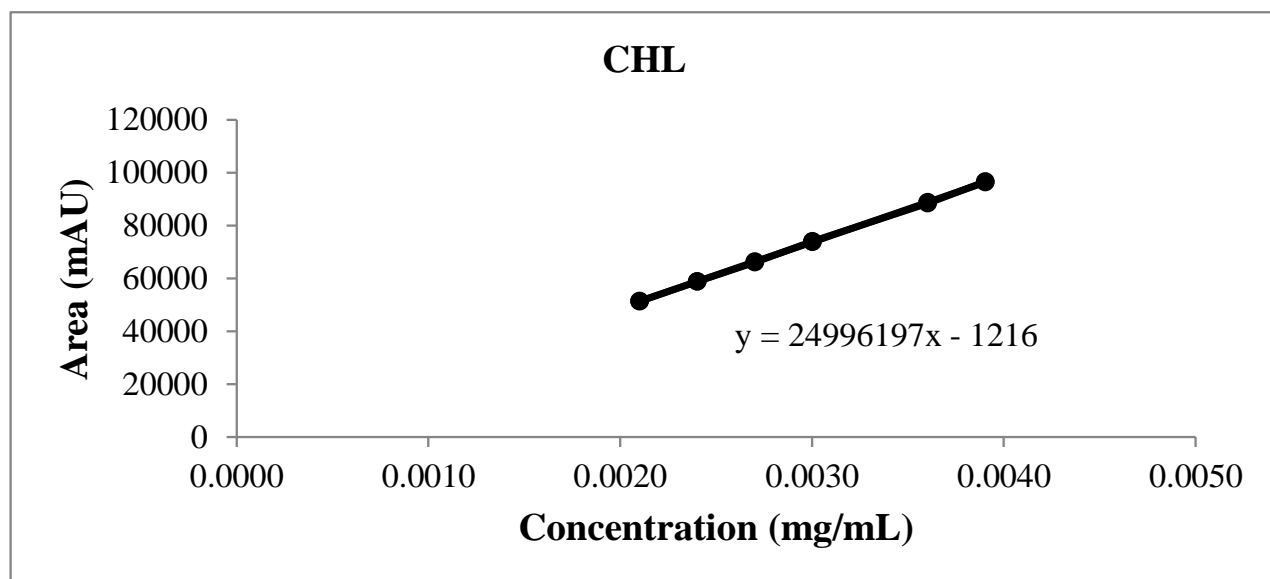
| Linearity Level (%) | Concentration (mg/mL) | Peak Area | Average Area |
|---------------------|-----------------------|-----------|--------------|
| <b>70</b>           | 0.031503              | 831763    | 830730       |
|                     |                       | 829697    |              |
| <b>80</b>           | 0.036004              | 948172    | 948157       |
|                     |                       | 948142    |              |
| <b>90</b>           | 0.040504              | 1067238   | 1067508      |
|                     |                       | 1067777   |              |
| <b>100</b>          | 0.045005              | 1188584   | 1188896      |
|                     |                       | 1189208   |              |
| <b>120</b>          | 0.054006              | 1415834   | 1416092      |
|                     |                       | 1416349   |              |
| <b>130</b>          | 0.058506              | 1526714   | 1529258      |
|                     |                       | 1531801   |              |



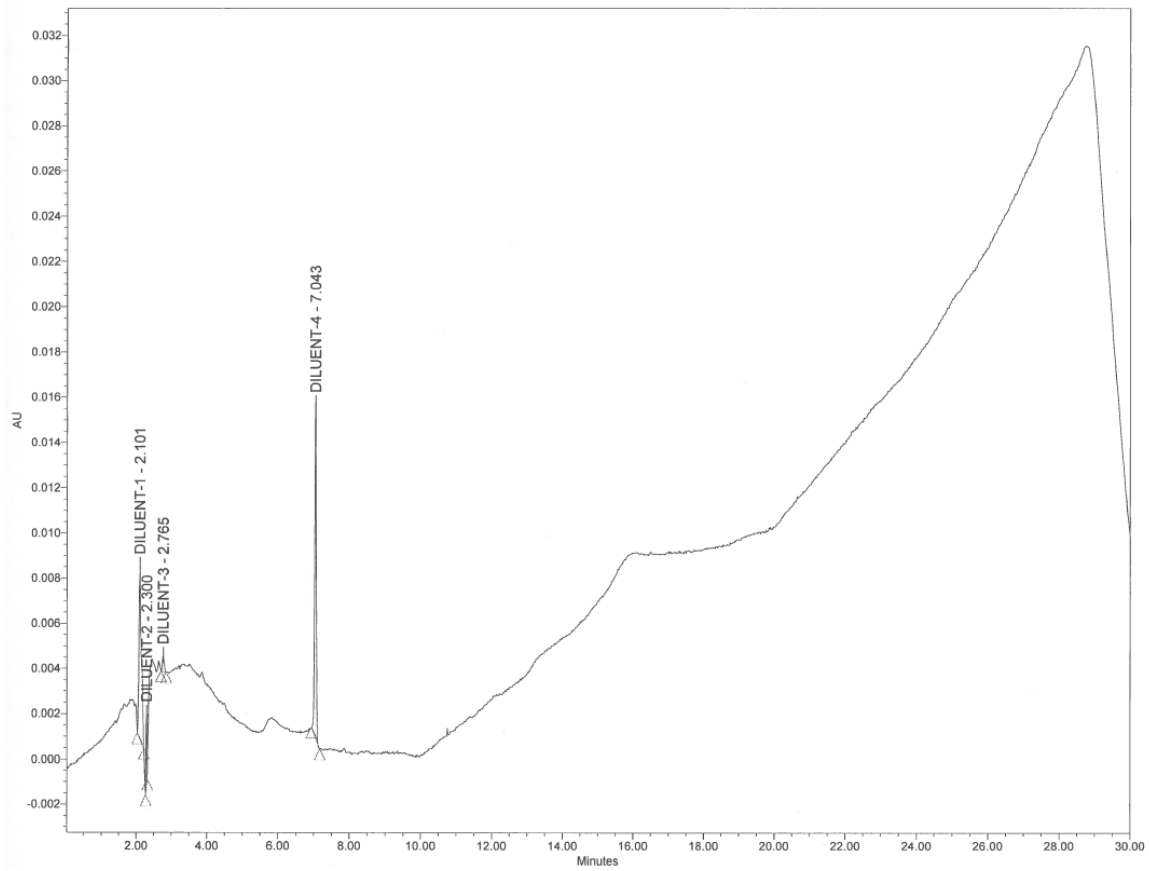
**Figure S2.** Linearity of PSEH (2)

**Table S5.** Linearity and range – CHL (3)

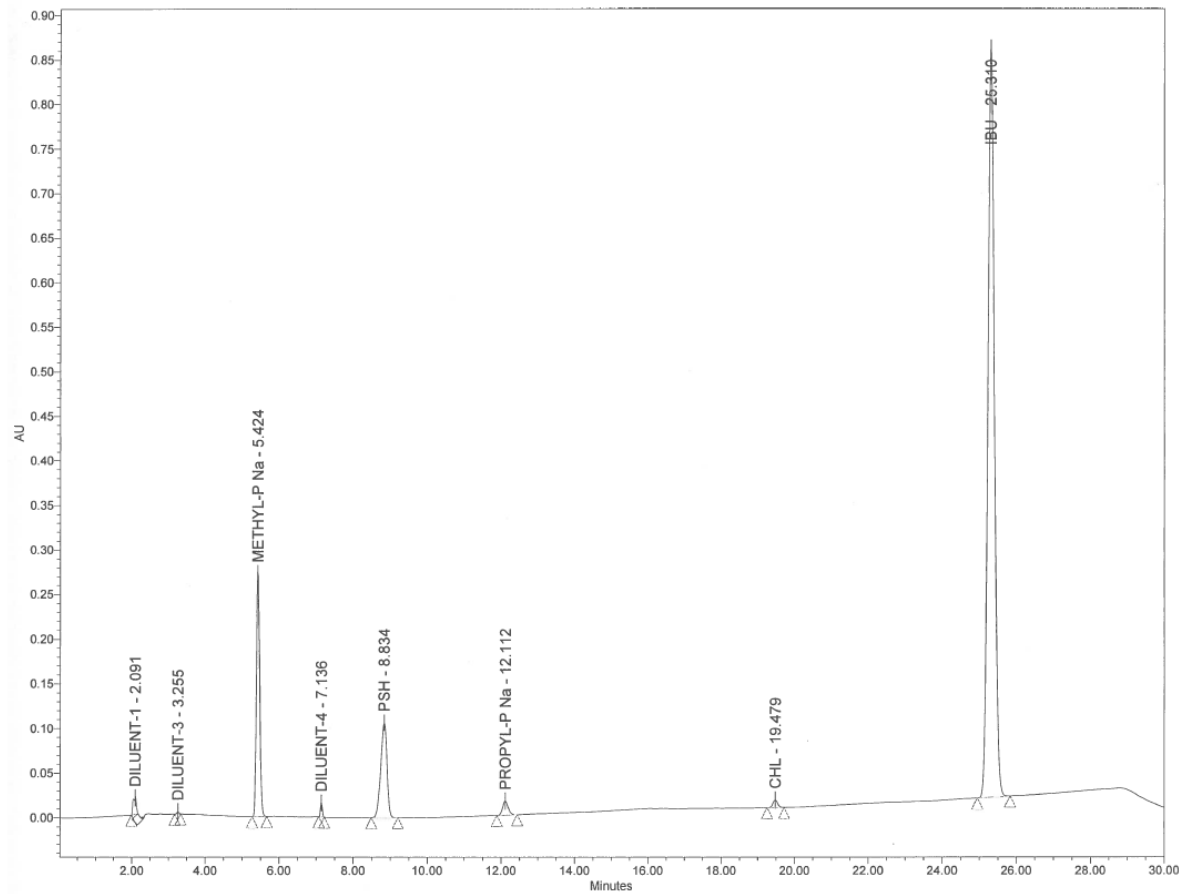
| <b>Linearity Level (%)</b> | <b>Concentration (mg/mL)</b> | <b>Peak Area</b> | <b>Average Area</b> |
|----------------------------|------------------------------|------------------|---------------------|
| <b>70</b>                  | 0.002102                     | 51201<br>51572   | 51387               |
| <b>80</b>                  | 0.002402                     | 58997<br>58730   | 58864               |
| <b>90</b>                  | 0.002703                     | 66172<br>66107   | 66140               |
| <b>100</b>                 | 0.003003                     | 74076<br>74089   | 74083               |
| <b>120</b>                 | 0.003603                     | 88351<br>88470   | 88411               |
| <b>130</b>                 | 0.003904                     | 96571<br>96780   | 96676               |



**Figure S3.** Linearity of CHL (3)



**Figure S4.** HPLC chromatogram of diluent



**Figure S5.** HPLC chromatogram of standards

**Table S6.** Repeatability (precision of the method) results of IBU, PSEH and CHL

| <b>Sample No</b>                        | <b>IBU (1)<br/>Assay %</b> | <b>PSEH (2)<br/>Assay %</b> | <b>CHL (3)<br/>Assay %</b> |
|---|----------------------------|-----------------------------|----------------------------|
| <b>1</b>                                | 98.0                       | 97.7                        | 97.8                       |
| <b>2</b>                                | 97.5                       | 97.6                        | 97.5                       |
| <b>3</b>                                | 97.6                       | 97.6                        | 97.7                       |
| <b>4</b>                                | 97.2                       | 98.0                        | 98.0                       |
| <b>5</b>                                | 98.2                       | 97.5                        | 97.5                       |
| <b>6</b>                                | 98.1                       | 98.0                        | 97.8                       |
| <b>Average</b>                          | <b>97.8</b>                | <b>97.7</b>                 | <b>97.7</b>                |
| <b>SD</b>                               | <b>0.393</b>               | <b>0.216</b>                | <b>0.194</b>               |
| <b>RSD%</b>                             | <b>0.41</b>                | <b>0.22</b>                 | <b>0.20</b>                |
| <b>Confidence Interval<br/>(CI 95%)</b> | <b>97.8 ± 0.30</b>         | <b>97.7 ± 0.20</b>          | <b>97.7 ± 0.20</b>         |

**Table S7.** Intermediate precision results of IBU, PSEH and CHL

| <b>Sample No</b>                        | <b>IBU (1)<br/>Assay %</b> | <b>PSEH (2)<br/>Assay %</b> | <b>CHL (3)<br/>Assay %</b> |
|---|----------------------------|-----------------------------|----------------------------|
| <b>1</b>                                | 97.3                       | 98.3                        | 98.2                       |
| <b>2</b>                                | 98.2                       | 97.9                        | 97.9                       |
| <b>3</b>                                | 97.7                       | 97.5                        | 97.6                       |
| <b>4</b>                                | 97.9                       | 97.7                        | 97.8                       |
| <b>5</b>                                | 97.8                       | 97.5                        | 97.5                       |
| <b>6</b>                                | 97.1                       | 97.9                        | 97.6                       |
| <b>Average</b>                          | <b>97.7</b>                | <b>97.8</b>                 | <b>97.8</b>                |
| <b>SD</b>                               | <b>0.40</b>                | <b>0.30</b>                 | <b>0.26</b>                |
| <b>RSD%</b>                             | <b>0.41</b>                | <b>0.31</b>                 | <b>0.26</b>                |
| <b>Confidence Interval<br/>(CI 95%)</b> | <b>97.7 ± 0.30</b>         | <b>97.8 ± 0.20</b>          | <b>97.8 ± 0.20</b>         |



**Table S8.** Comparison of repeatability and intermediate precision results of IBU, PSEH and CHL

|  | <b>Sample<br/>No</b> | <b>IBU (1)<br/>Assay %</b> | <b>PSEH (2)<br/>Assay %</b> | <b>CHL(3)<br/>Assay %</b> |
|--|----------------------|----------------------------|-----------------------------|---------------------------|
| <b>Repeatability<br/>(precision of the method)</b> | <b>1</b>             | 98.0                       | 97.7                        | 97.8                      |
|  | <b>2</b>             | 97.5                       | 97.6                        | 97.5                      |
|  | <b>3</b>             | 97.6                       | 97.6                        | 97.7                      |
|  | <b>4</b>             | 97.2                       | 98.0                        | 98.0                      |
|  | <b>5</b>             | 98.2                       | 97.5                        | 97.5                      |
|  | <b>6</b>             | 98.1                       | 98.0                        | 97.8                      |
| <b>Intermediate precision</b>                      | <b>1</b>             | 97.3                       | 98.3                        | 98.2                      |
|  | <b>2</b>             | 98.2                       | 97.9                        | 97.9                      |
|  | <b>3</b>             | 97.7                       | 97.5                        | 97.6                      |
|  | <b>4</b>             | 97.9                       | 97.7                        | 97.8                      |
|  | <b>5</b>             | 97.8                       | 97.5                        | 97.5                      |
|  | <b>6</b>             | 97.1                       | 97.9                        | 97.6                      |
| <b>Average</b>                                     |                      | <b>97.8</b>                | <b>97.7</b>                 | <b>97.7</b>               |
| <b>SD</b>  |                      | <b>0.25</b>                | <b>0.22</b>                 | <b>0.38</b>               |
| <b>RSD%</b>  |                      | <b>0.26</b>                | <b>0.22</b>                 | <b>0.39</b>               |
| <b>Confidence Interval<br/>(CI 95%)</b>            |                      | <b>97.8 ± 0.10</b>         | <b>97.7 ± 0.10</b>          | <b>97.7 ± 0.20</b>        |

**Table S9.** Comparison of robustness and repeatability test results – IBU (1)

| <b>Name of Analysis</b>  | <b>Assay %</b> | <b>Retention Time (min)</b> | <b>Symmetry Factor</b> |
|--------------------------|----------------|-----------------------------|------------------------|
| Repeatability            | 97.8           | 25.816                      | 1.1                    |
| Flow rate: 1.0 mL/min    | 98.1           | 27.956                      | 1.1                    |
| Flow rate: 1.4 mL/min    | 98.4           | 24.595                      | 1.2                    |
| Wavelength: 212 nm       | 97.3           | 25.679                      | 1.1                    |
| Wavelength: 216 nm       | 97.2           | 25.671                      | 1.1                    |
| Column Temperature: 48°C | 98.4           | 26.240                      | 1.3                    |
| Column Temperature: 52°C | 98.8           | 25.334                      | 1.3                    |

**Table S10.** Comparison of robustness and repeatability test results – PSEH (2)

| <b>Name of Analysis</b>  | <b>Assay %</b> | <b>Retention Time (min)</b> | <b>Symmetry Factor</b> |
|--------------------------|----------------|-----------------------------|------------------------|
| Repeatability            | 97.7           | 8.997                       | 0.9                    |
| Flow rate: 1.0 mL/min    | 97.3           | 10.965                      | 0.9                    |
| Flow rate: 1.4 mL/min    | 97.3           | 7.966                       | 1.1                    |
| Wavelength: 212 nm       | 97.3           | 9.151                       | 0.9                    |
| Wavelength: 216 nm       | 97.0           | 9.142                       | 0.9                    |
| Column Temperature: 48°C | 98.0           | 9.193                       | 1.2                    |
| Column Temperature: 52°C | 98.3           | 8.372                       | 1.1                    |

**Table S11.** Comparison of robustness and repeatability test results – CHL (3)

| <b>Name of Analysis</b>  | <b>Assay %</b> | <b>Retention Time (min)</b> | <b>Symmetry Factor</b> |
|--------------------------|----------------|-----------------------------|------------------------|
| Repeatability            | 97.7           | 19.980                      | 1.0                    |
| Flow rate: 1.0 mL/min    | 98.4           | 22.098                      | 1.0                    |
| Flow rate: 1.4 mL/min    | 97.5           | 18.287                      | 1.1                    |
| Wavelength: 212 nm       | 97.8           | 20.070                      | 1.0                    |
| Wavelength: 216 nm       | 98.1           | 20.061                      | 1.0                    |
| Column Temperature: 48°C | 98.3           | 19.856                      | 1.1                    |
| Column Temperature: 52°C | 98.4           | 18.852                      | 1.2                    |