

**RAW DATA OF**

**(INTERMEDIATE  
PRECISION)**

## RELATED SUBSTANCE VALIDATION

|                    |                                  |
|--------------------|----------------------------------|
| Product Name:      | Ramipril Tablets                 |
| Label claim (mg):  | 10 mg And 25 mg                  |
| AR No:             | 122404181193                     |
| Batch No.:         | GP180301                         |
| Parameter:         | Intermediate Precision (As Such) |
| L.NB No./ Page No. | 703/102                          |

Analysis Date: 27-Nov-18

|                     |       |
|---------------------|-------|
| Name                | RRF   |
| Ramipril Impurity A | 1.15  |
| Ramipril Impurity D | 1.21  |
| Ramipril Impurity E | 22.89 |

|                                               |                         |              |                      |                      |
|-----------------------------------------------|-------------------------|--------------|----------------------|----------------------|
| Preparation of standard solution for Ramipril | Weight of Standard (mg) | Diluted (mL) | Concentration (nmol) | Purity (As is Basis) |
|                                               | 25.46                   | 25.0         |                      |                      |
|                                               | 2.0                     | 100.0        | 2.04                 | 99.64                |
|                                               | 2.0                     | 20.0         |                      |                      |

| Injection No. | Retention Time | Peak Area | Retention Time | Area of IBA Standard |
|---------------|----------------|-----------|----------------|----------------------|
| 1             | 16.153         | 2465.087  | 16.066         | 2401.788             |
| 2             | 16.191         | 2227.525  | 16.109         | 2331.641             |
| 3             | 16.232         | 2305.521  |                |                      |
| 4             | 16.156         | 2248.426  |                |                      |
| 5             | 16.164         | 2276.692  |                |                      |
| 6             | 16.115         | 2310.580  |                |                      |
| Average       | 16.167         | 2395.385  | 16.147         | 2328.658             |
| SD            | 0.0364         | 84.4578   | 0.0493         | 79.8858              |
| %RSD          | 0.23           | 3.66      | 0.31           | 3.41                 |

|                    |      |
|--------------------|------|
| System Suitability |      |
| %RSD of Area       | 3.66 |
| NMT 5.0%           |      |

|                                                          |                         |              |                      |                      |
|----------------------------------------------------------|-------------------------|--------------|----------------------|----------------------|
| Preparation of standard solution for Hydrochlorothiazide | Weight of standard (mg) | Diluted (mL) | Concentration (nmol) | Purity (As is Basis) |
|                                                          | 25.59                   | 25.0         |                      |                      |
|                                                          | 2.5                     | 100.0        | 2.56                 | 99.24                |
|                                                          | 2.0                     | 20.0         |                      |                      |

| Injection No. | Retention Time | Peak Area | Retention Time | Area of IBA Standard |
|---------------|----------------|-----------|----------------|----------------------|
| 1             | 5.166          | 4380.832  | 5.106          | 4386.357             |
| 2             | 5.177          | 4451.909  | 5.129          | 4407.743             |
| 3             | 5.202          | 4419.675  |                |                      |
| 4             | 5.176          | 4335.516  |                |                      |
| 5             | 5.164          | 4382.866  |                |                      |
| 6             | 5.135          | 4409.777  |                |                      |
| Average       | 5.170          | 4446.766  | 5.157          | 4434.337             |
| SD            | 0.0218         | 55.2311   | 0.0311         | 52.2567              |
| %RSD          | 0.42           | 1.24      | 0.60           | 1.18                 |

|                    |      |
|--------------------|------|
| System Suitability |      |
| %RSD of Area       | 1.24 |
| NMT 5.0%           |      |

|                   |             |            |      |                 |
|-------------------|-------------|------------|------|-----------------|
| Sample solution : | Eq to 20 mg | diluted to | 20.0 | mL with Diluent |
|-------------------|-------------|------------|------|-----------------|

|                  |        |
|------------------|--------|
| Average wt. (mg) | 195.84 |
|------------------|--------|

| Sample Details | Sample wt. (mg) | Impurity name       | RT     | RRT  | Area       | %Impurity | Reported impurity | Total % Impurity |
|----------------|-----------------|---------------------|--------|------|------------|-----------|-------------------|------------------|
| Sample 1       | 391.84          | Unknown Impurity    | 4.095  | 0.26 | 340.361    | 0.03      | BQL               | 5.08             |
|                |                 | Unknown Impurity    | 7.868  | 0.50 | 152.133    | 0.01      | BQL               |                  |
|                |                 | Unknown Impurity    | 10.688 | 0.67 | 285.659    | 0.03      | BQL               |                  |
|                |                 | Unknown Impurity    | 17.702 | 1.12 | 380.212    | 0.03      | BQL               |                  |
|                |                 | Unknown Impurity    | 18.488 | 1.17 | 387.764    | 0.03      | BQL               |                  |
|                |                 | Ramipril Impurity E | 14.142 | 0.89 | 486.562    | 0.95      | 0.95              |                  |
|                |                 | Ramipril Impurity D | 23.902 | 1.51 | 38458.478  | 4.13      | 4.13              |                  |
|                |                 | Ramipril            | 15.855 | 1.00 | 757913.192 | -         | -                 |                  |
| Sample 2       | 391.70          | Unknown Impurity    | 4.111  | 0.26 | 301.293    | 0.03      | BQL               | 5.11             |
|                |                 | Unknown Impurity    | 7.938  | 0.50 | 134.163    | 0.01      | BQL               |                  |
|                |                 | Unknown Impurity    | 10.784 | 0.68 | 245.781    | 0.02      | BQL               |                  |
|                |                 | Unknown Impurity    | 17.704 | 1.11 | 427.536    | 0.04      | BQL               |                  |
|                |                 | Unknown Impurity    | 18.498 | 1.16 | 463.010    | 0.04      | BQL               |                  |
|                |                 | Ramipril Impurity E | 14.151 | 0.89 | 509.777    | 0.99      | 0.99              |                  |
|                |                 | Ramipril Impurity D | 23.904 | 1.50 | 38374.395  | 4.12      | 4.12              |                  |
|                |                 | Ramipril            | 15.898 | 1.00 | 775574.996 | -         | -                 |                  |
| Sample 3       | 391.40          | Unknown Impurity    | 4.112  | 0.26 | 313.886    | 0.03      | BQL               | 5.12             |
|                |                 | Unknown Impurity    | 7.945  | 0.50 | 185.921    | 0.02      | BQL               |                  |
|                |                 | Unknown Impurity    | 10.832 | 0.68 | 197.271    | 0.02      | BQL               |                  |
|                |                 | Unknown Impurity    | 17.705 | 1.11 | 411.055    | 0.04      | BQL               |                  |
|                |                 | Unknown Impurity    | 18.505 | 1.16 | 506.962    | 0.04      | BQL               |                  |
|                |                 | Ramipril Impurity E | 14.152 | 0.89 | 498.107    | 0.97      | 0.97              |                  |
|                |                 | Ramipril Impurity D | 23.912 | 1.50 | 38580.249  | 4.15      | 4.15              |                  |
|                |                 | Ramipril            | 15.899 | 1.00 | 780709.924 | -         | -                 |                  |
| Sample 4       | 391.54          | Unknown Impurity    | 4.116  | 0.26 | 308.719    | 0.03      | BQL               | 5.07             |
|                |                 | Unknown Impurity    | 7.942  | 0.50 | 167.903    | 0.01      | BQL               |                  |
|                |                 | Unknown Impurity    | 10.802 | 0.68 | 182.758    | 0.02      | BQL               |                  |
|                |                 | Unknown Impurity    | 17.702 | 1.11 | 407.329    | 0.04      | BQL               |                  |
|                |                 | Unknown Impurity    | 18.496 | 1.16 | 434.028    | 0.04      | BQL               |                  |
|                |                 | Ramipril Impurity E | 14.149 | 0.89 | 488.875    | 0.95      | 0.95              |                  |
|                |                 | Ramipril Impurity D | 23.909 | 1.51 | 38302.984  | 4.12      | 4.12              |                  |
|                |                 | Ramipril            | 15.882 | 1.00 | 777016.420 | -         | -                 |                  |
| Sample 5       | 391.42          | Unknown Impurity    | 4.108  | 0.26 | 276.705    | 0.02      | BQL               | 5.09             |
|                |                 | Unknown Impurity    | 7.894  | 0.50 | 164.511    | 0.01      | BQL               |                  |
|                |                 | Unknown Impurity    | 10.741 | 0.68 | 230.072    | 0.02      | BQL               |                  |
|                |                 | Unknown Impurity    | 17.701 | 1.12 | 405.091    | 0.04      | BQL               |                  |
|                |                 | Unknown Impurity    | 18.494 | 1.17 | 437.034    | 0.04      | BQL               |                  |
|                |                 | Ramipril Impurity E | 14.148 | 0.89 | 501.841    | 0.98      | 0.98              |                  |
|                |                 | Ramipril Impurity D | 23.894 | 1.51 | 38239.816  | 4.11      | 4.11              |                  |
|                |                 | Ramipril            | 15.868 | 1.00 | 774802.853 | -         | -                 |                  |
| Sample 6       | 391.38          | Unknown Impurity    | 4.101  | 0.26 | 205.116    | 0.02      | BQL               | 5.10             |
|                |                 | Unknown Impurity    | 7.887  | 0.50 | 156.283    | 0.01      | BQL               |                  |
|                |                 | Unknown Impurity    | 10.701 | 0.68 | 235.643    | 0.02      | BQL               |                  |
|                |                 | Unknown Impurity    | 17.707 | 1.12 | 406.775    | 0.04      | BQL               |                  |
|                |                 | Unknown Impurity    | 18.494 | 1.17 | 392.450    | 0.03      | BQL               |                  |
|                |                 | Ramipril Impurity E | 14.147 | 0.89 | 491.014    | 0.96      | 0.96              |                  |
|                |                 | Ramipril Impurity D | 23.888 | 1.51 | 38484.104  | 4.14      | 4.14              |                  |
|                |                 | Ramipril            | 15.847 | 1.00 | 779142.027 | -         | -                 |                  |

| Sample  | Ramipril Impurity E | Ramipril Impurity D | % Total Impurities |
|---------|---------------------|---------------------|--------------------|
| 1       | 0.95                | 4.13                | 5.08               |
| 2       | 0.99                | 4.12                | 5.11               |
| 3       | 0.97                | 4.15                | 5.12               |
| 4       | 0.95                | 4.12                | 5.07               |
| 5       | 0.98                | 4.11                | 5.09               |
| 6       | 0.96                | 4.14                | 5.10               |
| Average | 0.97                | 4.13                | 5.10               |
| SD      | 0.0200              | 0.0100              | 0.0200             |
| %RSD    | 2.06                | 0.24                | 0.39               |
| Limit   |                     | NMT 15 %            | NMT 10 %           |

Done by:

Date:

Checked by:

Date:

30-NOV-18



## RELATED SUBSTANCE VALIDATION

|                   |                                        |
|-------------------|----------------------------------------|
| Product Name:     | Ramipril Tablets                       |
| Label claim (mg): | 10 mg And 25 mg                        |
| AR No.:           | 02494181193                            |
| Batch No.:        | GP180301                               |
| Parameter:        | Intermediate Precision (Soaked Sample) |
| LNB No./ Page No. | 703/102                                |

Analysis Date: 27-Nov-18

|                     |       |
|---------------------|-------|
| Name                | RRF   |
| Ramipril Impurity A | 1.15  |
| Ramipril Impurity D | 1.22  |
| Ramipril Impurity E | 23.09 |

| Preparation of standard solution for Ramipril | Weight of standard (mg) | Diluted (mL) | Concentration (mg/mL) | Purity (As is Basis) |
|-----------------------------------------------|-------------------------|--------------|-----------------------|----------------------|
|                                               | 25.46                   | 25.0         |                       |                      |
|                                               | 2.0                     | 100.0        | 2.04                  | 99.64                |
|                                               | 2.0                     | 20.0         |                       |                      |

| Ramipril      |                |           |                |                      |
|---------------|----------------|-----------|----------------|----------------------|
| Injection No. | Retention Time | Peak Area | Retention Time | Area of Ikt Standard |
| 1             | 16.133         | 2465.987  | 16.106         | 4386.337             |
| 2             | 16.193         | 7227.525  | 16.109         | 2333.641             |
| 3             | 16.222         | 2303.521  |                |                      |
| 4             | 16.156         | 7248.436  |                |                      |
| 5             | 16.164         | 7276.692  |                |                      |
| 6             | 16.115         | 2310.580  |                |                      |
| Average       | 16.167         | 2385.385  | 16.117         | 2330.658             |
| SD            | 0.0364         | 84.4570   | 0.0493         | 79.0858              |
| %RSD          | 0.22           | 3.66      | 0.31           | 3.41                 |

| System Suitability |      |          |
|--------------------|------|----------|
| %RSD of Area       | 3.66 | NMT 5.0% |

| Preparation of standard solution for Hydrochlorothiazide | Weight of standard (mg) | Diluted (mL) | Concentration (mg/mL) | Purity (As is Basis) |
|----------------------------------------------------------|-------------------------|--------------|-----------------------|----------------------|
|                                                          | 25.50                   | 25.0         |                       |                      |
|                                                          | 2.5                     | 100.0        | 2.56                  | 99.24                |
|                                                          | 2.0                     | 20.0         |                       |                      |

| Hydrochlorothiazide |                |           |                |                      |
|---------------------|----------------|-----------|----------------|----------------------|
| Injection No.       | Retention Time | Peak Area | Retention Time | Area of Ikt Standard |
| 1                   | 5.105          | 4480.832  | 5.106          | 4386.337             |
| 2                   | 5.177          | 4451.909  | 5.129          | 4407.743             |
| 3                   | 5.202          | 4419.675  |                |                      |
| 4                   | 5.170          | 4535.536  |                |                      |
| 5                   | 5.164          | 4382.866  |                |                      |
| 6                   | 5.135          | 4409.777  |                |                      |
| Average             | 5.170          | 4448.766  | 5.157          | 4424.317             |
| SD                  | 0.0218         | 55.2311   | 0.0311         | 52.3507              |
| %RSD                | 0.41           | 1.24      | 0.60           | 1.18                 |

| System Suitability |      |          |
|--------------------|------|----------|
| %RSD of Area       | 1.24 | NMT 5.0% |

| Preparation of Ramipril Impurity A | Batch No.  | Weight of standard (mg) | Diluted (mL) | Concentration (mg/mL) |
|------------------------------------|------------|-------------------------|--------------|-----------------------|
|                                    | SP-023-144 | 2.50                    | 10.0         | 250.00                |

|                   |             |            |      |                 |
|-------------------|-------------|------------|------|-----------------|
| Sample solution:  | 10 to 20 mg | diluted to | 20.0 | mL with Diluent |
| Average wt. (mg): | 195.84      |            |      |                 |

| Sample Details | Sample wt. (mg) | Impurity name       | RT     | RRT  | Area       | %Impurity | Reported impurity | Total % Impurity |
|----------------|-----------------|---------------------|--------|------|------------|-----------|-------------------|------------------|
| Sample 1       | 391.40          | Unknown Impurity    | 4.086  | 0.26 | 305.586    | 0.03      | BQL               | 1.41             |
|                |                 | Unknown Impurity    | 7.839  | 0.50 | 163.970    | 0.01      | BQL               |                  |
|                |                 | Unknown Impurity    | 10.606 | 0.67 | 277.314    | 0.02      | BQL               |                  |
|                |                 | Unknown Impurity    | 17.712 | 1.12 | 407.102    | 0.04      | BQL               |                  |
|                |                 | Unknown Impurity    | 18.499 | 1.17 | 394.555    | 0.03      | BQL               |                  |
|                |                 | Ramipril Impurity E | 14.146 | 0.89 | 338.305    | 0.06      | -                 |                  |
|                |                 | Ramipril Impurity A | 14.626 | 0.92 | 13885.160  | 1.41      | 1.41              |                  |
|                |                 | Ramipril Impurity D | 23.892 | 1.51 | 37699.615  | 4.05      | -                 |                  |
|                |                 | Ramipril            | 15.826 | 1.00 | 769283.339 | -         | -                 |                  |
|                |                 | Unknown Impurity    | 4.074  | 0.26 | 289.442    | 0.03      | BQL               |                  |
| Sample 2       | 391.13          | Unknown Impurity    | 7.808  | 0.49 | 152.576    | 0.01      | BQL               | 1.40             |
|                |                 | Unknown Impurity    | 10.568 | 0.67 | 251.437    | 0.02      | BQL               |                  |
|                |                 | Unknown Impurity    | 17.714 | 1.12 | 402.559    | 0.04      | BQL               |                  |
|                |                 | Unknown Impurity    | 18.501 | 1.17 | 450.353    | 0.04      | BQL               |                  |
|                |                 | Ramipril Impurity E | 14.141 | 0.89 | 326.549    | 0.04      | -                 |                  |
|                |                 | Ramipril Impurity A | 14.608 | 0.92 | 13809.477  | 1.40      | 1.40              |                  |
|                |                 | Ramipril Impurity D | 23.888 | 1.51 | 37713.929  | 4.06      | -                 |                  |
|                |                 | Ramipril            | 15.808 | 1.00 | 767628.372 | -         | -                 |                  |
|                |                 | Unknown Impurity    | 4.079  | 0.26 | 262.011    | 0.02      | BQL               |                  |
|                |                 | Unknown Impurity    | 7.806  | 0.49 | 139.538    | 0.01      | BQL               |                  |
| Sample 3       | 391.35          | Unknown Impurity    | 10.566 | 0.67 | 258.169    | 0.02      | BQL               | 1.40             |
|                |                 | Unknown Impurity    | 17.726 | 1.12 | 410.204    | 0.04      | BQL               |                  |
|                |                 | Unknown Impurity    | 18.512 | 1.17 | 406.756    | 0.04      | BQL               |                  |
|                |                 | Ramipril Impurity E | 14.146 | 0.89 | 317.647    | 0.02      | -                 |                  |
|                |                 | Ramipril Impurity A | 14.606 | 0.92 | 13847.524  | 1.40      | 1.40              |                  |
|                |                 | Ramipril Impurity D | 23.906 | 1.51 | 37568.801  | 4.04      | -                 |                  |
|                |                 | Ramipril            | 15.806 | 1.00 | 768500.896 | -         | -                 |                  |
|                |                 | Unknown Impurity    | 4.082  | 0.26 | 264.165    | 0.02      | BQL               |                  |
|                |                 | Unknown Impurity    | 7.815  | 0.49 | 138.533    | 0.01      | BQL               |                  |
|                |                 | Unknown Impurity    | 10.575 | 0.67 | 265.322    | 0.02      | BQL               |                  |
| Sample 4       | 391.06          | Unknown Impurity    | 17.728 | 1.12 | 404.330    | 0.04      | BQL               | 1.41             |
|                |                 | Unknown Impurity    | 18.515 | 1.17 | 463.851    | 0.04      | BQL               |                  |
|                |                 | Ramipril Impurity E | 14.148 | 0.89 | 322.235    | 0.03      | -                 |                  |
|                |                 | Ramipril Impurity A | 14.615 | 0.92 | 13918.926  | 1.41      | 1.41              |                  |
|                |                 | Ramipril Impurity D | 23.915 | 1.51 | 37720.246  | 4.06      | -                 |                  |
|                |                 | Ramipril            | 15.815 | 1.00 | 767659.465 | -         | -                 |                  |
|                |                 | Unknown Impurity    | 4.112  | 0.26 | 322.459    | 0.03      | BQL               |                  |
|                |                 | Unknown Impurity    | 7.959  | 0.50 | 162.639    | 0.01      | BQL               |                  |
|                |                 | Unknown Impurity    | 10.865 | 0.68 | 167.724    | 0.01      | BQL               |                  |
|                |                 | Unknown Impurity    | 17.719 | 1.11 | 427.310    | 0.04      | BQL               |                  |
| Sample 5       | 391.46          | Unknown Impurity    | 18.532 | 1.16 | 636.125    | 0.06      | BQL               | 1.42             |
|                |                 | Ramipril Impurity E | 14.165 | 0.89 | 403.886    | 0.79      | -                 |                  |
|                |                 | Ramipril Impurity A | 14.732 | 0.92 | 13979.825  | 1.42      | 1.42              |                  |
|                |                 | Ramipril Impurity D | 23.979 | 1.50 | 38654.979  | 4.15      | -                 |                  |
|                |                 | Ramipril            | 15.932 | 1.00 | 789105.148 | -         | -                 |                  |
|                |                 | Unknown Impurity    | 4.106  | 0.26 | 645.299    | 0.06      | BQL               |                  |
|                |                 | Unknown Impurity    | 8.013  | 0.50 | 135.890    | 0.01      | BQL               |                  |
|                |                 | Unknown Impurity    | 10.926 | 0.69 | 112.735    | 0.01      | BQL               |                  |
|                |                 | Unknown Impurity    | 17.700 | 1.11 | 423.115    | 0.04      | BQL               |                  |
|                |                 | Unknown Impurity    | 18.505 | 1.16 | 486.654    | 0.04      | BQL               |                  |
| Sample 6       | 391.33          | Ramipril Impurity E | 14.153 | 0.89 | 401.431    | 0.78      | -                 | 1.40             |
|                |                 | Ramipril Impurity A | 14.706 | 0.92 | 13993.643  | 1.40      | 1.40              |                  |
|                |                 | Ramipril Impurity D | 23.966 | 1.50 | 37751.950  | 4.06      | -                 |                  |
|                |                 | Ramipril            | 15.920 | 1.00 | 789181.907 | -         | -                 |                  |
|                |                 | Unknown Impurity    | 4.106  | 0.26 | 645.299    | 0.06      | BQL               |                  |
|                |                 | Unknown Impurity    | 8.013  | 0.50 | 135.890    | 0.01      | BQL               |                  |

| Sample  | Ramipril Impurity A | % Total Impurities |
|---------|---------------------|--------------------|
| 1       | 1.41                | 1.41               |
| 2       | 1.40                | 1.40               |
| 3       | 1.40                | 1.40               |
| 4       | 1.41                | 1.41               |
| 5       | 1.42                | 1.42               |
| 6       | 1.40                | 1.40               |
| Average | 1.41                | 1.41               |
| SD      | 0.0106              | 0.0106             |
| %RSD    | 0.71                | 0.71               |
| Limit   | NMT 10 %            | NMT 15 %           |

Done by:

Date:

Checked by:

Date:

Ravi  
30-Nov-18

RELATED SUBSTANCE VALIDATION

|                   |                                                      |
|-------------------|------------------------------------------------------|
| Product Name:     | Ramithiazide Tablets                                 |
| Label claim (mg): | 10 mg And 25 mg                                      |
| AR No:            | D2404181193                                          |
| Batch No.:        | GPI80301                                             |
| Parameter:        | Method Precision & Intermediate Precision Comparison |
| LNB No./ Page No. | 703/102                                              |

Analysis Date: 27-Nov-18

| Sample (As Such)       | Ramipril Impurity E | Ramipril Impurity D | % Total Impurities |
|------------------------|---------------------|---------------------|--------------------|
| Precision              | 0.85                | 4.47                | 5.32               |
| Intermediate precision | 0.97                | 4.13                | 5.10               |
| % Difference           | 0.12                | 0.34                | 0.22               |

| Sample (Spiked)        | Ramipril Impurity A | % Total Impurities |
|------------------------|---------------------|--------------------|
| Precision              | 1.12                | 1.12               |
| Intermediate precision | 1.41                | 1.41               |
| % Difference           | 0.29                | 0.29               |

Done by:   
Date: 30-Nov-18

Checked by:   
Date: 30-Nov-18





# QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

Instrument ID :

QbD-INST-HPLC-05

Sequence Name :

HPLC-05\_27-Nov-18\_A1

Data Vault :

QbD\_2018

Seq. Created By : Gauri Rane

Seq. Last Updated By :

Gauri Rane

Seq. Created On : 26-11-2018 15:27:17

Seq. Last Updated On

27-11-2018 16:04:01

Sequence Path :

Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05\_27-Nov-18\_A1.seq

| Inj No. | Injection Name               | Injection Type | Volume µL | Vial No. | Status | Injection Time | Instrument Method        | Processing Method   | Level | AR_NO       | BATCH_NO | COLUMN_NO      |
|---------|------------------------------|----------------|-----------|----------|--------|----------------|--------------------------|---------------------|-------|-------------|----------|----------------|
| 1       | Blank Solution               | Unknown        | 30.00     | Vial:1   | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR  |       | D2404181193 | N/A      | QbD/LC/COL/128 |
| 2       | Blank Solution               | Unknown        | 30.00     | Vial:1   | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR  |       | D2404181193 | N/A      | QbD/LC/COL/128 |
| 3       | Placebo Solution             | Unknown        | 30.00     | Vial:3   | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR1 |       | D2404181193 | N/A      | QbD/LC/COL/128 |
| 4       | Standard Solution 1          | Unknown        | 30.00     | Vial:2   | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR2 |       | D2404181193 | N/A      | QbD/LC/COL/128 |
| 5       | Standard Solution 2          | Unknown        | 30.00     | Vial:2   | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR2 |       | D2404181193 | N/A      | QbD/LC/COL/128 |
| 6       | Standard Solution 3          | Unknown        | 30.00     | Vial:2   | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR2 |       | D2404181193 | N/A      | QbD/LC/COL/128 |
| 7       | Standard Solution 4          | Unknown        | 30.00     | Vial:2   | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR2 |       | D2404181193 | N/A      | QbD/LC/COL/128 |
| 8       | Standard Solution 5          | Unknown        | 30.00     | Vial:2   | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR2 |       | D2404181193 | N/A      | QbD/LC/COL/128 |
| 9       | Standard Solution 6          | Unknown        | 30.00     | Vial:2   | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR2 |       | D2404181193 | N/A      | QbD/LC/COL/128 |
| 10      | Sample Solution 1            | Unknown        | 30.00     | Vial:4   | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       | D2404181193 | GP180301 | QbD/LC/COL/128 |
| 11      | Sample Solution 2            | Unknown        | 30.00     | Vial:5   | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       | D2404181193 | GP180301 | QbD/LC/COL/128 |
| 12      | Sample Solution 3            | Unknown        | 30.00     | Vial:6   | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       | D2404181193 | GP180301 | QbD/LC/COL/128 |
| 13      | Sample Solution 4            | Unknown        | 30.00     | Vial:7   | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       | D2404181193 | GP180301 | QbD/LC/COL/128 |
| 14      | Sample Solution 5            | Unknown        | 30.00     | Vial:8   | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       | D2404181193 | GP180301 | QbD/LC/COL/128 |
| 15      | Sample Solution 6            | Unknown        | 30.00     | Vial:9   | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       | D2404181193 | GP180301 | QbD/LC/COL/128 |
| 16      | Blank Solution               | Unknown        | 30.00     | Vial:1   | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR  |       | D2404181193 | N/A      | QbD/LC/COL/128 |
| 17      | Bracketing Standard Solution | Unknown        | 30.00     | Vial:2   | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR2 |       | D2404181193 | N/A      | QbD/LC/COL/128 |
| 18      | Spiked Sample Solution 1     | Unknown        | 30.00     | Vial:10  | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       | D2404181193 | GP180301 | QbD/LC/COL/128 |
| 19      | Spiked Sample Solution 2     | Unknown        | 30.00     | Vial:11  | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       | D2404181193 | GP180301 | QbD/LC/COL/128 |
| 20      | Spiked Sample Solution 3     | Unknown        | 30.00     | Vial:12  | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       | D2404181193 | GP180301 | QbD/LC/COL/128 |
| 21      | Spiked Sample Solution 4     | Unknown        | 30.00     | Vial:13  | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       | D2404181193 | GP180301 | QbD/LC/COL/128 |
| 22      | Spiked Sample Solution 5     | Unknown        | 30.00     | Vial:14  | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       | D2404181193 | GP180301 | QbD/LC/COL/128 |
| 23      | Spiked Sample Solution 6     | Unknown        | 30.00     | Vial:15  | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       | D2404181193 | GP180301 | QbD/LC/COL/128 |
| 24      | Blank Solution               | Unknown        | 30.00     | Vial:1   | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR  |       | D2404181193 | N/A      | QbD/LC/COL/128 |
| 25      | Bracketing Standard Solution | Unknown        | 30.00     | Vial:2   | Idle   | n.a.           | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR2 |       | D2404181193 | N/A      | QbD/LC/COL/128 |
| 26      | Shut                         | Unknown        | 30.00     | Vial:1   | Idle   | n.a.           | Shut method _HPLC 05 new | Ramithiazide_RS_PR  |       | D2404181193 | N/A      | QbD/LC/COL/128 |

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n.a.



|             |                                                                                                                     |
|-------------|---------------------------------------------------------------------------------------------------------------------|
| Name        | HPLC-05_Ramithiazide Tablet_RS_Met                                                                                  |
| Data Vault  | XVault                                                                                                              |
| Path        | chrom://qbd-pc-16/XVault/QbD-INST-HPLC-05/1198/HPLC-05_27-Nov-18_A1.seq/HPLC-05_Ramithiazide Tablet_RS_Met.instmeth |
| Comment     | Ramithiazide Tablet                                                                                                 |
| Description | Ramithiazide Tablet instrument method created                                                                       |
| Run time    | 30.000 [min]                                                                                                        |
| Instrument  | QbD-INST-HPLC-05 on qbd-pc-16                                                                                       |
| Created     | 26-Nov-18 15:21:29 +05:30 Gauri Rane                                                                                |
| Last Update | 26-Nov-18 15:21:29 +05:30 Gauri Rane                                                                                |

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| Stage              | Time<br>min | Command                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                | Value                   | Comment |
|--------------------|-------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-------------------------|---------|
| Instrument Setup   | initial     |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                         |         |
| Inject Preparation | 0.000       | Wait                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   | LCSystem.Ready          |         |
| Inject             | 0.000       | LCSystem.ALS.Inject                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                    | Blank=Inject            |         |
| Start Run          | 0.000       | LCSystem.ALS_Temperature.AcqOn<br>LCSystem.DAD_Board_Temperature.AcqOn<br>LCSystem.DAD_OpticalUnit_Temp.AcqOn<br>LCSystem.DAD_UVLamp_AnodeVoltage.AcqOn<br>LCSystem.QuatPump_Dir_PistonA.AcqOn<br>LCSystem.QuatPump_Flow.AcqOn<br>LCSystem.QuatPump_Pressure.AcqOn<br>LCSystem.QuatPump_SolventRatioA.AcqOn<br>LCSystem.QuatPump_SolventRatioB.AcqOn<br>LCSystem.QuatPump_SolventRatioC.AcqOn<br>LCSystem.QuatPump_SolventRatioD.AcqOn<br>LCSystem.TCC_Left_Temperature.AcqOn<br>LCSystem.TCC_Right_Temperature.AcqOn<br><br>LCSystem.DAD_Signal_A.AcqOn<br>LCSystem.DAD_Spectra.AcqOn |                         |         |
| Run                |             |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        | Duration = 30.000 [min] |         |
| Stop Run           | 0.000       |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |                         |         |
|                    | 30.000      | LCSystem.ALS_Temperature.AcqOff<br>LCSystem.DAD_Board_Temperature.AcqOff<br>LCSystem.DAD_OpticalUnit_Temp.AcqOff<br>LCSystem.DAD_UVLamp_AnodeVoltage.AcqOff<br>LCSystem.QuatPump_Dir_PistonA.AcqOff<br>LCSystem.QuatPump_Flow.AcqOff<br>LCSystem.QuatPump_Pressure.AcqOff<br>LCSystem.QuatPump_SolventRatioA.AcqOff<br>LCSystem.QuatPump_SolventRatioB.AcqOff                                                                                                                                                                                                                          |                         |         |

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LCSystem.QuatPump\_SolventRatioC.AcqOff  
LCSystem.QuatPump\_SolventRatioD.AcqOff  
LCSystem.TCC\_Left\_Temperature.AcqOff  
LCSystem.TCC\_Right\_Temperature.AcqOff  
  
LCSystem.DAD\_Signal\_A.AcqOff  
LCSystem.DAD\_Spectra.AcqOff

End

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| Property                                               | Value                          |
|--------------------------------------------------------|--------------------------------|
| Settings for module Quat. Pump (G1311C - Pump: PUMP.0) |                                |
| Flow                                                   | 1.000 [mL/min]                 |
| Low Pressure Limit                                     | 0.00 [bar]                     |
| High Pressure Limit                                    | 400.00 [bar]                   |
| Maximum Flow Gradient                                  | 100.000 [mL/min <sup>2</sup> ] |
| Primary Channel                                        | Automatic                      |
| Section Stroke (StrokeA)                               |                                |
| Automatic Stroke Calculation                           | Yes                            |
| Section Compress (CompressA)                           |                                |
| Compressibility Mode                                   | Compressibility Value Set      |
| Compressibility                                        | 100 [10e-6/bar]                |
| Section Stop Time (StopTime)                           |                                |
| Stoptime Mode                                          | Time set                       |
| Stoptime                                               | 30.00 [min]                    |
| Section Post Time (PostTime)                           |                                |
| Posttime Mode                                          | Off                            |
| Solvent Composition (SolventComposition)               |                                |
| 0                                                      |                                |
| Channel                                                | A                              |
| Name 1                                                 | Mobile Phase A                 |
| Used                                                   | Yes                            |
| Percent                                                | 70.0 [%]                       |
| 1                                                      |                                |
| Channel                                                | B                              |
| Name 1                                                 | Mobile Phase B                 |
| Used                                                   | Yes                            |
| Percent                                                | 30.0 [%]                       |
| 2                                                      |                                |
| Channel                                                | C                              |
| Name 1                                                 |                                |
| Used                                                   | No                             |
| 3                                                      |                                |
| Channel                                                | D                              |
| Name 1                                                 |                                |
| Used                                                   | No                             |
| Timetable (Timetable)                                  |                                |
| 0                                                      |                                |
| Time                                                   | 7.00 [min]                     |
| A                                                      | 70.0 [%]                       |
| B                                                      | 30.0 [%]                       |
| C                                                      | 0.0 [%]                        |
| D                                                      | 0.0 [%]                        |
| Flow                                                   | 1.000 [mL/min]                 |
| Pressure                                               | 400.00 [bar]                   |
| 1                                                      |                                |
| Time                                                   | 9.00 [min]                     |
| A                                                      | 50.0 [%]                       |
| B                                                      | 50.0 [%]                       |
| C                                                      | 0.0 [%]                        |

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|          |                |
|----------|----------------|
| D        | 0.0 [%]        |
| Flow     | 1.000 [mL/min] |
| Pressure | 400.00 [bar]   |
| 2        |                |
| Time     | 25.00 [min]    |
| A        | 50.0 [%]       |
| B        | 50.0 [%]       |
| C        | 0.0 [%]        |
| D        | 0.0 [%]        |
| Flow     | 1.000 [mL/min] |
| Pressure | 400.00 [bar]   |
| 3        |                |
| Time     | 30.00 [min]    |
| A        | 70.0 [%]       |
| B        | 30.0 [%]       |
| C        | 0.0 [%]        |
| D        | 0.0 [%]        |
| Flow     | 1.000 [mL/min] |
| Pressure | 400.00 [bar]   |

Settings for module Sampler (G1329B -  
Sampler: SAMPLER.0)

|                                                                      |                                         |
|----------------------------------------------------------------------|-----------------------------------------|
| Section Auxiliary (Auxiliary)                                        |                                         |
| Draw Speed                                                           | 200 [µL/min]                            |
| Eject Speed                                                          | 200 [µL/min]                            |
| Draw Position Offset                                                 | 0.0 [mm]                                |
| Section Injection (Injection)                                        |                                         |
| Injection Mode                                                       | Injection with needle<br>wash           |
| Injection Volume                                                     | 30.00 [µL]                              |
| Section Needle Wash<br>(Injection_NeedleWash)                        |                                         |
| Needle Wash Location                                                 | Wash Vial                               |
| Wash Location                                                        | Vial 100                                |
| Section High throughput (HighThroughput)                             |                                         |
| Section Overlapped Injection<br>(HighThroughput_OverlappedInjection) |                                         |
| Enable Overlapped Injection                                          | No                                      |
| Section Thermostat (Thermostat)                                      |                                         |
| Not Ready Temperature Mode                                           | Enable Analysis With Any<br>Temperature |
| Thermostat Control                                                   | Thermostat Control Set<br>Value         |
| Thermostat Temperature                                               | 25 [°C]                                 |
| Section Stop Time (StopTime)                                         |                                         |
| Stoptime Mode                                                        | As pump/No limit                        |
| Section Post Time (PostTime)                                         |                                         |
| Posttime Mode                                                        | Off                                     |
| Section Timetable (Timetable)                                        |                                         |
| Timetable (Timetable_TimetableEntry)                                 |                                         |

Settings for module Column Comp. (G1316A -  
Column Comp.: COLCOMP.0)

Section Left Temperature Control  
(LeftTemperatureControl)

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|                                                                                      |                                        |
|--------------------------------------------------------------------------------------|----------------------------------------|
| Temperature Control Mode                                                             | Not Controlled                         |
| Section Enable Analysis Left Temperature<br>(LeftTemperatureControl_NotReadyLimit)   |                                        |
| Enable Analysis Left Temperature On                                                  | Yes                                    |
| Value Enable Analysis Left Temperature                                               | 0.80 [°C]                              |
| Section Right Temperature Control<br>(RightTemperatureControl)                       |                                        |
| Right temperature Control Mode                                                       | Combined                               |
| Section Enable Analysis Right Temperature<br>(RightTemperatureControl_NotReadyLimit) |                                        |
| On Enable Analysis Right Temperature                                                 | Yes                                    |
| Value Enable Analysis Right Temperature                                              | 0.80 [°C]                              |
| Section Stop Time (StopTime)                                                         |                                        |
| Stoptime Mode                                                                        | As pump/injector                       |
| Section Post Time (PostTime)                                                         |                                        |
| Posttime Mode                                                                        | Off                                    |
| Section Timetable (Timetable)                                                        |                                        |
| Timetable (Timetable_TimetableEntry)                                                 |                                        |
| Settings for module DAD (G4212B - DAD: DAD.0)                                        |                                        |
| Peakwidth                                                                            | > 0.1 min (2 s response time) (2.5 Hz) |
| UV Lamp Required                                                                     | Yes                                    |
| Section Analog Output 1 (AnalogOutput1)                                              |                                        |
| Analog 1 Zero Offset                                                                 | 5 [%]                                  |
| Analog 1 Attenuation                                                                 | 1000 [mAU]                             |
| Section Signals (Signals)                                                            |                                        |
| Signal table (Signals_Signal)                                                        |                                        |
| 0                                                                                    |                                        |
| Use Sig.                                                                             | Yes                                    |
| Signal                                                                               | Signal A                               |
| Wavelength                                                                           | 210.0 [nm]                             |
| Bandwidth                                                                            | 4.0 [nm]                               |
| Use Ref.                                                                             | No                                     |
| 1                                                                                    |                                        |
| Use Sig.                                                                             | No                                     |
| Signal                                                                               | Signal B                               |
| 2                                                                                    |                                        |
| Use Sig.                                                                             | No                                     |
| Signal                                                                               | Signal C                               |
| 3                                                                                    |                                        |
| Use Sig.                                                                             | No                                     |
| Signal                                                                               | Signal D                               |
| 4                                                                                    |                                        |
| Use Sig.                                                                             | No                                     |
| Signal                                                                               | Signal E                               |
| 5                                                                                    |                                        |
| Use Sig.                                                                             | No                                     |

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|                                         |                  |
|-----------------------------------------|------------------|
| Signal                                  | Signal F         |
| 6                                       |                  |
| Use Sig.                                | No               |
| Signal                                  | Signal G         |
| 7                                       |                  |
| Use Sig.                                | No               |
| Signal                                  | Signal H         |
| Section Prepare Mode (PrepareMode)      |                  |
| Margin for negative Absorbance          | 100 [mAU]        |
| Section Autobalance (PrepareAutomation) |                  |
| Autobalance Prerun                      | Yes              |
| Autobalance Postrun                     | No               |
| Section Spectrum (SpectraAcquisition)   |                  |
| Spectrum Range WL from                  | 190.0 [nm]       |
| Spectrum Range WL to                    | 400.0 [nm]       |
| Spectrum Step                           | 2.0 [nm]         |
| Spectrum Store                          | All              |
| Section Stoptime (StopTime)             |                  |
| Stoptime Mode                           | As pump/injector |
| Section Posttime (PostTime)             |                  |
| Posttime Mode                           | Off              |
| Section Timetable (Timetable)           |                  |
| Timetable (Timetable_TimetableEntry)    |                  |

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| Property                                                                        | Value |
|---------------------------------------------------------------------------------|-------|
| Settings for module Sampler (G1329B -<br>Pretreatment (PretreatmentInstruction) |       |

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## QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

**Instrument ID :** QbD-INST-HPLC-05  
**Sequence Name :** HPLC-05\_27-Nov-18\_A1  
**Data Vault :** QbD\_2018  
**Sequence Path :** Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05\_27-Nov-18\_A1.seq

**Seq. Created By :** Gauri Rane  
**Seq. Created On :** 26-11-2018 15:27:17

| Inj No. | Injection Name               | Injection Type | Volume µL | Vial No. | Status   | Injection Time      | Instrument Method        | Processing Method   | Level |
|---------|------------------------------|----------------|-----------|----------|----------|---------------------|--------------------------|---------------------|-------|
| 1       | Blank Solution               | Unknown        | 30.00     | Vial:1   | Finished | 27-11-2018 16:07:44 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR  |       |
| 2       | Blank Solution               | Unknown        | 30.00     | Vial:1   | Finished | 27-11-2018 16:39:41 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR  |       |
| 3       | Placebo Solution             | Unknown        | 30.00     | Vial:3   | Finished | 27-11-2018 17:32:56 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR1 |       |
| 4       | Standard Solution 1          | Unknown        | 30.00     | Vial:2   | Finished | 27-11-2018 18:04:54 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR2 |       |
| 5       | Standard Solution 2          | Unknown        | 30.00     | Vial:2   | Finished | 27-11-2018 18:36:58 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR2 |       |
| 6       | Standard Solution 3          | Unknown        | 30.00     | Vial:2   | Finished | 27-11-2018 19:08:56 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR2 |       |
| 7       | Standard Solution 4          | Unknown        | 30.00     | Vial:2   | Finished | 27-11-2018 19:40:53 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR2 |       |
| 8       | Standard Solution 5          | Unknown        | 30.00     | Vial:2   | Finished | 27-11-2018 20:12:51 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR2 |       |
| 9       | Standard Solution 6          | Unknown        | 30.00     | Vial:2   | Finished | 27-11-2018 20:44:48 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR2 |       |
| 10      | Sample Solution 1            | Unknown        | 30.00     | Vial:4   | Finished | 27-11-2018 21:16:42 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       |
| 11      | Sample Solution 2            | Unknown        | 30.00     | Vial:5   | Finished | 27-11-2018 21:48:37 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       |
| 12      | Sample Solution 3            | Unknown        | 30.00     | Vial:6   | Finished | 27-11-2018 22:20:35 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       |
| 13      | Sample Solution 4            | Unknown        | 30.00     | Vial:7   | Finished | 27-11-2018 22:52:28 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       |
| 14      | Sample Solution 5            | Unknown        | 30.00     | Vial:8   | Finished | 27-11-2018 23:24:21 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       |
| 15      | Sample Solution 6            | Unknown        | 30.00     | Vial:9   | Finished | 27-11-2018 23:56:15 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       |
| 16      | Blank Solution               | Unknown        | 30.00     | Vial:1   | Finished | 28-11-2018 00:28:09 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR  |       |
| 17      | Bracketing Standard Solution | Unknown        | 30.00     | Vial:2   | Finished | 28-11-2018 01:00:05 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR2 |       |
| 18      | Spiked Sample Solution 1     | Unknown        | 30.00     | Vial:10  | Finished | 28-11-2018 01:32:03 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       |
| 19      | Spiked Sample Solution 2     | Unknown        | 30.00     | Vial:11  | Finished | 28-11-2018 02:04:02 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       |
| 20      | Spiked Sample Solution 3     | Unknown        | 30.00     | Vial:12  | Finished | 28-11-2018 02:35:57 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       |
| 21      | Spiked Sample Solution 4     | Unknown        | 30.00     | Vial:13  | Finished | 28-11-2018 03:07:52 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       |
| 22      | Spiked Sample Solution 5     | Unknown        | 30.00     | Vial:14  | Finished | 28-11-2018 03:39:48 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       |
| 23      | Spiked Sample Solution 6     | Unknown        | 30.00     | Vial:15  | Finished | 28-11-2018 04:11:43 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR3 |       |
| 24      | Blank Solution               | Unknown        | 30.00     | Vial:1   | Finished | 28-11-2018 04:43:39 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR  |       |
| 25      | Bracketing Standard Solution | Unknown        | 30.00     | Vial:2   | Finished | 28-11-2018 05:15:39 | 05_Ramithiazide Tablet_R | Ramithiazide_RS_PR2 |       |
| 26      | Shut                         | Unknown        | 30.00     | Vial:1   | Finished | 28-11-2018 05:46:53 | Shut method_HPLC 05 nev  | Ramithiazide_RS_PR  |       |



**Seq. Last Updated By :** Gauri Rane  
**Seq. Last Updated On :** 30-11-2018 17:05:57

| AR_NO       | BATCH_NO | COLUMN_NO      |
|-------------|----------|----------------|
| D2404181193 | N/A      | QbD/LC/COL/128 |
| D2404181193 | N/A      | QbD/LC/COL/128 |
| D2404181193 | N/A      | QbD/LC/COL/128 |
| D2404181193 | N/A      | QbD/LC/COL/128 |
| D2404181193 | N/A      | QbD/LC/COL/128 |
| D2404181193 | N/A      | QbD/LC/COL/128 |
| D2404181193 | N/A      | QbD/LC/COL/128 |
| D2404181193 | N/A      | QbD/LC/COL/128 |
| D2404181193 | N/A      | QbD/LC/COL/128 |
| D2404181193 | N/A      | QbD/LC/COL/128 |
| D2404181193 | GP180301 | QbD/LC/COL/128 |
| D2404181193 | GP180301 | QbD/LC/COL/128 |
| D2404181193 | GP180301 | QbD/LC/COL/128 |
| D2404181193 | GP180301 | QbD/LC/COL/128 |
| D2404181193 | GP180301 | QbD/LC/COL/128 |
| D2404181193 | GP180301 | QbD/LC/COL/128 |
| D2404181193 | N/A      | QbD/LC/COL/128 |
| D2404181193 | N/A      | QbD/LC/COL/128 |
| D2404181193 | GP180301 | QbD/LC/COL/128 |
| D2404181193 | GP180301 | QbD/LC/COL/128 |
| D2404181193 | GP180301 | QbD/LC/COL/128 |
| D2404181193 | GP180301 | QbD/LC/COL/128 |
| D2404181193 | GP180301 | QbD/LC/COL/128 |
| D2404181193 | GP180301 | QbD/LC/COL/128 |
| D2404181193 | GP180301 | QbD/LC/COL/128 |
| D2404181193 | N/A      | QbD/LC/COL/128 |
| D2404181193 | N/A      | QbD/LC/COL/128 |
| D2404181193 | N/A      | QbD/LC/COL/128 |



**QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.****Processing Method**

**Processing Method Name :** Ramithiazide\_RS\_PR  
**Processing Method Path :** Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05\_27-Nov-18\_A1.seq  
**Processing Method Created By :** Gauri Rane  
**Processing Method Created On :** 26-11-2018 15:33:18  
**Processing Method Last Updated By :** Gauri Rane  
**Processing Method Last Updated On :** 27-11-2018 11:11:44

|                     |              |         |   |
|---------------------|--------------|---------|---|
| Detection Alogrithm | Chromeleon 6 | Version | 1 |
|---------------------|--------------|---------|---|

**Detection Parameter**

| Ret. Time<br>min | Param. Name    | Param. Value         | Inj. Type | Channel      |
|------------------|----------------|----------------------|-----------|--------------|
| 0.000            | Minimum Area   | 50.0000 [Signal*min] | Any       | All Channels |
| 0.000            | Minimum Height | 2000.000 [Signal]    | Any       | All Channels |
| 0.000            | Minimum Width  | 1.000 [min]          | Any       | All Channels |

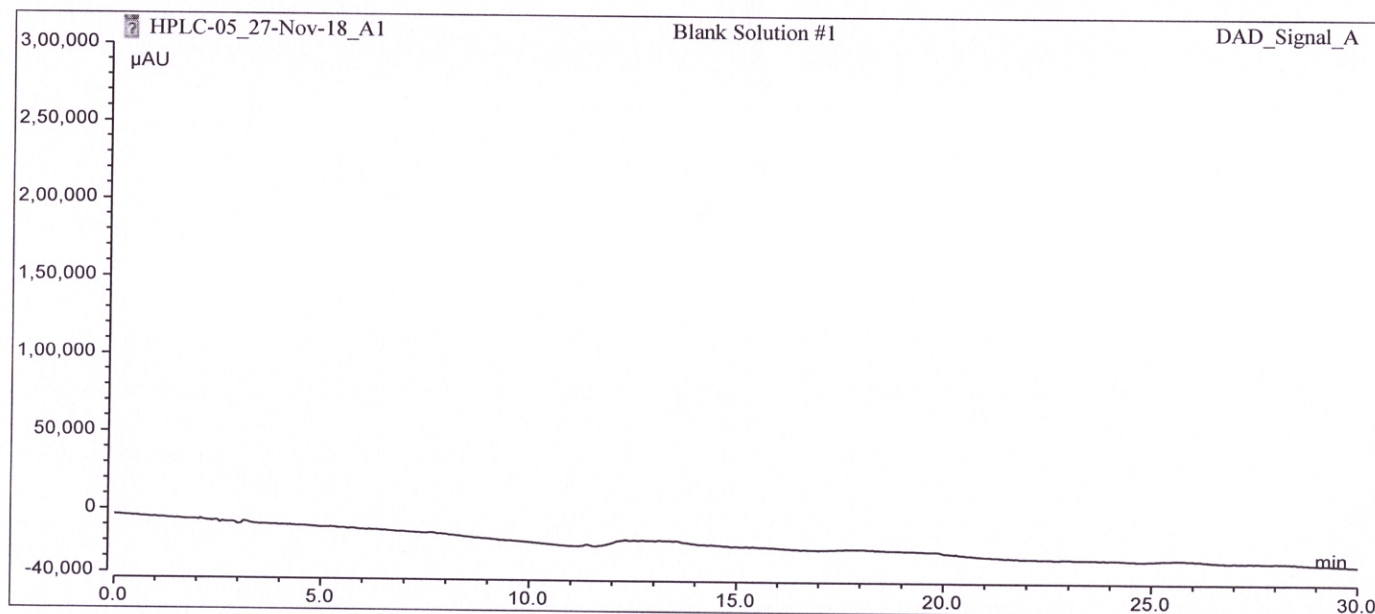
**Peak Table**

| No. | Peak Name | Ret. Time |
|-----|-----------|-----------|
|-----|-----------|-----------|



## QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

|                          |                                                                                                      |                                      |                                  |
|--------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------------------|
| Product Name :-          | Ramithiazide Tablet                                                                                  | Batch No. :-                         | N/A                              |
| Sample Name :-           | Blank Solution                                                                                       | AR. No. :-                           | D2404181193                      |
| Sample Number :-         | 1                                                                                                    | Instrument Method :-                 | HPLC-05_Ramithiazide Tablet_RS_M |
| Sample Type :-           | Unknown                                                                                              | Instrument Method Created By :-      | Gauri Rane                       |
| Injection Volume :-      | 30.00 µL                                                                                             | Instrument Method Created On :-      | 26-11-2018 15:21:29              |
| Vial Position :-         | Vial:1                                                                                               | Processing Method :-                 | Ramithiazide_RS_PR               |
| Column No. :-            | QbD/LC/COL/128                                                                                       | Processing Method Last Updated By :- | Gauri Rane                       |
| Instrument ID. :-        | QbD-INST-HPLC-05                                                                                     | Processing Method Last Updated On :- | 27-11-2018 11:11:44              |
| Injection Date & Time :- | 27-11-2018 16:07:44                                                                                  | Experiment Name:-                    | Intermediate precision           |
| Analyst :-               | Gauri Rane                                                                                           | Wavelength:-                         | n.a.                             |
| Sequence Path :-         | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                      |                                  |



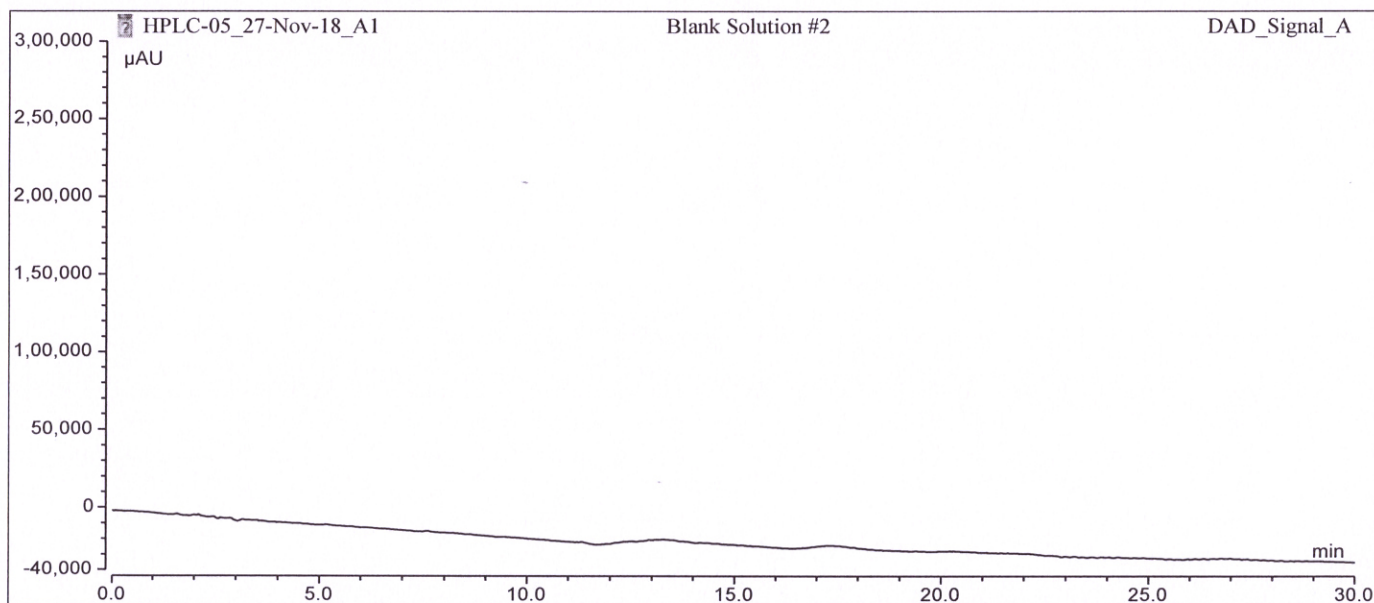
| Peak No. | Peak Name | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|-----------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
|----------|-----------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|





## QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

|                                     |                                                                                                      |                                             |                                  |
|-------------------------------------|------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------------------|
| <b>Product Name :-</b>              | Ramithiazide Tablet                                                                                  | <b>Batch No. :-</b>                         | N/A                              |
| <b>Sample Name :-</b>               | Blank Solution                                                                                       | <b>AR. No. :-</b>                           | D2404181193                      |
| <b>Sample Number :-</b>             | 2                                                                                                    | <b>Instrument Method :-</b>                 | HPLC-05_Ramithiazide Tablet_RS_N |
| <b>Sample Type :-</b>               | Unknown                                                                                              | <b>Instrument Method Created By :-</b>      | Gauri Rane                       |
| <b>Injection Volume :-</b>          | 30.00 µL                                                                                             | <b>Instrument Method Created On :-</b>      | 26-11-2018 15:21:29              |
| <b>Vial Position :-</b>             | Vial:1                                                                                               | <b>Processing Method :-</b>                 | Ramithiazide_RS_PR               |
| <b>Column No. :-</b>                | QbD/LC/COL/128                                                                                       | <b>Processing Method Last Updated By :-</b> | Gauri Rane                       |
| <b>Instrument ID. :-</b>            | QbD-INST-HPLC-05                                                                                     | <b>Processing Method Last Updated On :-</b> | 27-11-2018 11:11:44              |
| <b>Injection Date &amp; Time :-</b> | 27-11-2018 16:39:41                                                                                  | <b>Experiment Name:-</b>                    | Intermediate precision           |
| <b>Analyst :-</b>                   | Gauri Rane                                                                                           | <b>Wavelength:-</b>                         | n.a.                             |
| <b>Sequence Path :-</b>             | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                             |                                  |

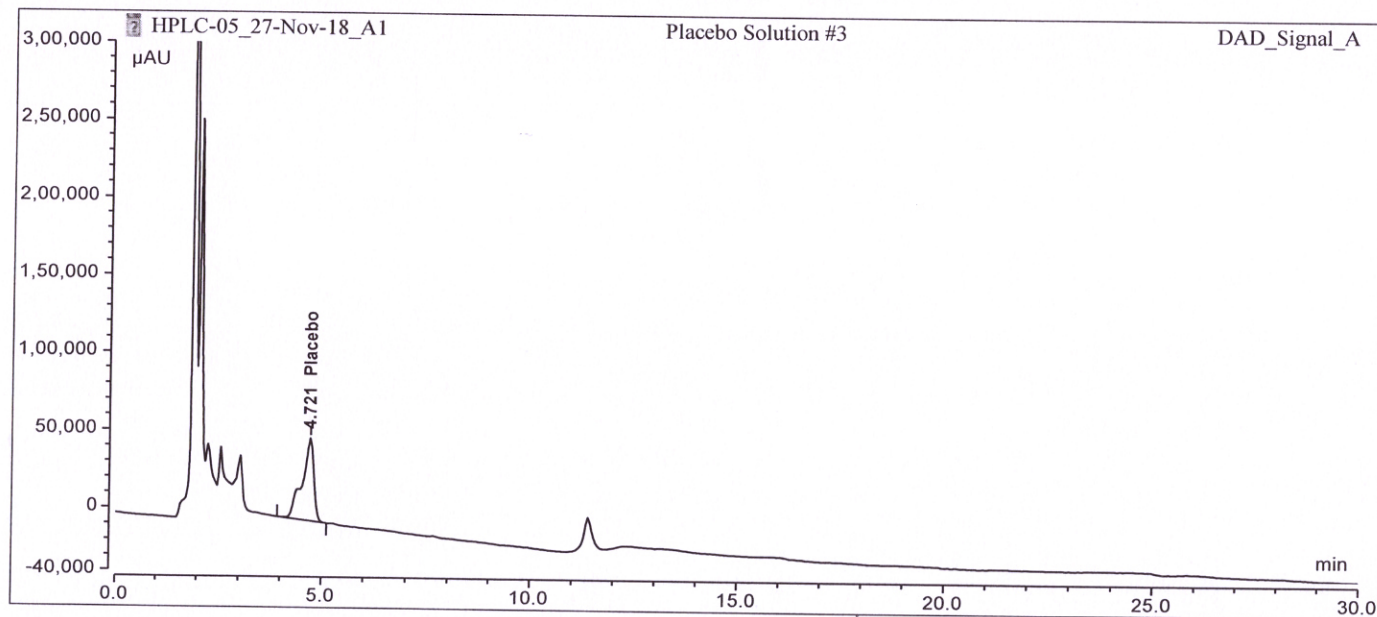


| Peak No. | Peak Name | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|-----------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
|----------|-----------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|



## QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

|                          |                                                                                                      |                                      |                                  |
|--------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------------------|
| Product Name :-          | Ramithiazide Tablet                                                                                  | Batch No. :-                         | N/A                              |
| Sample Name :-           | Placebo Solution                                                                                     | AR. No. :-                           | D2404181193                      |
| Sample Number :-         | 3                                                                                                    | Instrument Method :-                 | HPLC-05_Ramithiazide Tablet_RS_M |
| Sample Type :-           | Unknown                                                                                              | Instrument Method Created By :-      | Gauri Rane                       |
| Injection Volume :-      | 30.00 µL                                                                                             | Instrument Method Created On :-      | 26-11-2018 15:21:29              |
| Vial Position :-         | Vial:3                                                                                               | Processing Method :-                 | Ramithiazide_RS_PR1              |
| Column No. :-            | QbD/LC/COL/128                                                                                       | Processing Method Last Updated By :- | Gauri Rane                       |
| Instrument ID. :-        | QbD-INST-HPLC-05                                                                                     | Processing Method Last Updated On :- | 30-11-2018 17:05:57              |
| Injection Date & Time :- | 27-11-2018 17:32:56                                                                                  | Experiment Name:-                    | Intermediate precision           |
| Analyst :-               | Gauri Rane                                                                                           | Wavelength:-                         | n.a.                             |
| Sequence Path :-         | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                      |                                  |



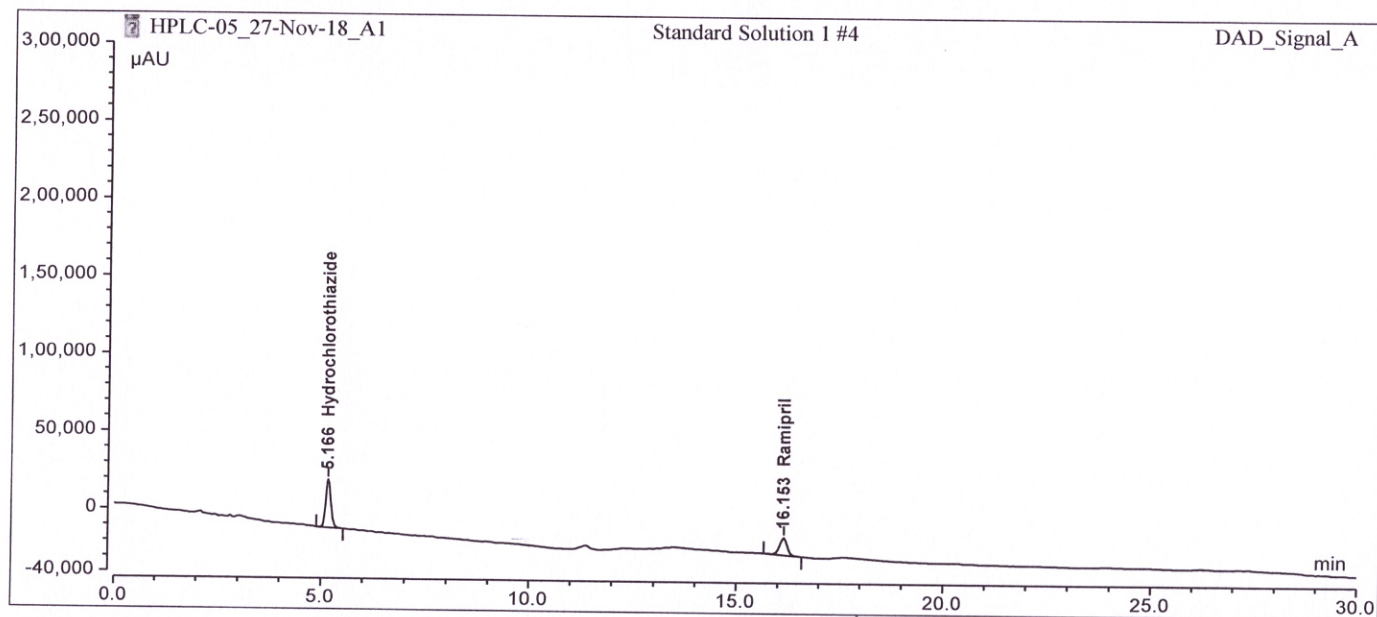
| Peak No. | Peak Name | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|-----------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
| 1        | Placebo   | 4.721         | 17166.152    | 100.00 | 0.71               | 1996         | FALSE       | n.a.             |





## QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

|                          |                                                                                                      |                                      |                                  |
|--------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------------------|
| Product Name :-          | Ramithiazide Tablet                                                                                  | Batch No. :-                         | N/A                              |
| Sample Name :-           | Standard Solution 1                                                                                  | AR. No. :-                           | D2404181193                      |
| Sample Number :-         | 4                                                                                                    | Instrument Method :-                 | HPLC-05_Ramithiazide Tablet_RS_M |
| Sample Type :-           | Unknown                                                                                              | Instrument Method Created By :-      | Gauri Rane                       |
| Injection Volume :-      | 30.00 µL                                                                                             | Instrument Method Created On :-      | 26-11-2018 15:21:29              |
| Vial Position :-         | Vial:2                                                                                               | Processing Method :-                 | Ramithiazide_RS_PR2              |
| Column No. :-            | QbD/LC/COL/128                                                                                       | Processing Method Last Updated By :- | Gauri Rane                       |
| Instrument ID. :-        | QbD-INST-HPLC-05                                                                                     | Processing Method Last Updated On :- | 28-11-2018 09:59:24              |
| Injection Date & Time :- | 27-11-2018 18:04:54                                                                                  | Experiment Name:-                    | Intermediate precision           |
| Analyst :-               | Gauri Rane                                                                                           | Wavelength:-                         | n.a.                             |
| Sequence Path :-         | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                      |                                  |

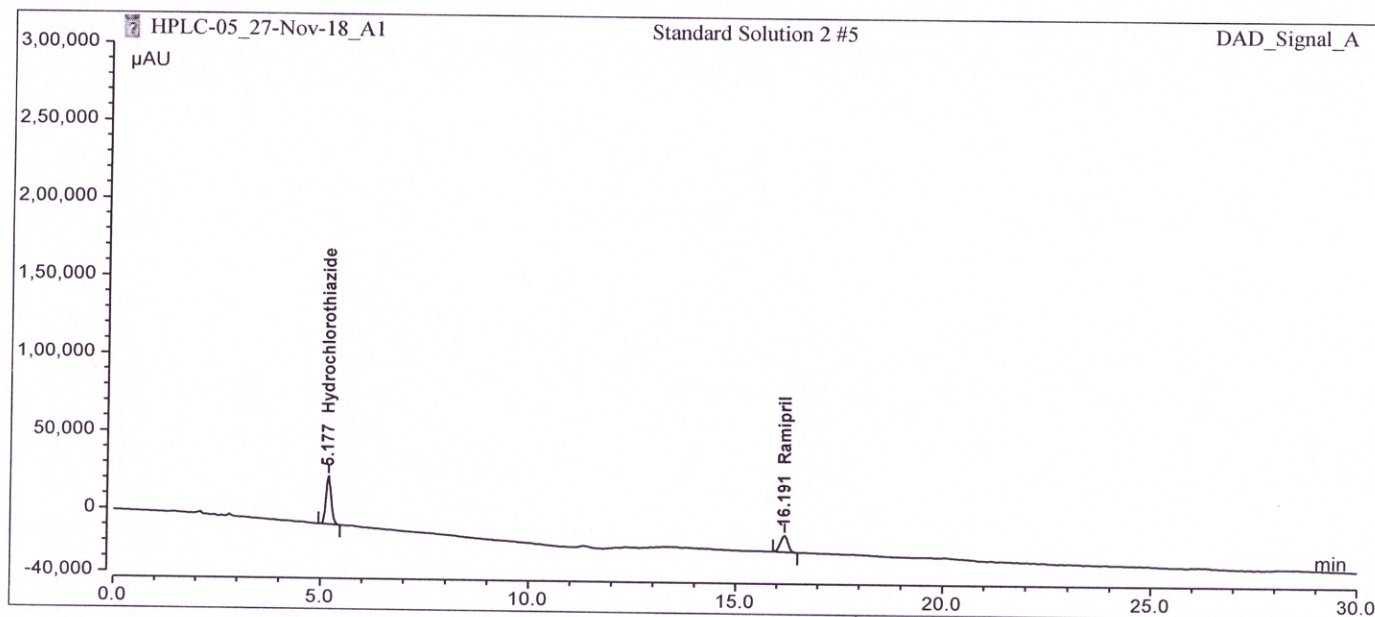


| Peak No. | Peak Name           | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|---------------------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
| 1        | Hydrochlorothiazide | 5.166         | 4480.832     | 64.51  | 1.17               | 8425         | FALSE       | n.a.             |
| 2        | Ramipril            | 16.153        | 2465.087     | 35.49  | 0.95               | 35853        | FALSE       | 38.80            |



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|                                     |                                                                                                      |                                             |                                  |
|-------------------------------------|------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------------------|
| <b>Product Name :-</b>              | Ramithiazide Tablet                                                                                  | <b>Batch No. :-</b>                         | N/A                              |
| <b>Sample Name :-</b>               | Standard Solution 2                                                                                  | <b>AR. No. :-</b>                           | D2404181193                      |
| <b>Sample Number :-</b>             | 5                                                                                                    | <b>Instrument Method :-</b>                 | HPLC-05_Ramithiazide Tablet_RS_M |
| <b>Sample Type :-</b>               | Unknown                                                                                              | <b>Instrument Method Created By :-</b>      | Gauri Rane                       |
| <b>Injection Volume :-</b>          | 30.00 µL                                                                                             | <b>Instrument Method Created On :-</b>      | 26-11-2018 15:21:29              |
| <b>Vial Position :-</b>             | Vial:2                                                                                               | <b>Processing Method :-</b>                 | Ramithiazide_RS_PR2              |
| <b>Column No. :-</b>                | QbD/LC/COL/128                                                                                       | <b>Processing Method Last Updated By :-</b> | Gauri Rane                       |
| <b>Instrument ID. :-</b>            | QbD-INST-HPLC-05                                                                                     | <b>Processing Method Last Updated On :-</b> | 28-11-2018 09:59:24              |
| <b>Injection Date &amp; Time :-</b> | 27-11-2018 18:36:58                                                                                  | <b>Experiment Name:-</b>                    | Intermediate precision           |
| <b>Analyst :-</b>                   | Gauri Rane                                                                                           | <b>Wavelength:-</b>                         | n.a.                             |
| <b>Sequence Path :-</b>             | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                             |                                  |



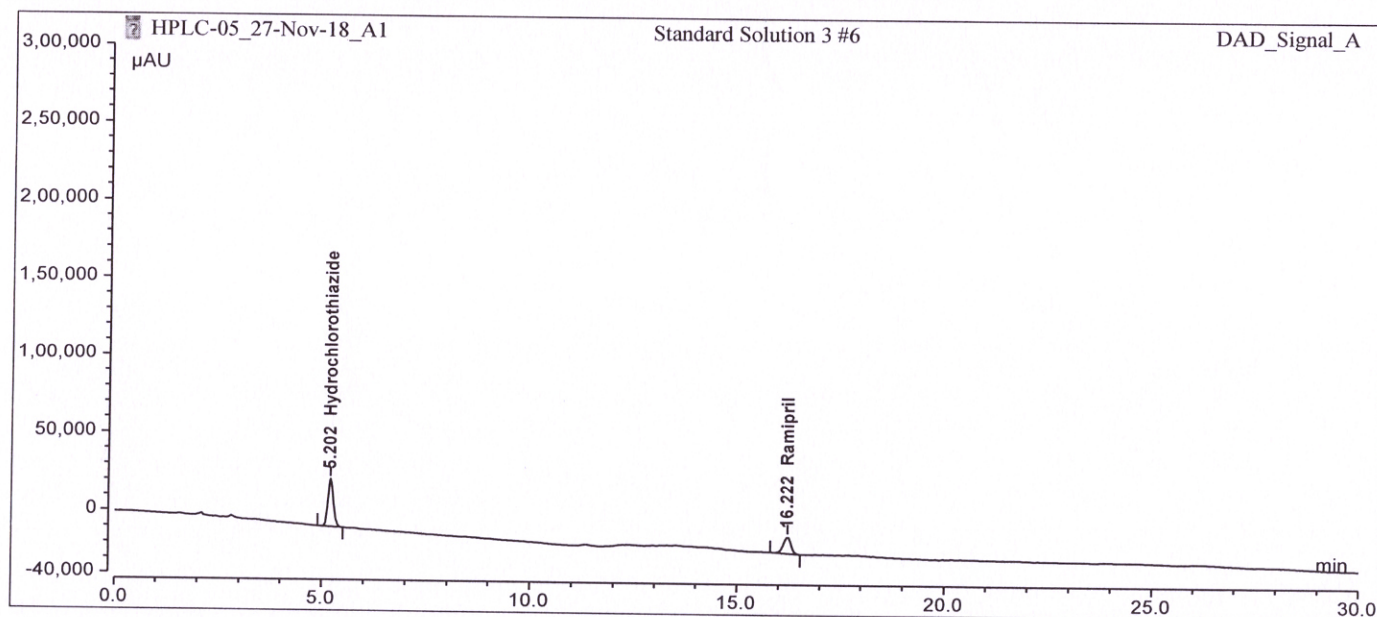
| Peak No. | Peak Name           | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|---------------------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
| 1        | Hydrochlorothiazide | 5.177         | 4451.909     | 66.65  | 1.19               | 8357         | FALSE       | n.a.             |
| 2        | Ramipril            | 16.191        | 2227.525     | 33.35  | 0.95               | 35971        | FALSE       | 38.78            |





## QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

|                          |                                                                                                      |                                      |                                  |
|--------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------------------|
| Product Name :-          | Ramithiazide Tablet                                                                                  | Batch No. :-                         | N/A                              |
| Sample Name :-           | Standard Solution 3                                                                                  | AR. No. :-                           | D2404181193                      |
| Sample Number :-         | 6                                                                                                    | Instrument Method :-                 | HPLC-05_Ramithiazide Tablet_RS_M |
| Sample Type :-           | Unknown                                                                                              | Instrument Method Created By :-      | Gauri Rane                       |
| Injection Volume :-      | 30.00 µL                                                                                             | Instrument Method Created On :-      | 26-11-2018 15:21:29              |
| Vial Position :-         | Vial:2                                                                                               | Processing Method :-                 | Ramithiazide_RS_PR2              |
| Column No. :-            | QbD/LC/COL/128                                                                                       | Processing Method Last Updated By :- | Gauri Rane                       |
| Instrument ID. :-        | QbD-INST-HPLC-05                                                                                     | Processing Method Last Updated On :- | 28-11-2018 09:59:24              |
| Injection Date & Time :- | 27-11-2018 19:08:56                                                                                  | Experiment Name:-                    | Intermediate precision           |
| Analyst :-               | Gauri Rane                                                                                           | Wavelength:-                         | n.a.                             |
| Sequence Path :-         | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                      |                                  |

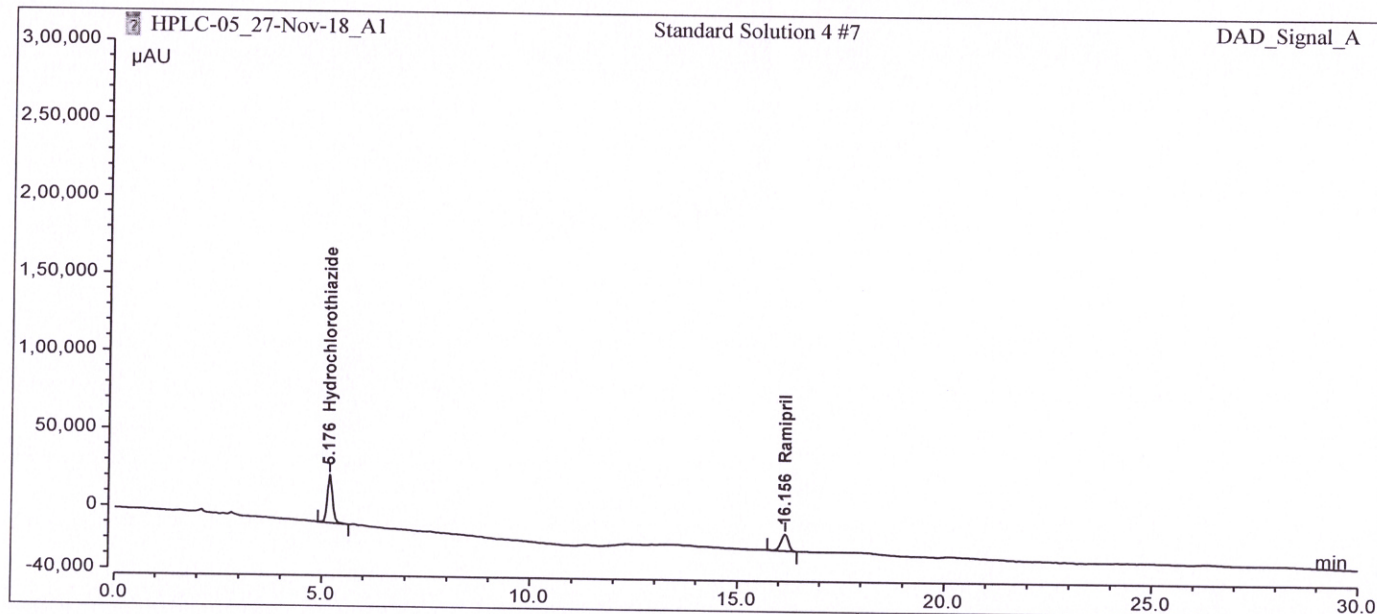


| Peak No. | Peak Name           | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|---------------------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
| 1        | Hydrochlorothiazide | 5.202         | 4419.675     | 65.74  | 1.18               | 8414         | FALSE       | n.a.             |
| 2        | Ramipril            | 16.222        | 2303.521     | 34.26  | 0.92               | 36676        | FALSE       | 38.96            |



**QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.**

|                                     |                                                                                                      |                                             |                                  |
|-------------------------------------|------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------------------|
| <b>Product Name :-</b>              | Ramithiazide Tablet                                                                                  | <b>Batch No. :-</b>                         | N/A                              |
| <b>Sample Name :-</b>               | Standard Solution 4                                                                                  | <b>AR. No. :-</b>                           | D2404181193                      |
| <b>Sample Number :-</b>             | 7                                                                                                    | <b>Instrument Method :-</b>                 | HPLC-05_Ramithiazide Tablet_RS_M |
| <b>Sample Type :-</b>               | Unknown                                                                                              | <b>Instrument Method Created By :-</b>      | Gauri Rane                       |
| <b>Injection Volume :-</b>          | 30.00 µL                                                                                             | <b>Instrument Method Created On :-</b>      | 26-11-2018 15:21:29              |
| <b>Vial Position :-</b>             | Vial:2                                                                                               | <b>Processing Method :-</b>                 | Ramithiazide_RS_PR2              |
| <b>Column No. :-</b>                | QbD/LC/COL/128                                                                                       | <b>Processing Method Last Updated By :-</b> | Gauri Rane                       |
| <b>Instrument ID. :-</b>            | QbD-INST-HPLC-05                                                                                     | <b>Processing Method Last Updated On :-</b> | 28-11-2018 09:59:24              |
| <b>Injection Date &amp; Time :-</b> | 27-11-2018 19:40:53                                                                                  | <b>Experiment Name:-</b>                    | Intermediate precision           |
| <b>Analyst :-</b>                   | Gauri Rane                                                                                           | <b>Wavelength:-</b>                         | n.a.                             |
| <b>Sequence Path :-</b>             | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                             |                                  |



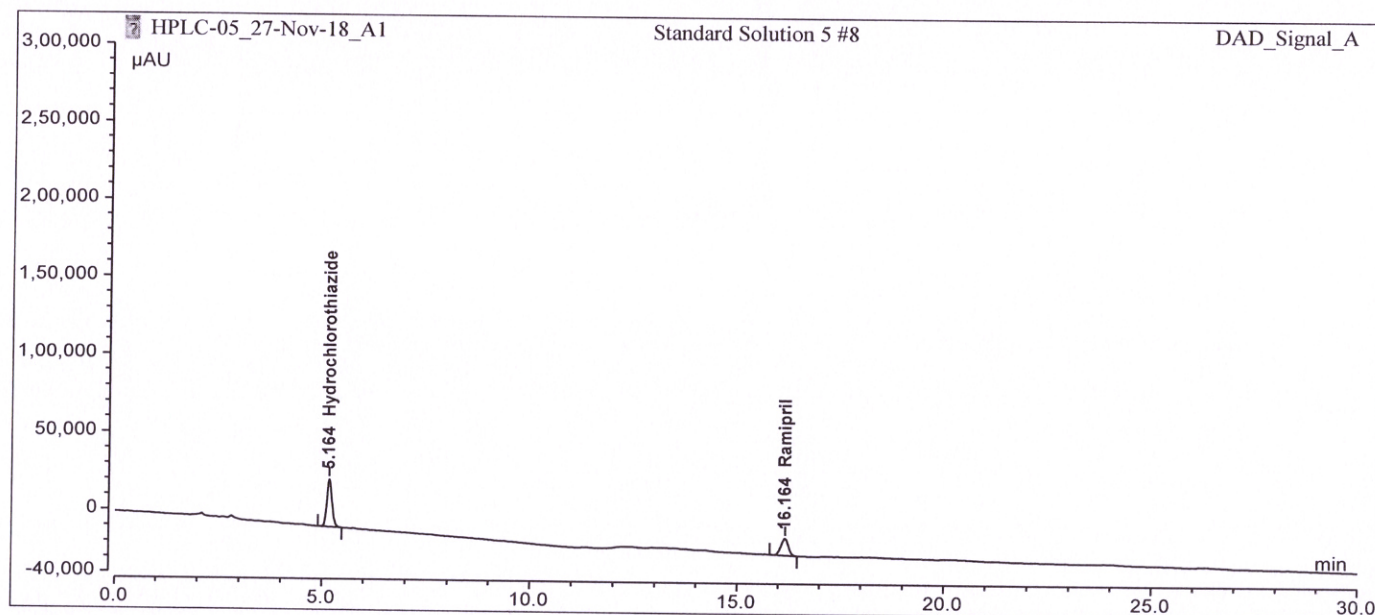
| Peak No. | Peak Name           | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|---------------------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
| 1        | Hydrochlorothiazide | 5.176         | 4535.536     | 66.86  | 1.20               | 8288         | FALSE       | n.a.             |
| 2        | Ramipril            | 16.156        | 2248.426     | 33.14  | 0.93               | 37318        | FALSE       | 39.08            |





**QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.**

|                                     |                                                                                                      |                                             |                                  |
|-------------------------------------|------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------------------|
| <b>Product Name :-</b>              | Ramithiazide Tablet                                                                                  | <b>Batch No. :-</b>                         | N/A                              |
| <b>Sample Name :-</b>               | Standard Solution 5                                                                                  | <b>AR. No. :-</b>                           | D2404181193                      |
| <b>Sample Number :-</b>             | 8                                                                                                    | <b>Instrument Method :-</b>                 | HPLC-05_Ramithiazide Tablet_RS_M |
| <b>Sample Type :-</b>               | Unknown                                                                                              | <b>Instrument Method Created By :-</b>      | Gauri Rane                       |
| <b>Injection Volume :-</b>          | 30.00 µL                                                                                             | <b>Instrument Method Created On :-</b>      | 26-11-2018 15:21:29              |
| <b>Vial Position :-</b>             | Vial:2                                                                                               | <b>Processing Method :-</b>                 | Ramithiazide_RS_PR2              |
| <b>Column No. :-</b>                | QbD/LC/COL/128                                                                                       | <b>Processing Method Last Updated By :-</b> | Gauri Rane                       |
| <b>Instrument ID. :-</b>            | QbD-INST-HPLC-05                                                                                     | <b>Processing Method Last Updated On :-</b> | 28-11-2018 09:59:24              |
| <b>Injection Date &amp; Time :-</b> | 27-11-2018 20:12:51                                                                                  | <b>Experiment Name:-</b>                    | Intermediate precision           |
| <b>Analyst :-</b>                   | Gauri Rane                                                                                           | <b>Wavelength:-</b>                         | n.a.                             |
| <b>Sequence Path :-</b>             | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                             |                                  |

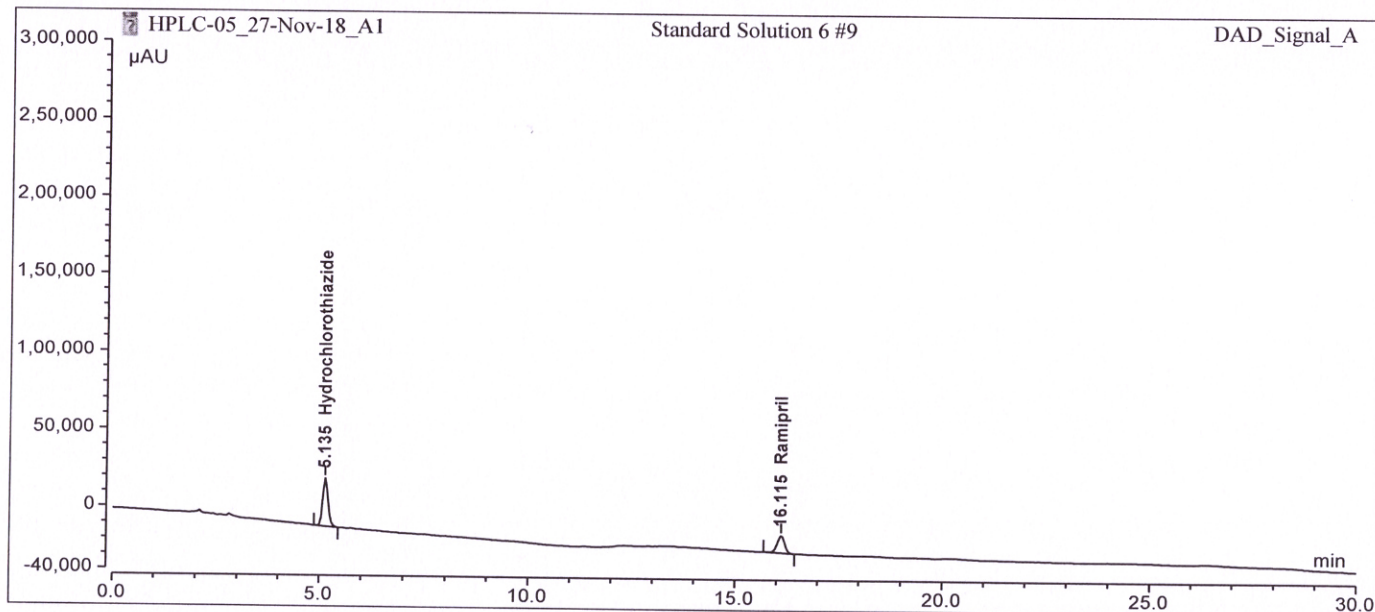


| Peak No. | Peak Name           | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|---------------------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
| 1        | Hydrochlorothiazide | 5.164         | 4382.866     | 65.81  | 1.19               | 8480         | FALSE       | n.a.             |
| 2        | Ramipril            | 16.164        | 2276.692     | 34.19  | 0.96               | 37436        | FALSE       | 39.39            |



**QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.**

|                                     |                                                                                                      |                                             |                                  |
|-------------------------------------|------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------------------|
| <b>Product Name :-</b>              | Ramithiazide Tablet                                                                                  | <b>Batch No. :-</b>                         | N/A                              |
| <b>Sample Name :-</b>               | Standard Solution 6                                                                                  | <b>AR. No. :-</b>                           | D2404181193                      |
| <b>Sample Number :-</b>             | 9                                                                                                    | <b>Instrument Method :-</b>                 | HPLC-05_Ramithiazide Tablet_RS_M |
| <b>Sample Type :-</b>               | Unknown                                                                                              | <b>Instrument Method Created By :-</b>      | Gauri Rane                       |
| <b>Injection Volume :-</b>          | 30.00 µL                                                                                             | <b>Instrument Method Created On :-</b>      | 26-11-2018 15:21:29              |
| <b>Vial Position :-</b>             | Vial:2                                                                                               | <b>Processing Method :-</b>                 | Ramithiazide_RS_PR2              |
| <b>Column No. :-</b>                | QbD/LC/COL/128                                                                                       | <b>Processing Method Last Updated By :-</b> | Gauri Rane                       |
| <b>Instrument ID. :-</b>            | QbD-INST-HPLC-05                                                                                     | <b>Processing Method Last Updated On :-</b> | 28-11-2018 09:59:24              |
| <b>Injection Date &amp; Time :-</b> | 27-11-2018 20:44:48                                                                                  | <b>Experiment Name:-</b>                    | Intermediate precision           |
| <b>Analyst :-</b>                   | Gauri Rane                                                                                           | <b>Wavelength:-</b>                         | n.a.                             |
| <b>Sequence Path :-</b>             | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                             |                                  |



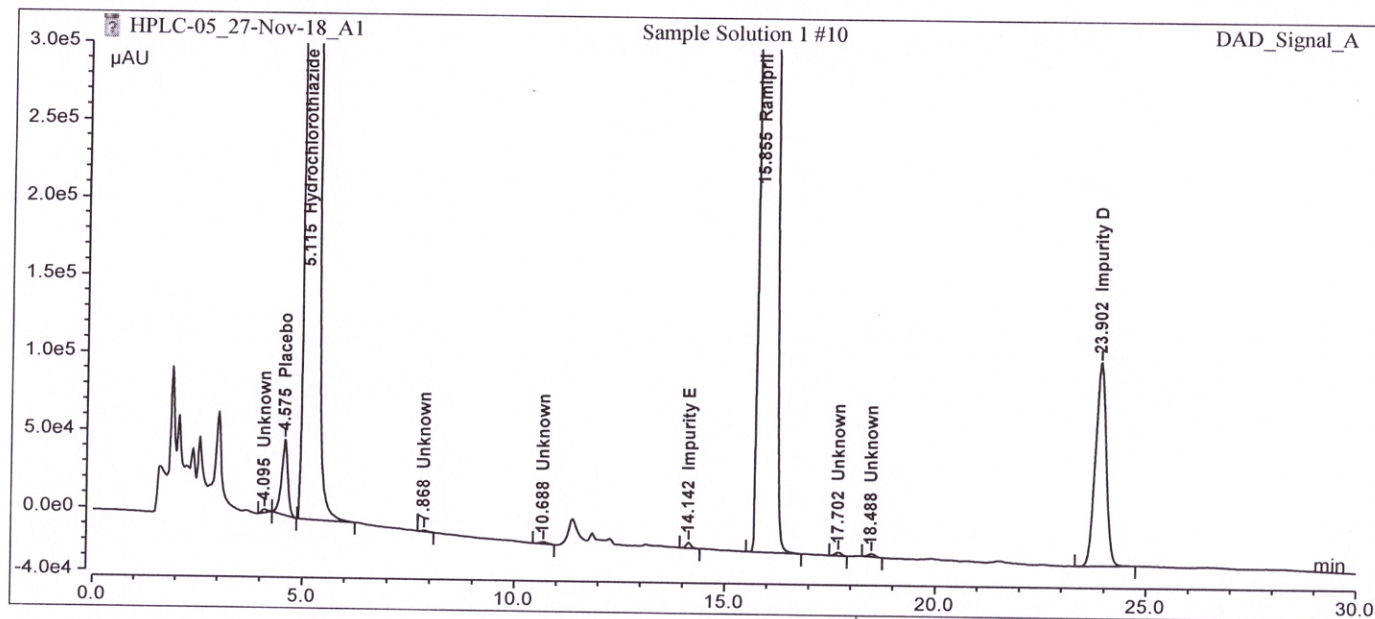
| Peak No. | Peak Name           | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|---------------------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
| 1        | Hydrochlorothiazide | 5.135         | 4409.777     | 65.62  | 1.18               | 8483         | FALSE       | n.a.             |
| 2        | Ramipril            | 16.115        | 2310.580     | 34.38  | 0.94               | 38390        | FALSE       | 39.78            |





## QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

|                          |                                                                                                      |                                      |                                  |
|--------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------------------|
| Product Name :-          | Ramithiazide Tablet                                                                                  | Batch No. :-                         | GP180301                         |
| Sample Name :-           | Sample Solution 1                                                                                    | AR. No. :-                           | D2404181193                      |
| Sample Number :-         | 10                                                                                                   | Instrument Method :-                 | HPLC-05_Ramithiazide Tablet_RS_M |
| Sample Type :-           | Unknown                                                                                              | Instrument Method Created By :-      | Gauri Rane                       |
| Injection Volume :-      | 30.00 µL                                                                                             | Instrument Method Created On :-      | 26-11-2018 15:21:29              |
| Vial Position :-         | Vial:4                                                                                               | Processing Method :-                 | Ramithiazide_RS_PR3              |
| Column No. :-            | QbD/LC/COL/128                                                                                       | Processing Method Last Updated By :- | Swaraj A. Jadhav                 |
| Instrument ID. :-        | QbD-INST-HPLC-05                                                                                     | Processing Method Last Updated On :- | 28-11-2018 15:09:53              |
| Injection Date & Time :- | 27-11-2018 21:16:42                                                                                  | Experiment Name:-                    | Intermediate precision           |
| Analyst :-               | Gauri Rane                                                                                           | Wavelength:-                         | n.a.                             |
| Sequence Path :-         | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                      |                                  |



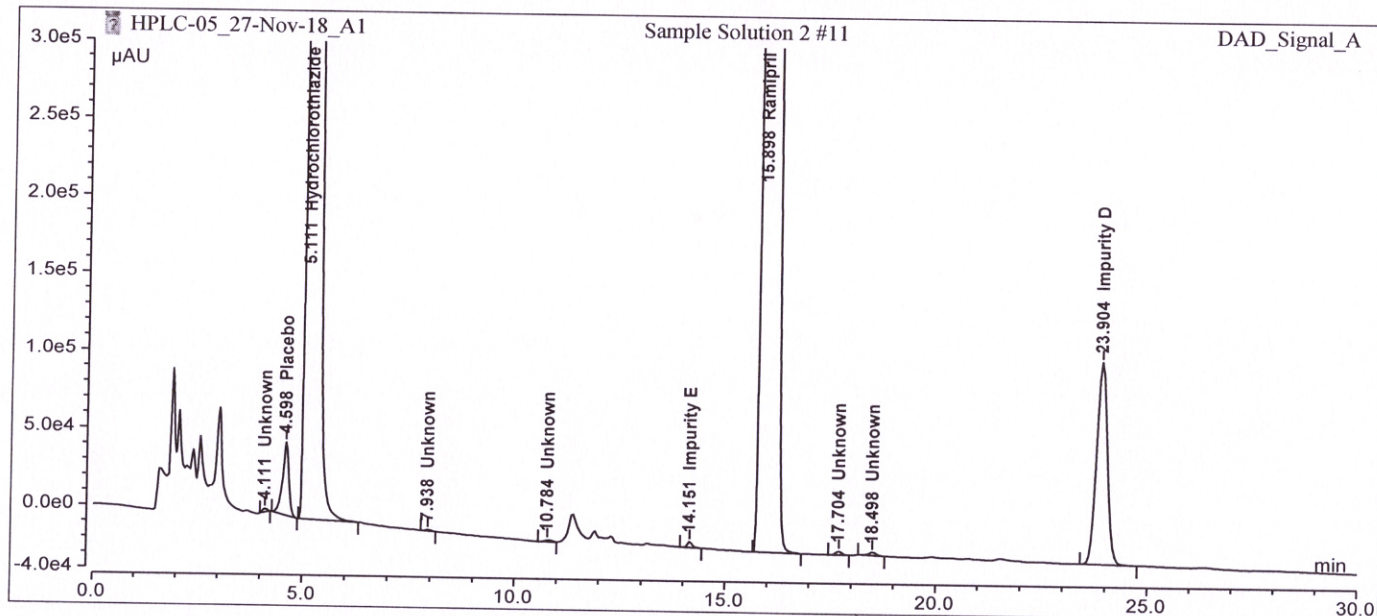
| Peak No. | Peak Name           | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|---------------------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
| 1        | Unknown             | 4.095         | 340.361      | 0.02   | 1.23               | 4215         | FALSE       | n.a.             |
| 2        | Placebo             | 4.575         | 7963.207     | 0.51   | 0.92               | 5638         | FALSE       | 1.94             |
| 3        | Hydrochlorothiazide | 5.115         | 753436.632   | 48.30  | 1.33               | 3399         | FALSE       | 1.82             |
| 4        | Unknown             | 7.868         | 152.133      | 0.01   | 1.27               | 13597        | FALSE       | 8.87             |
| 5        | Unknown             | 10.688        | 285.659      | 0.02   | 1.04               | 12523        | FALSE       | 8.65             |
| 6        | Impurity E          | 14.142        | 486.562      | 0.03   | 1.25               | 85294        | FALSE       | 12.00            |
| 7        | Ramipril            | 15.855        | 757913.192   | 48.59  | 1.82               | 19502        | FALSE       | 5.29             |
| 8        | Unknown             | 17.702        | 380.212      | 0.02   | 1.04               | 64399        | FALSE       | 5.04             |
| 9        | Unknown             | 18.488        | 387.764      | 0.02   | 1.11               | 58244        | FALSE       | 2.69             |
| 10       | Impurity D          | 23.902        | 38458.478    | 2.47   | 1.02               | 42001        | FALSE       | 14.01            |





**QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.**

|                                     |                                                                                                      |                                             |                                  |
|-------------------------------------|------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------------------|
| <b>Product Name :-</b>              | Ramithiazide Tablet                                                                                  | <b>Batch No. :-</b>                         | GP180301                         |
| <b>Sample Name :-</b>               | Sample Solution 2                                                                                    | <b>AR. No. :-</b>                           | D2404181193                      |
| <b>Sample Number :-</b>             | 11                                                                                                   | <b>Instrument Method :-</b>                 | HPLC-05_Ramithiazide Tablet_RS_M |
| <b>Sample Type :-</b>               | Unknown                                                                                              | <b>Instrument Method Created By :-</b>      | Gauri Rane                       |
| <b>Injection Volume :-</b>          | 30.00 µL                                                                                             | <b>Instrument Method Created On :-</b>      | 26-11-2018 15:21:29              |
| <b>Vial Position :-</b>             | Vial:5                                                                                               | <b>Processing Method :-</b>                 | Ramithiazide_RS_PR3              |
| <b>Column No. :-</b>                | QbD/LC/COL/128                                                                                       | <b>Processing Method Last Updated By :-</b> | Swaraj A. Jadhav                 |
| <b>Instrument ID. :-</b>            | QbD-INST-HPLC-05                                                                                     | <b>Processing Method Last Updated On :-</b> | 28-11-2018 15:09:53              |
| <b>Injection Date &amp; Time :-</b> | 27-11-2018 21:48:37                                                                                  | <b>Experiment Name:-</b>                    | Intermediate precision           |
| <b>Analyst :-</b>                   | Gauri Rane                                                                                           | <b>Wavelength:-</b>                         | n.a.                             |
| <b>Sequence Path :-</b>             | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                             |                                  |



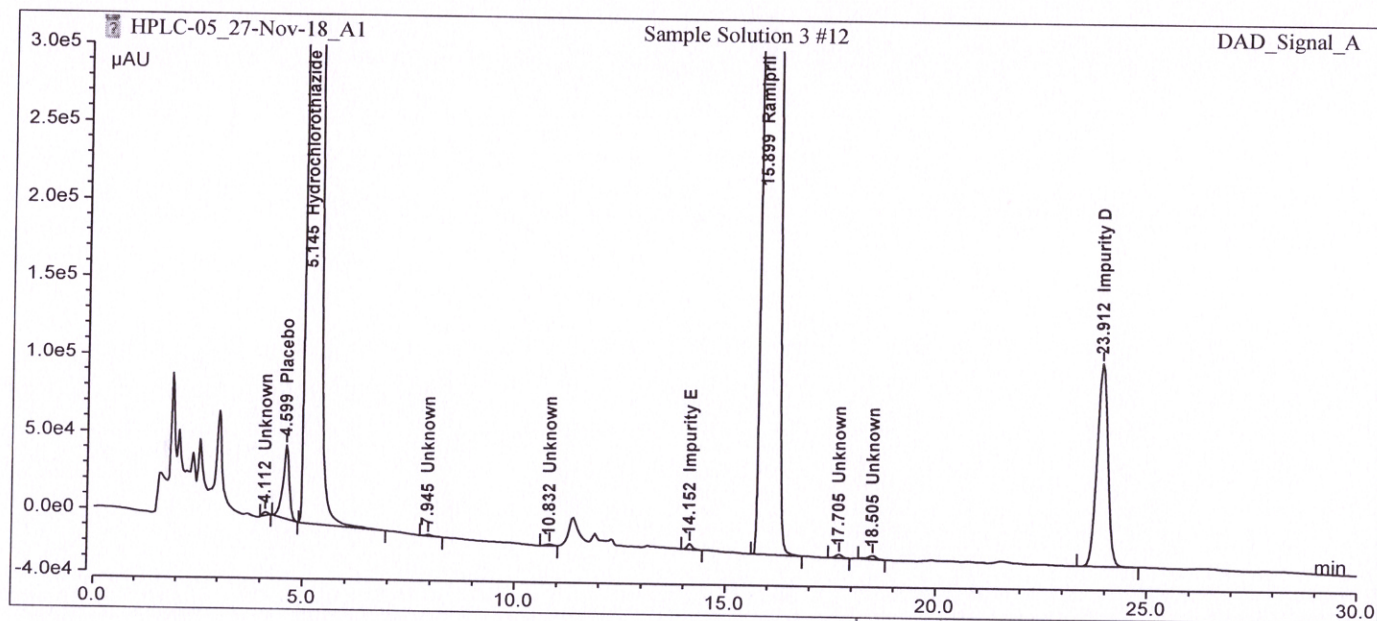
| Peak No. | Peak Name           | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|---------------------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
| 1        | Unknown             | 4.111         | 301.293      | 0.02   | 1.05               | 5785         | FALSE       | n.a.             |
| 2        | Placebo             | 4.598         | 7836.227     | 0.49   | 0.88               | 5631         | FALSE       | 2.11             |
| 3        | Hydrochlorothiazide | 5.111         | 775160.864   | 48.48  | 1.66               | 3406         | FALSE       | 1.72             |
| 4        | Unknown             | 7.938         | 134.163      | 0.01   | 1.13               | 15627        | FALSE       | 9.36             |
| 5        | Unknown             | 10.784        | 245.781      | 0.02   | 1.06               | 15993        | FALSE       | 9.57             |
| 6        | Impurity E          | 14.151        | 509.777      | 0.03   | 1.51               | 83732        | FALSE       | 12.55            |
| 7        | Ramipril            | 15.898        | 775574.996   | 48.50  | 1.73               | 19470        | FALSE       | 5.36             |
| 8        | Unknown             | 17.704        | 427.536      | 0.03   | 1.02               | 60718        | FALSE       | 4.86             |
| 9        | Unknown             | 18.498        | 463.010      | 0.03   | 0.85               | 52521        | FALSE       | 2.60             |
| 10       | Impurity D          | 23.904        | 38374.395    | 2.40   | 1.03               | 41589        | FALSE       | 13.66            |





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|                          |                                                                                                      |                                      |                                  |
|--------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------------------|
| Product Name :-          | Ramithiazide Tablet                                                                                  | Batch No. :-                         | GP180301                         |
| Sample Name :-           | Sample Solution 3                                                                                    | AR. No. :-                           | D2404181193                      |
| Sample Number :-         | 12                                                                                                   | Instrument Method :-                 | HPLC-05_Ramithiazide Tablet_RS_M |
| Sample Type :-           | Unknown                                                                                              | Instrument Method Created By :-      | Gauri Rane                       |
| Injection Volume :-      | 30.00 µL                                                                                             | Instrument Method Created On :-      | 26-11-2018 15:21:29              |
| Vial Position :-         | Vial:6                                                                                               | Processing Method :-                 | Ramithiazide_RS_PR3              |
| Column No. :-            | QbD/LC/COL/128                                                                                       | Processing Method Last Updated By :- | Swaraj A. Jadhav                 |
| Instrument ID. :-        | QbD-INST-HPLC-05                                                                                     | Processing Method Last Updated On :- | 28-11-2018 15:09:53              |
| Injection Date & Time :- | 27-11-2018 22:20:35                                                                                  | Experiment Name:-                    | Intermediate precision           |
| Analyst :-               | Gauri Rane                                                                                           | Wavelength:-                         | n.a.                             |
| Sequence Path :-         | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                      |                                  |



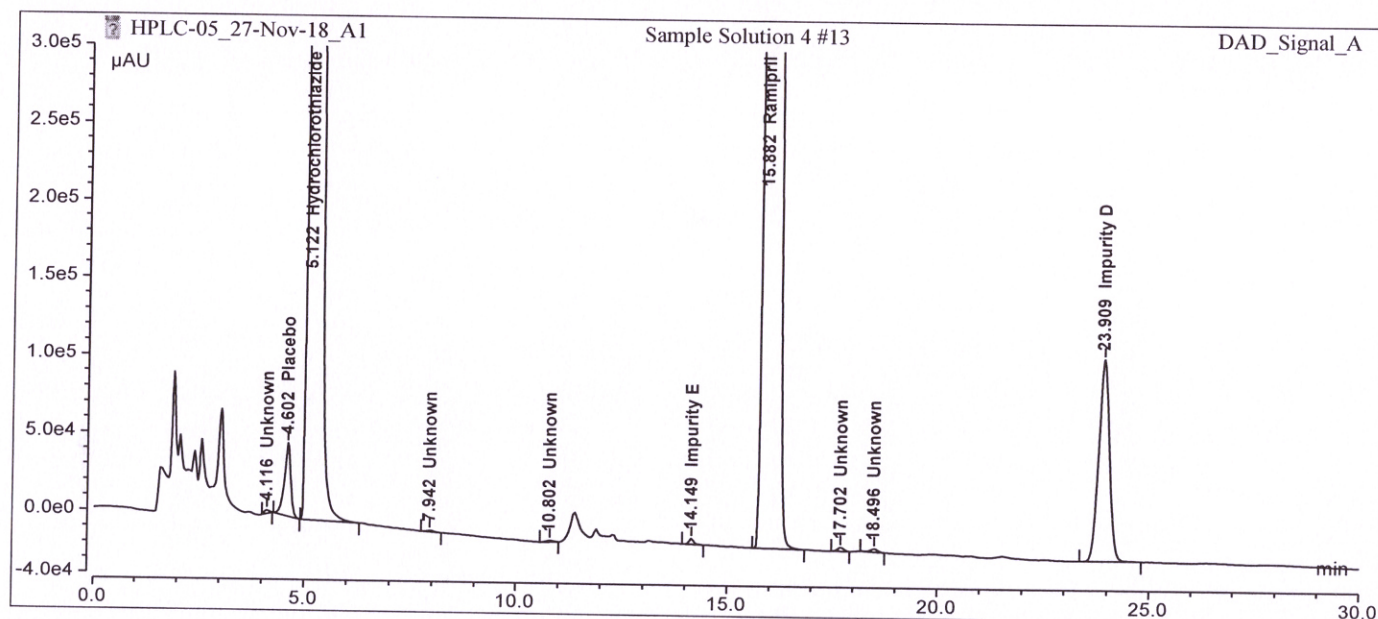
| Peak No. | Peak Name           | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|---------------------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
| 1        | Unknown             | 4.112         | 313.886      | 0.02   | 1.09               | 5436         | FALSE       | n.a.             |
| 2        | Placebo             | 4.599         | 8003.698     | 0.50   | 0.88               | 5615         | FALSE       | 2.08             |
| 3        | Hydrochlorothiazide | 5.145         | 781488.809   | 48.51  | 1.33               | 3444         | FALSE       | 1.83             |
| 4        | Unknown             | 7.945         | 185.921      | 0.01   | 1.53               | 15081        | FALSE       | 9.19             |
| 5        | Unknown             | 10.832        | 197.271      | 0.01   | 0.91               | 16944        | FALSE       | 9.76             |
| 6        | Impurity E          | 14.152        | 498.107      | 0.03   | 1.31               | 82754        | FALSE       | 12.54            |
| 7        | Ramipril            | 15.899        | 780709.924   | 48.46  | 1.76               | 19319        | FALSE       | 5.34             |
| 8        | Unknown             | 17.705        | 411.055      | 0.03   | 1.00               | 59392        | FALSE       | 4.83             |
| 9        | Unknown             | 18.505        | 506.962      | 0.03   | 0.87               | 51671        | FALSE       | 2.60             |
| 10       | Impurity D          | 23.912        | 38580.249    | 2.39   | 1.04               | 41532        | FALSE       | 13.60            |





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|                          |                                                                                                      |                                      |                                  |
|--------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------------------|
| Product Name :-          | Ramithiazide Tablet                                                                                  | Batch No. :-                         | GP180301                         |
| Sample Name :-           | Sample Solution 4                                                                                    | AR. No. :-                           | D2404181193                      |
| Sample Number :-         | 13                                                                                                   | Instrument Method :-                 | HPLC-05_Ramithiazide Tablet_RS_M |
| Sample Type :-           | Unknown                                                                                              | Instrument Method Created By :-      | Gauri Rane                       |
| Injection Volume :-      | 30.00 µL                                                                                             | Instrument Method Created On :-      | 26-11-2018 15:21:29              |
| Vial Position :-         | Vial:7                                                                                               | Processing Method :-                 | Ramithiazide_RS_PR3              |
| Column No. :-            | QbD/LC/COL/128                                                                                       | Processing Method Last Updated By :- | Swaraj A. Jadhav                 |
| Instrument ID. :-        | QbD-INST-HPLC-05                                                                                     | Processing Method Last Updated On :- | 28-11-2018 15:09:53              |
| Injection Date & Time :- | 27-11-2018 22:52:28                                                                                  | Experiment Name:-                    | Intermediate precision           |
| Analyst :-               | Gauri Rane                                                                                           | Wavelength:-                         | n.a.                             |
| Sequence Path :-         | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                      |                                  |



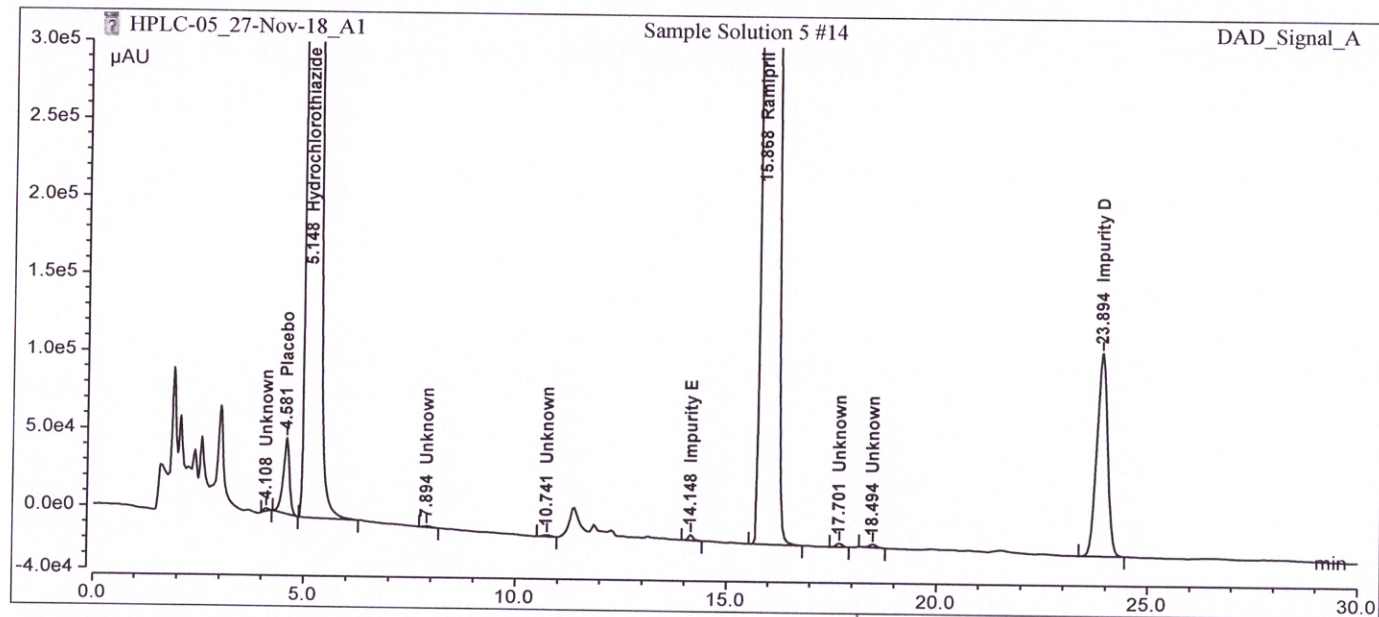
| Peak No. | Peak Name           | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|---------------------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
| 1        | Unknown             | 4.116         | 308.719      | 0.02   | 1.05               | 5769         | FALSE       | n.a.             |
| 2        | Placebo             | 4.602         | 7899.080     | 0.49   | 0.89               | 5616         | FALSE       | 2.11             |
| 3        | Hydrochlorothiazide | 5.122         | 783526.687   | 48.70  | 1.58               | 3420         | FALSE       | 1.74             |
| 4        | Unknown             | 7.942         | 167.903      | 0.01   | 1.16               | 13890        | FALSE       | 9.10             |
| 5        | Unknown             | 10.802        | 182.758      | 0.01   | 1.10               | 19519        | FALSE       | 9.88             |
| 6        | Impurity E          | 14.149        | 488.875      | 0.03   | 1.28               | 83707        | FALSE       | 13.26            |
| 7        | Ramipril            | 15.882        | 777016.420   | 48.30  | 1.79               | 19519        | FALSE       | 5.33             |
| 8        | Unknown             | 17.702        | 407.329      | 0.03   | 1.02               | 61417        | FALSE       | 4.92             |
| 9        | Unknown             | 18.496        | 434.028      | 0.03   | 0.84               | 55770        | FALSE       | 2.65             |
| 10       | Impurity D          | 23.909        | 38302.984    | 2.38   | 1.03               | 41675        | FALSE       | 13.85            |





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|                          |                                                                                                      |                                      |                                  |
|--------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------------------|
| Product Name :-          | Ramithiazide Tablet                                                                                  | Batch No. :-                         | GP180301                         |
| Sample Name :-           | Sample Solution 5                                                                                    | AR. No. :-                           | D2404181193                      |
| Sample Number :-         | 14                                                                                                   | Instrument Method :-                 | HPLC-05_Ramithiazide Tablet_RS_M |
| Sample Type :-           | Unknown                                                                                              | Instrument Method Created By :-      | Gauri Rane                       |
| Injection Volume :-      | 30.00 µL                                                                                             | Instrument Method Created On :-      | 26-11-2018 15:21:29              |
| Vial Position :-         | Vial:8                                                                                               | Processing Method :-                 | Ramithiazide_RS_PR3              |
| Column No. :-            | QbD/LC/COL/128                                                                                       | Processing Method Last Updated By :- | Swaraj A. Jadhav                 |
| Instrument ID. :-        | QbD-INST-HPLC-05                                                                                     | Processing Method Last Updated On :- | 28-11-2018 15:09:53              |
| Injection Date & Time :- | 27-11-2018 23:24:21                                                                                  | Experiment Name:-                    | Intermediate precision           |
| Analyst :-               | Gauri Rane                                                                                           | Wavelength:-                         | n.a.                             |
| Sequence Path :-         | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                      |                                  |



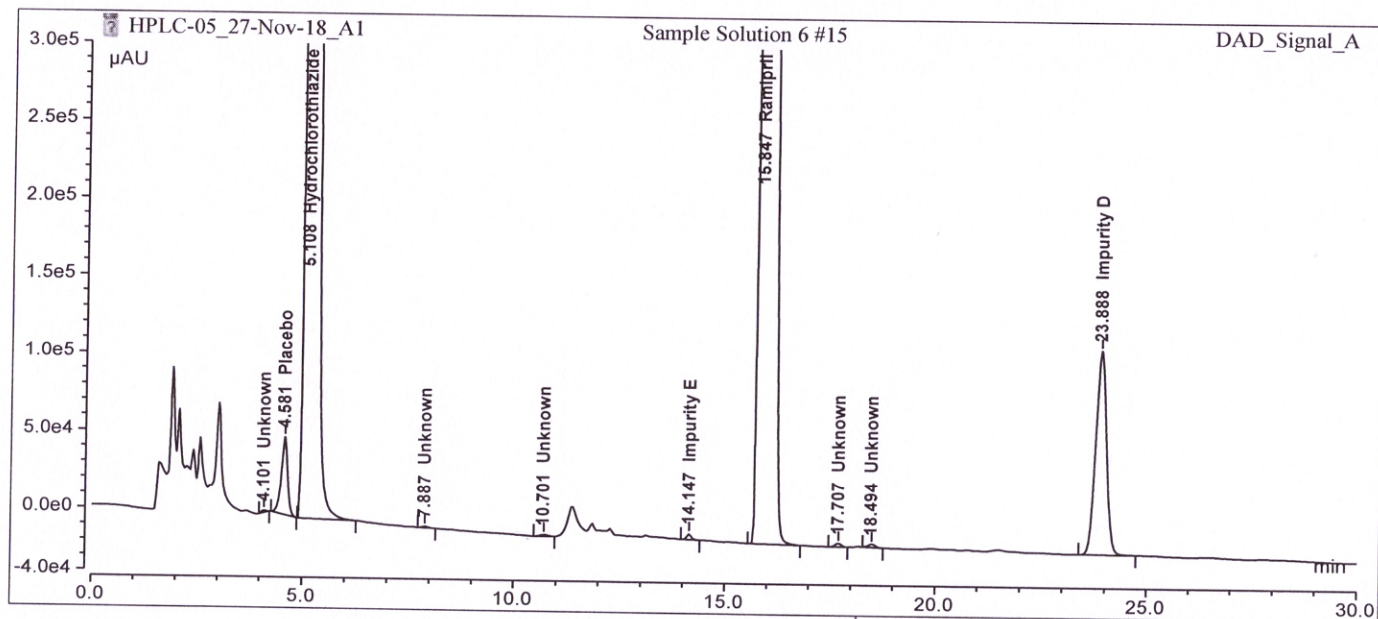
| Peak No. | Peak Name           | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|---------------------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
| 1        | Unknown             | 4.108         | 276.705      | 0.02   | 1.08               | 5387         | FALSE       | n.a.             |
| 2        | Placebo             | 4.581         | 8071.352     | 0.50   | 0.91               | 5646         | FALSE       | 2.02             |
| 3        | Hydrochlorothiazide | 5.148         | 781183.406   | 48.69  | 1.15               | 3473         | FALSE       | 1.91             |
| 4        | Unknown             | 7.894         | 164.511      | 0.01   | 1.22               | 12090        | FALSE       | 8.63             |
| 5        | Unknown             | 10.741        | 230.072      | 0.01   | 0.99               | 15766        | FALSE       | 9.05             |
| 6        | Impurity E          | 14.148        | 501.841      | 0.03   | 1.21               | 82209        | FALSE       | 12.63            |
| 7        | Ramipril            | 15.868        | 774802.853   | 48.30  | 1.82               | 19630        | FALSE       | 5.29             |
| 8        | Unknown             | 17.701        | 405.091      | 0.03   | 1.02               | 60496        | FALSE       | 4.95             |
| 9        | Unknown             | 18.494        | 437.034      | 0.03   | 0.86               | 57727        | FALSE       | 2.66             |
| 10       | Impurity D          | 23.894        | 38239.816    | 2.38   | 1.04               | 41700        | FALSE       | 13.92            |





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|                          |                                                                                                      |                                      |                                  |
|--------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------------------|
| Product Name :-          | Ramithiazide Tablet                                                                                  | Batch No. :-                         | GP180301                         |
| Sample Name :-           | Sample Solution 6                                                                                    | AR. No. :-                           | D2404181193                      |
| Sample Number :-         | 15                                                                                                   | Instrument Method :-                 | HPLC-05_Ramithiazide Tablet_RS_M |
| Sample Type :-           | Unknown                                                                                              | Instrument Method Created By :-      | Gauri Rane                       |
| Injection Volume :-      | 30.00 µL                                                                                             | Instrument Method Created On :-      | 26-11-2018 15:21:29              |
| Vial Position :-         | Vial:9                                                                                               | Processing Method :-                 | Ramithiazide_RS_PR3              |
| Column No. :-            | QbD/LC/COL/128                                                                                       | Processing Method Last Updated By :- | Swaraj A. Jadhav                 |
| Instrument ID. :-        | QbD-INST-HPLC-05                                                                                     | Processing Method Last Updated On :- | 28-11-2018 15:09:53              |
| Injection Date & Time :- | 27-11-2018 23:56:15                                                                                  | Experiment Name:-                    | Intermediate precision           |
| Analyst :-               | Gauri Rane                                                                                           | Wavelength:-                         | n.a.                             |
| Sequence Path :-         | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                      |                                  |



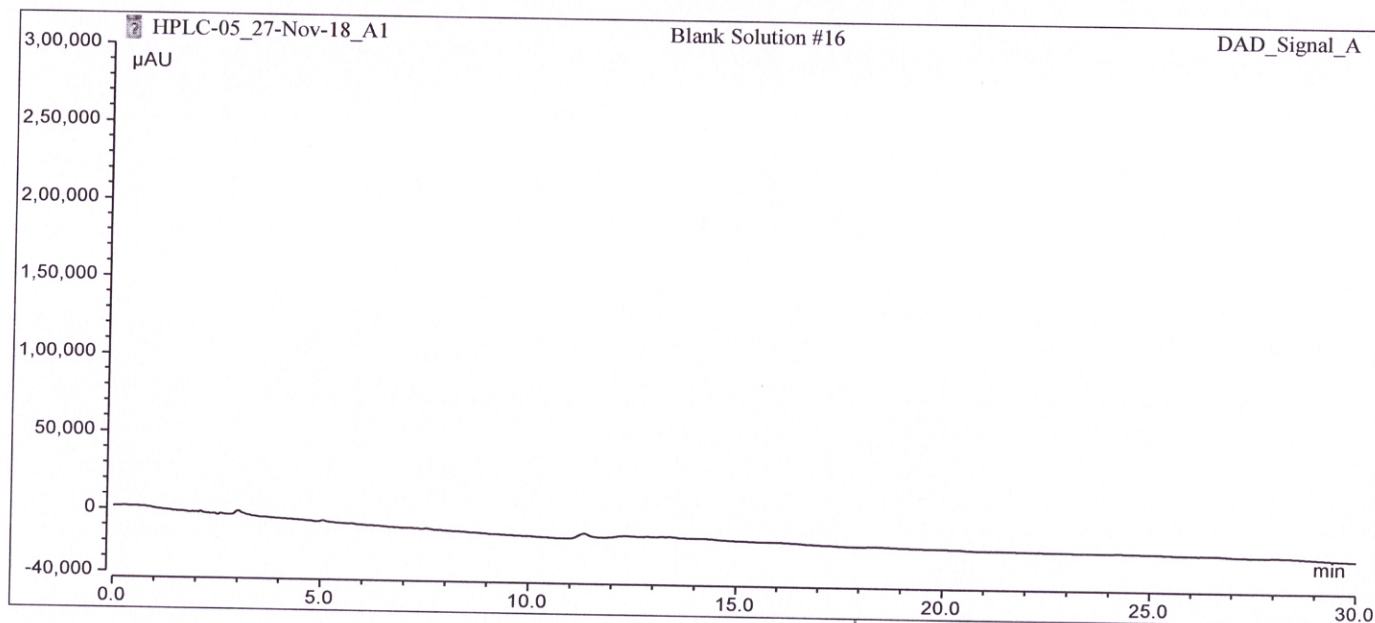
| Peak No. | Peak Name           | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|---------------------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
| 1        | Unknown             | 4.101         | 203.116      | 0.01   | 1.06               | 6233         | FALSE       | n.a.             |
| 2        | Placebo             | 4.581         | 8217.762     | 0.51   | 0.90               | 5687         | FALSE       | 2.13             |
| 3        | Hydrochlorothiazide | 5.108         | 786398.137   | 48.72  | 1.41               | 3463         | FALSE       | 1.78             |
| 4        | Unknown             | 7.887         | 156.283      | 0.01   | 1.23               | 13884        | FALSE       | 9.04             |
| 5        | Unknown             | 10.701        | 235.643      | 0.01   | 1.03               | 14680        | FALSE       | 9.06             |
| 6        | Impurity E          | 14.147        | 493.014      | 0.03   | 1.22               | 84225        | FALSE       | 12.57            |
| 7        | Ramipril            | 15.847        | 779142.027   | 48.27  | 1.78               | 19831        | FALSE       | 5.27             |
| 8        | Unknown             | 17.707        | 406.773      | 0.03   | 0.99               | 60921        | FALSE       | 5.05             |
| 9        | Unknown             | 18.494        | 392.450      | 0.02   | 1.09               | 58445        | FALSE       | 2.65             |
| 10       | Impurity D          | 23.888        | 38484.104    | 2.38   | 1.03               | 41965        | FALSE       | 13.96            |





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|                          |                                                                                                      |                                      |                                  |
|--------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------------------|
| Product Name :-          | Ramithiazide Tablet                                                                                  | Batch No. :-                         | N/A                              |
| Sample Name :-           | Blank Solution                                                                                       | AR. No. :-                           | D2404181193                      |
| Sample Number :-         | 16                                                                                                   | Instrument Method :-                 | HPLC-05_Ramithiazide Tablet_RS_M |
| Sample Type :-           | Unknown                                                                                              | Instrument Method Created By :-      | Gauri Rane                       |
| Injection Volume :-      | 30.00 µL                                                                                             | Instrument Method Created On :-      | 26-11-2018 15:21:29              |
| Vial Position :-         | Vial:1                                                                                               | Processing Method :-                 | Ramithiazide_RS_PR               |
| Column No. :-            | QbD/LC/COL/128                                                                                       | Processing Method Last Updated By :- | Gauri Rane                       |
| Instrument ID. :-        | QbD-INST-HPLC-05                                                                                     | Processing Method Last Updated On :- | 27-11-2018 11:11:44              |
| Injection Date & Time :- | 28-11-2018 00:28:09                                                                                  | Experiment Name:-                    | Intermediate precision           |
| Analyst :-               | Gauri Rane                                                                                           | Wavelength:-                         | n.a.                             |
| Sequence Path :-         | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                      |                                  |

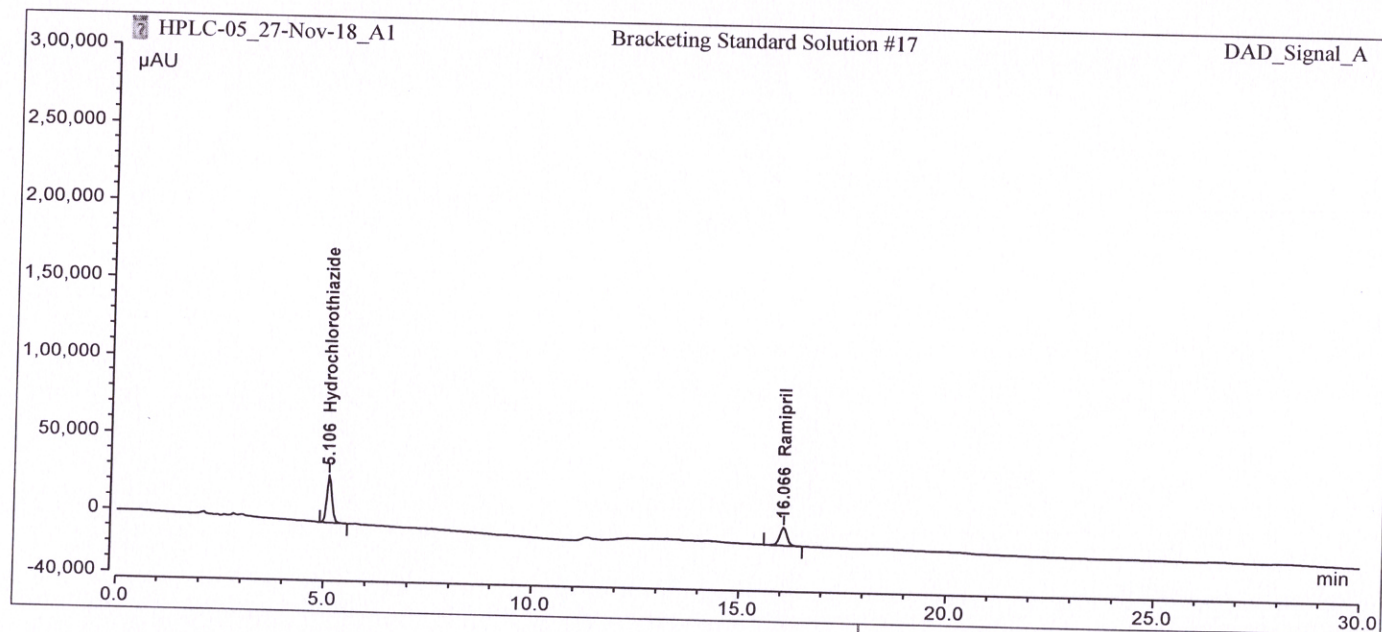


| Peak No. | Peak Name | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|-----------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
|----------|-----------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|



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|                          |                                                                                                      |                                      |                                  |
|--------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------------------|
| Product Name :-          | Ramithiazide Tablet                                                                                  | Batch No. :-                         | N/A                              |
| Sample Name :-           | Bracketing Standard Solution                                                                         | AR. No. :-                           | D2404181193                      |
| Sample Number :-         | 17                                                                                                   | Instrument Method :-                 | HPLC-05_Ramithiazide Tablet_RS_M |
| Sample Type :-           | Unknown                                                                                              | Instrument Method Created By :-      | Gauri Rane                       |
| Injection Volume :-      | 30.00 µL                                                                                             | Instrument Method Created On :-      | 26-11-2018 15:21:29              |
| Vial Position :-         | Vial:2                                                                                               | Processing Method :-                 | Ramithiazide_RS_PR2              |
| Column No. :-            | QbD/LC/COL/128                                                                                       | Processing Method Last Updated By :- | Gauri Rane                       |
| Instrument ID. :-        | QbD-INST-HPLC-05                                                                                     | Processing Method Last Updated On :- | 28-11-2018 09:59:24              |
| Injection Date & Time :- | 28-11-2018 01:00:05                                                                                  | Experiment Name:-                    | Intermediate precision           |
| Analyst :-               | Gauri Rane                                                                                           | Wavelength:-                         | n.a.                             |
| Sequence Path :-         | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                      |                                  |



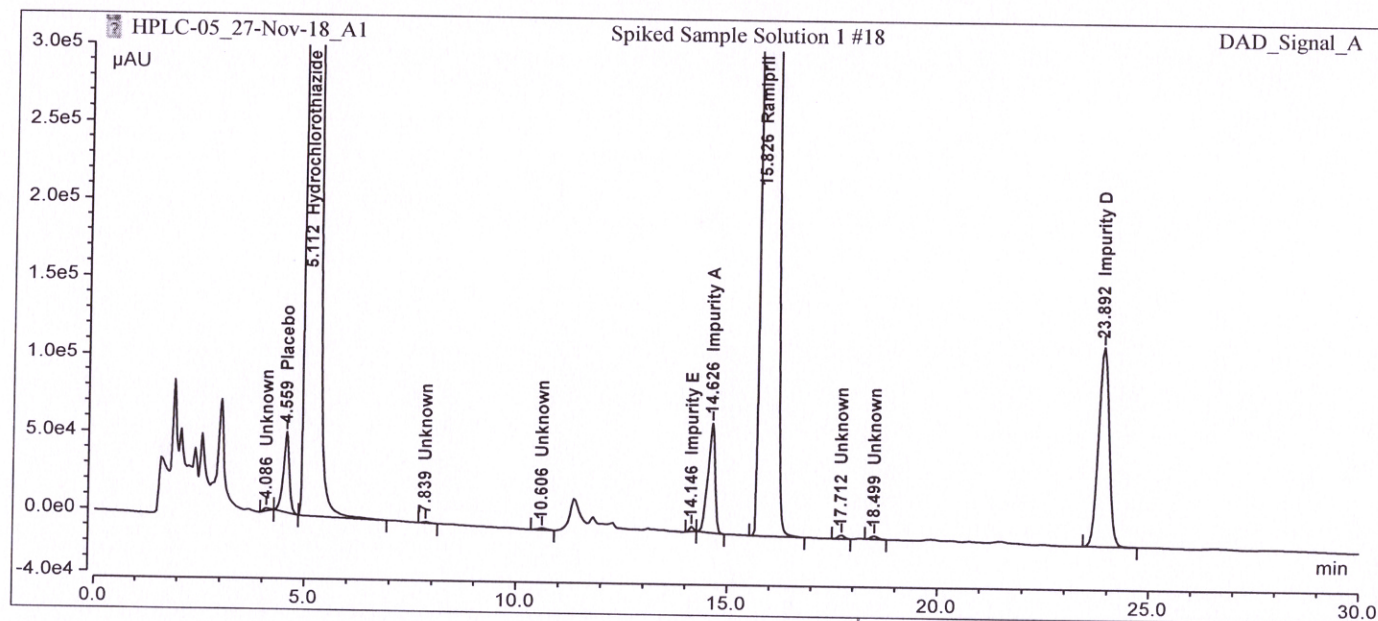
| Peak No. | Peak Name           | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|---------------------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
| 1        | Hydrochlorothiazide | 5.106         | 4386.357     | 64.62  | 1.20               | 8376         | FALSE       | n.a.             |
| 2        | Ramipril            | 16.066        | 2401.788     | 35.38  | 0.98               | 38726        | FALSE       | 39.87            |





## QBD RESEARCH AND DEVELOPMENT LAB PVT. LTD.

|                          |                                                                                                      |                                      |                                  |
|--------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------------------|
| Product Name :-          | Ramithiazide Tablet                                                                                  | Batch No. :-                         | GP180301                         |
| Sample Name :-           | Spiked Sample Solution 1                                                                             | AR. No. :-                           | D2404181193                      |
| Sample Number :-         | 18                                                                                                   | Instrument Method :-                 | HPLC-05_Ramithiazide Tablet_RS_M |
| Sample Type :-           | Unknown                                                                                              | Instrument Method Created By :-      | Gauri Rane                       |
| Injection Volume :-      | 30.00 µL                                                                                             | Instrument Method Created On :-      | 26-11-2018 15:21:29              |
| Vial Position :-         | Vial:10                                                                                              | Processing Method :-                 | Ramithiazide_RS_PR3              |
| Column No. :-            | QbD/LC/COL/128                                                                                       | Processing Method Last Updated By :- | Swaraj A. Jadhav                 |
| Instrument ID. :-        | QbD-INST-HPLC-05                                                                                     | Processing Method Last Updated On :- | 28-11-2018 15:09:53              |
| Injection Date & Time :- | 28-11-2018 01:32:03                                                                                  | Experiment Name:-                    | Intermediate precision           |
| Analyst :-               | Gauri Rane                                                                                           | Wavelength:-                         | n.a.                             |
| Sequence Path :-         | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                      |                                  |



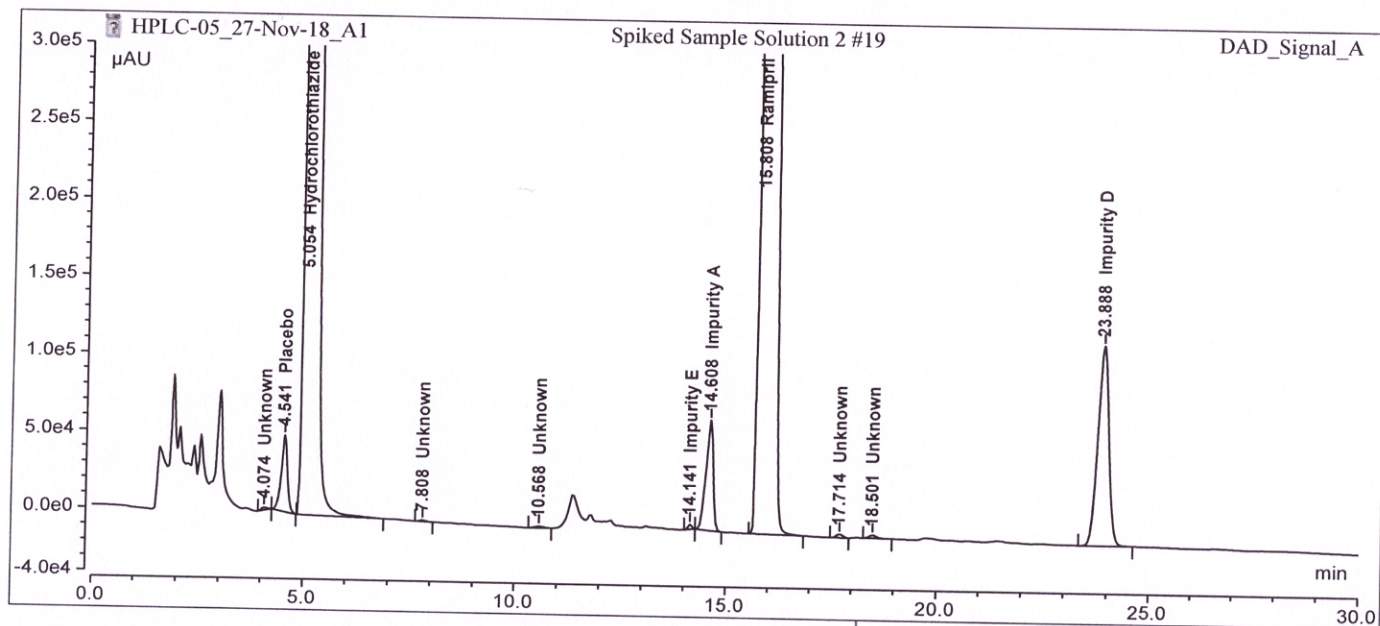
| Peak No. | Peak Name           | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|---------------------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
| 1        | Unknown             | 4.086         | 305.586      | 0.02   | 1.20               | 3961         | FALSE       | n.a.             |
| 2        | Placebo             | 4.559         | 8333.580     | 0.51   | 0.93               | 5806         | FALSE       | 1.90             |
| 3        | Hydrochlorothiazide | 5.112         | 787272.547   | 48.65  | 1.17               | 3512         | FALSE       | 1.89             |
| 4        | Unknown             | 7.839         | 163.970      | 0.01   | 1.35               | 12070        | FALSE       | 8.65             |
| 5        | Unknown             | 10.606        | 277.314      | 0.02   | 1.12               | 12019        | FALSE       | 8.23             |
| 6        | Impurity E          | 14.146        | 338.305      | 0.02   | 1.00               | 109817       | FALSE       | 12.69            |
| 7        | Impurity A          | 14.626        | 13885.160    | 0.86   | 0.82               | 33964        | FALSE       | 1.97             |
| 8        | Ramipril            | 15.826        | 769283.339   | 47.53  | 1.82               | 20274        | FALSE       | 3.15             |
| 9        | Unknown             | 17.712        | 407.102      | 0.03   | 1.01               | 62275        | FALSE       | 5.18             |
| 10       | Unknown             | 18.499        | 394.555      | 0.02   | 1.12               | 56023        | FALSE       | 2.64             |
| 11       | Impurity D          | 23.892        | 37699.615    | 2.33   | 1.03               | 41909        | FALSE       | 13.84            |





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|                          |                                                                                                      |                                      |                                  |
|--------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------------------|
| Product Name :-          | Ramithiazide Tablet                                                                                  | Batch No. :-                         | GP180301                         |
| Sample Name :-           | Spiked Sample Solution 2                                                                             | AR. No. :-                           | D2404181193                      |
| Sample Number :-         | 19                                                                                                   | Instrument Method :-                 | HPLC-05_Ramithiazide Tablet_RS_M |
| Sample Type :-           | Unknown                                                                                              | Instrument Method Created By :-      | Gauri Rane                       |
| Injection Volume :-      | 30.00 µL                                                                                             | Instrument Method Created On :-      | 26-11-2018 15:21:29              |
| Vial Position :-         | Vial:11                                                                                              | Processing Method :-                 | Ramithiazide_RS_PR3              |
| Column No. :-            | QbD/LC/COL/128                                                                                       | Processing Method Last Updated By :- | Swaraj A. Jadhav                 |
| Instrument ID. :-        | QbD-INST-HPLC-05                                                                                     | Processing Method Last Updated On :- | 28-11-2018 15:09:53              |
| Injection Date & Time :- | 28-11-2018 02:04:02                                                                                  | Experiment Name:-                    | Intermediate precision           |
| Analyst :-               | Gauri Rane                                                                                           | Wavelength:-                         | n.a.                             |
| Sequence Path :-         | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                      |                                  |



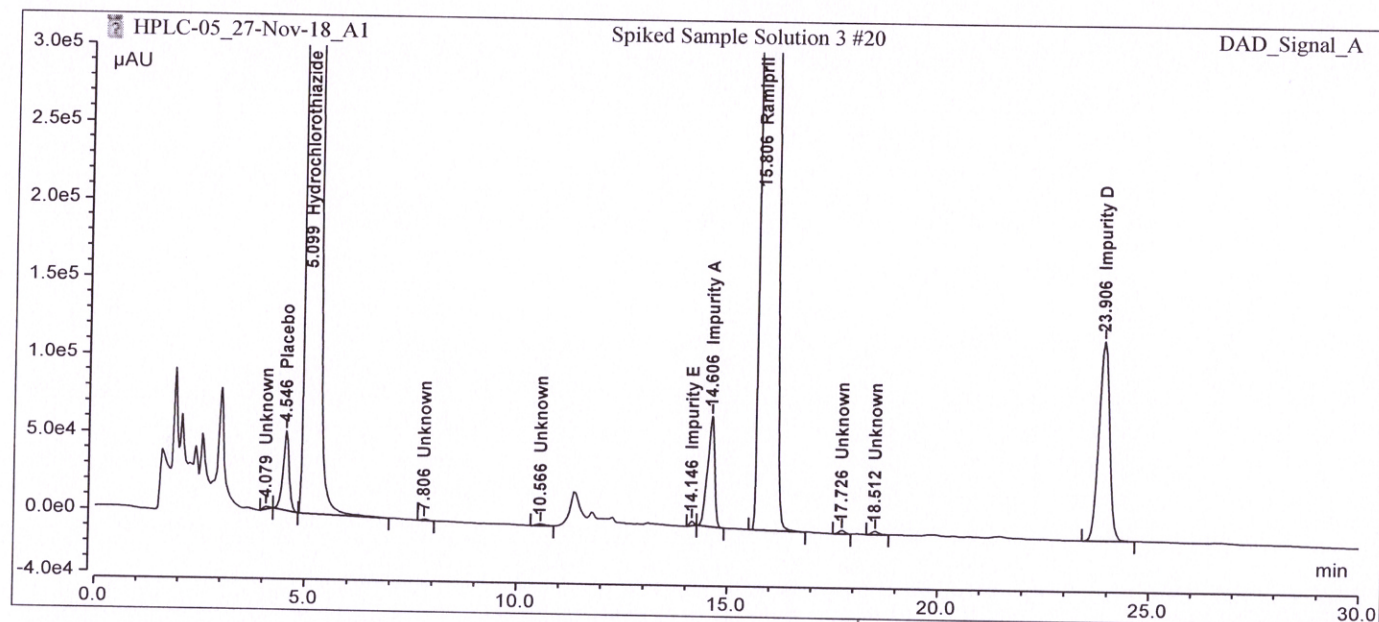
| Peak No. | Peak Name           | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|---------------------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
| 1        | Unknown             | 4.074         | 289.442      | 0.02   | 1.16               | 3851         | FALSE       | n.a.             |
| 2        | Placebo             | 4.541         | 8015.366     | 0.49   | 0.96               | 5605         | FALSE       | 1.85             |
| 3        | Hydrochlorothiazide | 5.054         | 793022.653   | 48.89  | 1.51               | 3412         | FALSE       | 1.74             |
| 4        | Unknown             | 7.808         | 152.576      | 0.01   | 1.24               | 13848        | FALSE       | 9.00             |
| 5        | Unknown             | 10.568        | 253.437      | 0.02   | 1.15               | 13432        | FALSE       | 8.76             |
| 6        | Impurity E          | 14.141        | 326.549      | 0.02   | 1.03               | 111022       | FALSE       | 13.37            |
| 7        | Impurity A          | 14.608        | 13809.477    | 0.85   | 0.83               | 33896        | FALSE       | 1.92             |
| 8        | Ramipril            | 15.808        | 767628.372   | 47.32  | 1.82               | 20457        | FALSE       | 3.16             |
| 9        | Unknown             | 17.714        | 402.539      | 0.02   | 1.01               | 62068        | FALSE       | 5.25             |
| 10       | Unknown             | 18.501        | 450.353      | 0.03   | 1.30               | 53222        | FALSE       | 2.60             |
| 11       | Impurity D          | 23.888        | 37713.929    | 2.33   | 1.03               | 41966        | FALSE       | 13.69            |





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|                          |                                                                                                      |                                      |                                  |
|--------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------------------|
| Product Name :-          | Ramithiazide Tablet                                                                                  | Batch No. :-                         | GP180301                         |
| Sample Name :-           | Spiked Sample Solution 3                                                                             | AR. No. :-                           | D2404181193                      |
| Sample Number :-         | 20                                                                                                   | Instrument Method :-                 | HPLC-05_Ramithiazide Tablet_RS_M |
| Sample Type :-           | Unknown                                                                                              | Instrument Method Created By :-      | Gauri Rane                       |
| Injection Volume :-      | 30.00 µL                                                                                             | Instrument Method Created On :-      | 26-11-2018 15:21:29              |
| Vial Position :-         | Vial:12                                                                                              | Processing Method :-                 | Ramithiazide_RS_PR3              |
| Column No. :-            | QbD/LC/COL/128                                                                                       | Processing Method Last Updated By :- | Swaraj A. Jadhav                 |
| Instrument ID. :-        | QbD-INST-HPLC-05                                                                                     | Processing Method Last Updated On :- | 28-11-2018 15:09:53              |
| Injection Date & Time :- | 28-11-2018 02:35:57                                                                                  | Experiment Name:-                    | Intermediate precision           |
| Analyst :-               | Gauri Rane                                                                                           | Wavelength:-                         | n.a.                             |
| Sequence Path :-         | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                      |                                  |



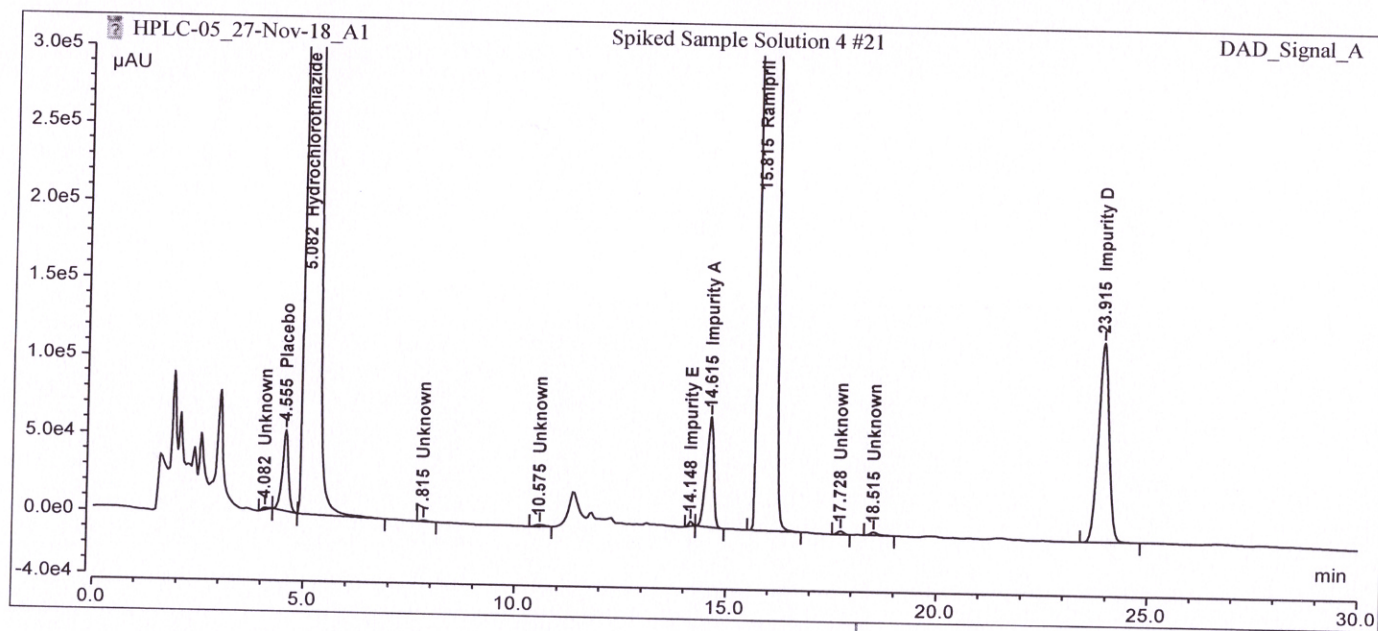
| Peak No. | Peak Name           | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|---------------------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
| 1        | Unknown             | 4.079         | 262.011      | 0.02   | 1.14               | 4217         | FALSE       | n.a.             |
| 2        | Placebo             | 4.546         | 8310.005     | 0.51   | 0.97               | 5652         | FALSE       | 1.89             |
| 3        | Hydrochlorothiazide | 5.099         | 797402.645   | 49.00  | 1.16               | 3457         | FALSE       | 1.88             |
| 4        | Unknown             | 7.806         | 139.538      | 0.01   | 1.21               | 14720        | FALSE       | 8.96             |
| 5        | Unknown             | 10.566        | 258.169      | 0.02   | 1.13               | 13318        | FALSE       | 8.85             |
| 6        | Impurity E          | 14.146        | 317.647      | 0.02   | 1.00               | 115424       | FALSE       | 13.44            |
| 7        | Impurity A          | 14.606        | 13847.524    | 0.85   | 0.83               | 33943        | FALSE       | 1.90             |
| 8        | Ramipril            | 15.806        | 768500.896   | 47.22  | 1.78               | 20468        | FALSE       | 3.16             |
| 9        | Unknown             | 17.726        | 410.204      | 0.03   | 1.04               | 57480        | FALSE       | 5.21             |
| 10       | Unknown             | 18.512        | 406.756      | 0.02   | 1.20               | 57654        | FALSE       | 2.60             |
| 11       | Impurity D          | 23.906        | 37568.801    | 2.31   | 1.02               | 42325        | FALSE       | 13.95            |





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|                          |                                                                                                      |                                      |                                  |
|--------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------------------|
| Product Name :-          | Ramithiazide Tablet                                                                                  | Batch No. :-                         | GP180301                         |
| Sample Name :-           | Spiked Sample Solution 4                                                                             | AR. No. :-                           | D2404181193                      |
| Sample Number :-         | 21                                                                                                   | Instrument Method :-                 | HPLC-05_Ramithiazide Tablet_RS_M |
| Sample Type :-           | Unknown                                                                                              | Instrument Method Created By :-      | Gauri Rane                       |
| Injection Volume :-      | 30.00 µL                                                                                             | Instrument Method Created On :-      | 26-11-2018 15:21:29              |
| Vial Position :-         | Vial:13                                                                                              | Processing Method :-                 | Ramithiazide_RS_PR3              |
| Column No. :-            | QbD/LC/COL/128                                                                                       | Processing Method Last Updated By :- | Swaraj A. Jadhav                 |
| Instrument ID. :-        | QbD-INST-HPLC-05                                                                                     | Processing Method Last Updated On :- | 28-11-2018 15:09:53              |
| Injection Date & Time :- | 28-11-2018 03:07:52                                                                                  | Experiment Name:-                    | Intermediate precision           |
| Analyst :-               | Gauri Rane                                                                                           | Wavelength:-                         | n.a.                             |
| Sequence Path :-         | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                      |                                  |



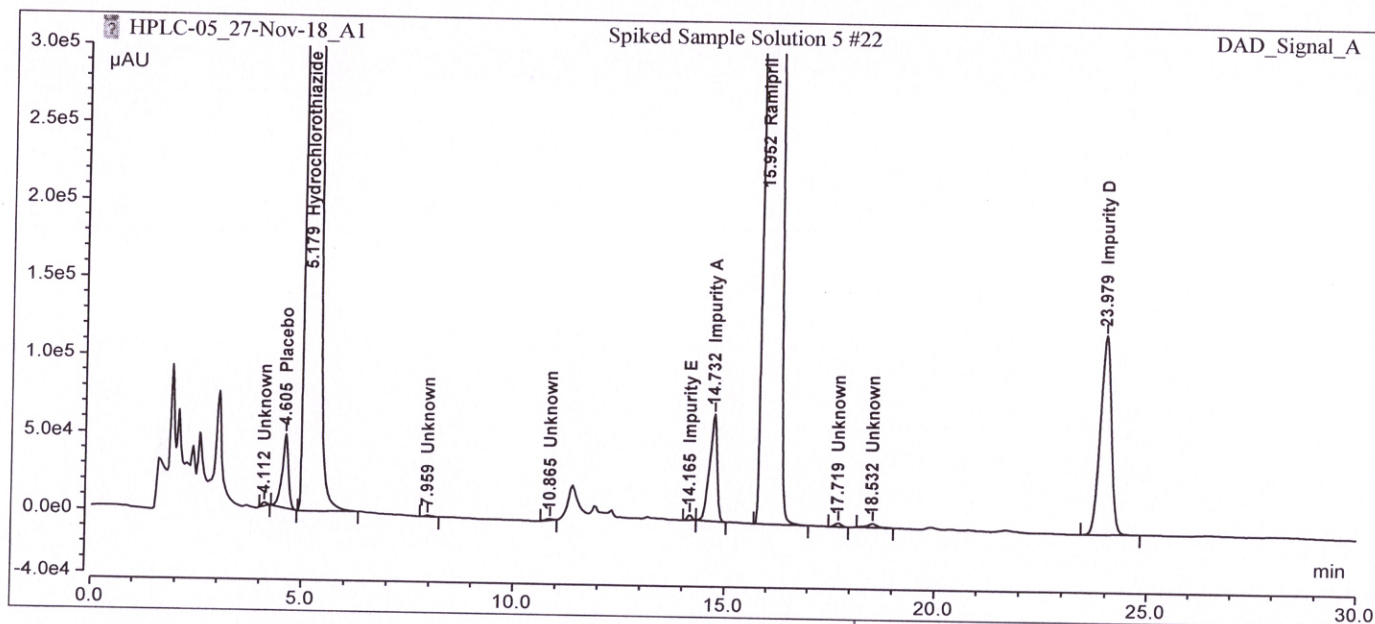
| Peak No. | Peak Name           | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|---------------------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
| 1        | Unknown             | 4.082         | 264.163      | 0.02   | 1.21               | 4094         | FALSE       | n.a.             |
| 2        | Placebo             | 4.555         | 8394.536     | 0.52   | 0.95               | 5758         | FALSE       | 1.91             |
| 3        | Hydrochlorothiazide | 5.082         | 794197.278   | 48.91  | 1.35               | 3488         | FALSE       | 1.80             |
| 4        | Unknown             | 7.815         | 138.533      | 0.01   | 1.36               | 14314        | FALSE       | 9.03             |
| 5        | Unknown             | 10.575        | 265.322      | 0.02   | 1.09               | 12742        | FALSE       | 8.68             |
| 6        | Impurity E          | 14.148        | 322.235      | 0.02   | 1.02               | 113401       | FALSE       | 13.17            |
| 7        | Impurity A          | 14.615        | 13918.926    | 0.86   | 0.82               | 33701        | FALSE       | 1.92             |
| 8        | Ramipril            | 15.815        | 767659.465   | 47.28  | 1.78               | 20739        | FALSE       | 3.17             |
| 9        | Unknown             | 17.728        | 404.330      | 0.02   | 1.03               | 60263        | FALSE       | 5.26             |
| 10       | Unknown             | 18.515        | 463.851      | 0.03   | 1.66               | 51870        | FALSE       | 2.56             |
| 11       | Impurity D          | 23.915        | 37720.256    | 2.32   | 1.04               | 42048        | FALSE       | 13.64            |





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|                          |                                                                                                      |                                      |                                  |
|--------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------------------|
| Product Name :-          | Ramithiazide Tablet                                                                                  | Batch No. :-                         | GP180301                         |
| Sample Name :-           | Spiked Sample Solution 5                                                                             | AR. No. :-                           | D2404181193                      |
| Sample Number :-         | 22                                                                                                   | Instrument Method :-                 | HPLC-05_Ramithiazide Tablet_RS_M |
| Sample Type :-           | Unknown                                                                                              | Instrument Method Created By :-      | Gauri Rane                       |
| Injection Volume :-      | 30.00 µL                                                                                             | Instrument Method Created On :-      | 26-11-2018 15:21:29              |
| Vial Position :-         | Vial:14                                                                                              | Processing Method :-                 | Ramithiazide_RS_PR3              |
| Column No. :-            | QbD/LC/COL/128                                                                                       | Processing Method Last Updated By :- | Swaraj A. Jadhav                 |
| Instrument ID. :-        | QbD-INST-HPLC-05                                                                                     | Processing Method Last Updated On :- | 28-11-2018 15:09:53              |
| Injection Date & Time :- | 28-11-2018 03:39:48                                                                                  | Experiment Name:-                    | Intermediate precision           |
| Analyst :-               | Gauri Rane                                                                                           | Wavelength:-                         | n.a.                             |
| Sequence Path :-         | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                      |                                  |



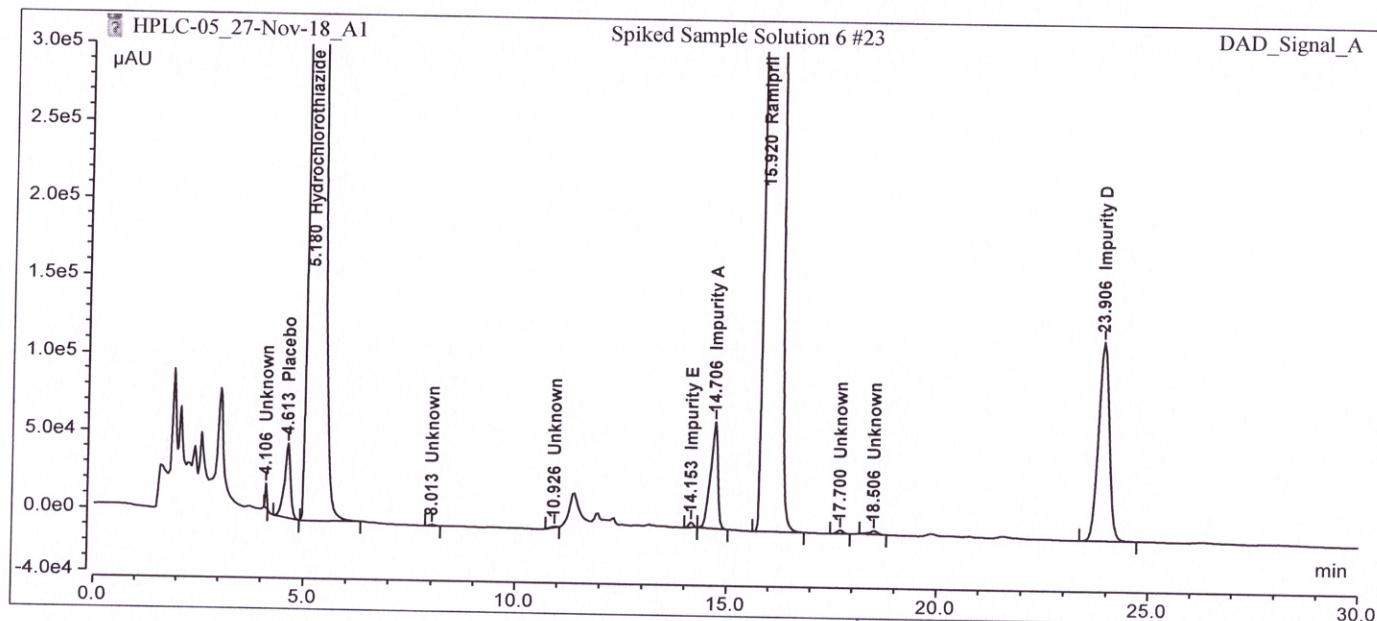
| Peak No. | Peak Name           | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|---------------------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
| 1        | Unknown             | 4.112         | 322.459      | 0.02   | 1.08               | 5467         | FALSE       | n.a.             |
| 2        | Placebo             | 4.605         | 7975.993     | 0.48   | 0.86               | 5675         | FALSE       | 2.11             |
| 3        | Hydrochlorothiazide | 5.179         | 799247.447   | 48.41  | 1.09               | 3566         | FALSE       | 1.94             |
| 4        | Unknown             | 7.959         | 162.639      | 0.01   | 1.18               | 12149        | FALSE       | 8.75             |
| 5        | Unknown             | 10.865        | 167.724      | 0.01   | 0.86               | 19973        | FALSE       | 9.75             |
| 6        | Impurity E          | 14.165        | 403.886      | 0.02   | 1.05               | 92897        | FALSE       | 13.38            |
| 7        | Impurity A          | 14.732        | 13979.825    | 0.85   | 0.80               | 35042        | FALSE       | 2.26             |
| 8        | Ramipril            | 15.952        | 789105.388   | 47.79  | 1.77               | 19478        | FALSE       | 3.16             |
| 9        | Unknown             | 17.719        | 427.310      | 0.03   | 1.02               | 59926        | FALSE       | 4.73             |
| 10       | Unknown             | 18.532        | 636.125      | 0.04   | 1.05               | 41120        | FALSE       | 2.48             |
| 11       | Impurity D          | 23.979        | 38654.979    | 2.34   | 1.02               | 40296        | FALSE       | 12.92            |





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|                                     |                                                                                                      |                                             |                                  |
|-------------------------------------|------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------------------|
| <b>Product Name :-</b>              | Ramithiazide Tablet                                                                                  | <b>Batch No. :-</b>                         | GP180301                         |
| <b>Sample Name :-</b>               | Spiked Sample Solution 6                                                                             | <b>AR. No. :-</b>                           | D2404181193                      |
| <b>Sample Number :-</b>             | 23                                                                                                   | <b>Instrument Method :-</b>                 | HPLC-05_Ramithiazide Tablet_RS_M |
| <b>Sample Type :-</b>               | Unknown                                                                                              | <b>Instrument Method Created By :-</b>      | Gauri Rane                       |
| <b>Injection Volume :-</b>          | 30.00 µL                                                                                             | <b>Instrument Method Created On :-</b>      | 26-11-2018 15:21:29              |
| <b>Vial Position :-</b>             | Vial:15                                                                                              | <b>Processing Method :-</b>                 | Ramithiazide_RS_PR3              |
| <b>Column No. :-</b>                | QbD/LC/COL/128                                                                                       | <b>Processing Method Last Updated By :-</b> | Swaraj A. Jadhav                 |
| <b>Instrument ID. :-</b>            | QbD-INST-HPLC-05                                                                                     | <b>Processing Method Last Updated On :-</b> | 28-11-2018 15:09:53              |
| <b>Injection Date &amp; Time :-</b> | 28-11-2018 04:11:43                                                                                  | <b>Experiment Name:-</b>                    | Intermediate precision           |
| <b>Analyst :-</b>                   | Gauri Rane                                                                                           | <b>Wavelength:-</b>                         | n.a.                             |
| <b>Sequence Path :-</b>             | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                             |                                  |



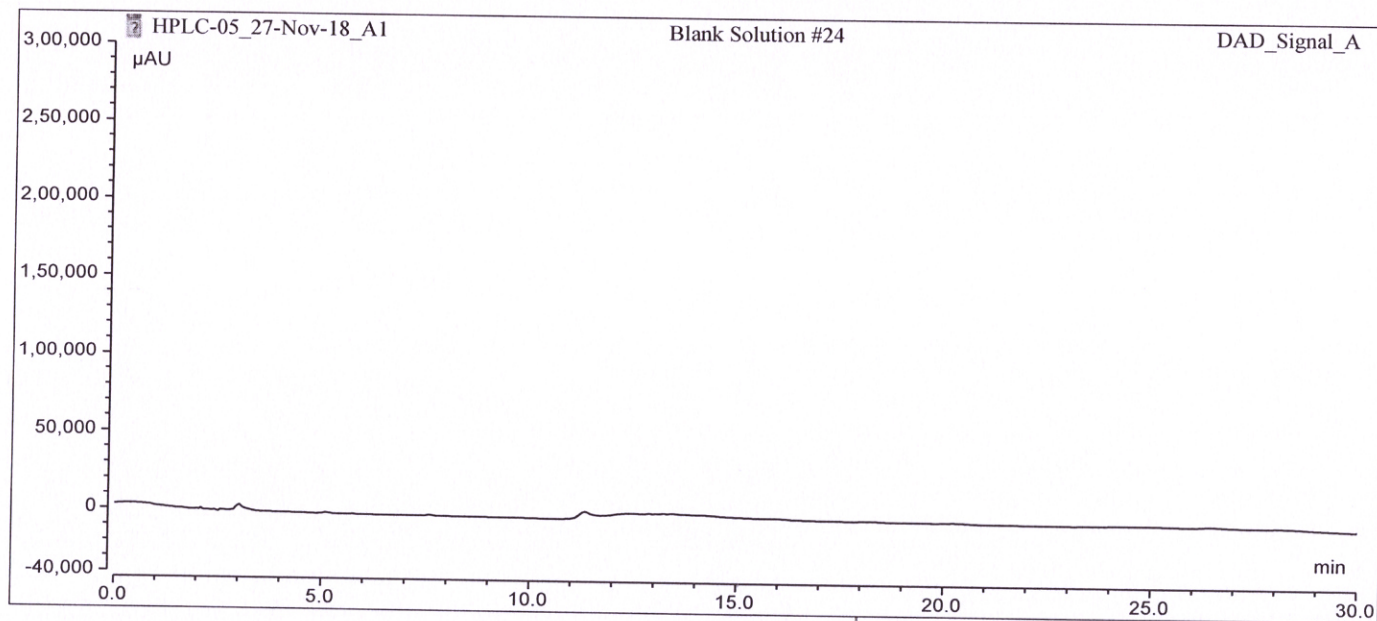
| Peak No. | Peak Name           | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|---------------------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
| 1        | Unknown             | 4.106         | 645.299      | 0.04   | 1.07               | n.a.         | FALSE       | n.a.             |
| 2        | Placebo             | 4.613         | 7819.784     | 0.47   | 0.88               | 5902         | FALSE       | n.a.             |
| 3        | Hydrochlorothiazide | 5.180         | 822188.654   | 49.15  | 1.30               | 3519         | FALSE       | 1.92             |
| 4        | Unknown             | 8.013         | 135.890      | 0.01   | 1.05               | 14904        | FALSE       | 9.26             |
| 5        | Unknown             | 10.926        | 112.735      | 0.01   | 0.76               | 25739        | FALSE       | 10.89            |
| 6        | Impurity E          | 14.153        | 401.431      | 0.02   | 0.99               | 97446        | FALSE       | 14.22            |
| 7        | Impurity A          | 14.706        | 13793.643    | 0.82   | 0.80               | 35404        | FALSE       | 2.24             |
| 8        | Ramipril            | 15.920        | 789181.907   | 47.17  | 1.82               | 19466        | FALSE       | 3.16             |
| 9        | Unknown             | 17.700        | 423.115      | 0.03   | 1.02               | 60343        | FALSE       | 4.78             |
| 10       | Unknown             | 18.506        | 486.654      | 0.03   | 0.83               | 49854        | FALSE       | 2.60             |
| 11       | Impurity D          | 23.906        | 37751.950    | 2.26   | 1.03               | 41729        | FALSE       | 13.51            |





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|                                     |                                                                                                      |                                             |                                  |
|-------------------------------------|------------------------------------------------------------------------------------------------------|---------------------------------------------|----------------------------------|
| <b>Product Name :-</b>              | Ramithiazide Tablet                                                                                  | <b>Batch No. :-</b>                         | N/A                              |
| <b>Sample Name :-</b>               | Blank Solution                                                                                       | <b>AR. No. :-</b>                           | D2404181193                      |
| <b>Sample Number :-</b>             | 24                                                                                                   | <b>Instrument Method :-</b>                 | HPLC-05_Ramithiazide Tablet_RS_M |
| <b>Sample Type :-</b>               | Unknown                                                                                              | <b>Instrument Method Created By :-</b>      | Gauri Rane                       |
| <b>Injection Volume :-</b>          | 30.00 µL                                                                                             | <b>Instrument Method Created On :-</b>      | 26-11-2018 15:21:29              |
| <b>Vial Position :-</b>             | Vial:1                                                                                               | <b>Processing Method :-</b>                 | Ramithiazide_RS_PR               |
| <b>Column No. :-</b>                | QbD/LC/COL/128                                                                                       | <b>Processing Method Last Updated By :-</b> | Gauri Rane                       |
| <b>Instrument ID. :-</b>            | QbD-INST-HPLC-05                                                                                     | <b>Processing Method Last Updated On :-</b> | 27-11-2018 11:11:44              |
| <b>Injection Date &amp; Time :-</b> | 28-11-2018 04:43:39                                                                                  | <b>Experiment Name:-</b>                    | Intermediate precision           |
| <b>Analyst :-</b>                   | Gauri Rane                                                                                           | <b>Wavelength:-</b>                         | n.a.                             |
| <b>Sequence Path :-</b>             | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                             |                                  |

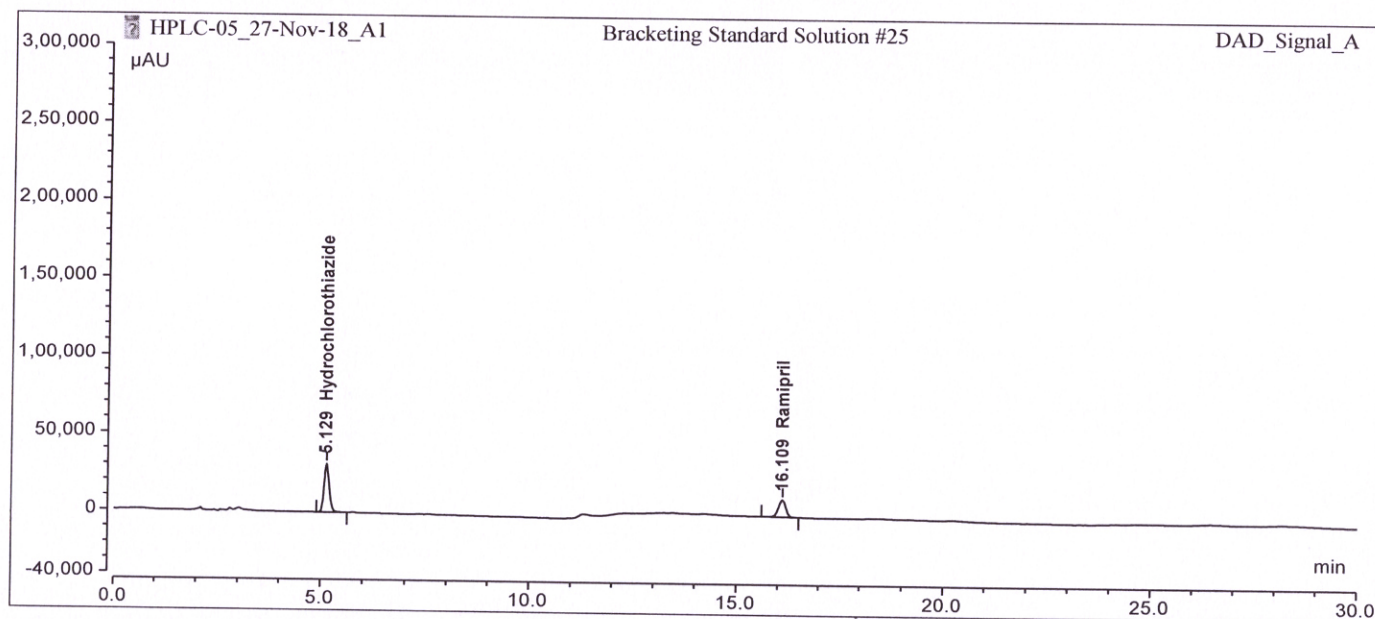


| Peak No. | Peak Name | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|-----------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
|----------|-----------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|



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|                          |                                                                                                      |                                      |                                  |
|--------------------------|------------------------------------------------------------------------------------------------------|--------------------------------------|----------------------------------|
| Product Name :-          | Ramithiazide Tablet                                                                                  | Batch No. :-                         | N/A                              |
| Sample Name :-           | Bracketing Standard Solution                                                                         | AR. No. :-                           | D2404181193                      |
| Sample Number :-         | 25                                                                                                   | Instrument Method :-                 | HPLC-05_Ramithiazide Tablet_RS_M |
| Sample Type :-           | Unknown                                                                                              | Instrument Method Created By :-      | Gauri Rane                       |
| Injection Volume :-      | 30.00 µL                                                                                             | Instrument Method Created On :-      | 26-11-2018 15:21:29              |
| Vial Position :-         | Vial:2                                                                                               | Processing Method :-                 | Ramithiazide_RS_PR2              |
| Column No. :-            | QbD/LC/COL/128                                                                                       | Processing Method Last Updated By :- | Gauri Rane                       |
| Instrument ID. :-        | QbD-INST-HPLC-05                                                                                     | Processing Method Last Updated On :- | 28-11-2018 09:59:24              |
| Injection Date & Time :- | 28-11-2018 05:15:39                                                                                  | Experiment Name:-                    | Intermediate precision           |
| Analyst :-               | Gauri Rane                                                                                           | Wavelength:-                         | n.a.                             |
| Sequence Path :-         | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                      |                                  |



| Peak No. | Peak Name           | Ret. Time min | Area µAU*min | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|---------------------|---------------|--------------|--------|--------------------|--------------|-------------|------------------|
| 1        | Hydrochlorothiazide | 5.129         | 4407.743     | 65.40  | 1.18               | 8774         | FALSE       | n.a.             |
| 2        | Ramipril            | 16.109        | 2331.641     | 34.60  | 0.94               | 38059        | FALSE       | 39.98            |





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|                                     |                                                                                                      |                                             |                          |
|-------------------------------------|------------------------------------------------------------------------------------------------------|---------------------------------------------|--------------------------|
| <b>Product Name :-</b>              |                                                                                                      | <b>Batch No. :-</b>                         | N/A                      |
| <b>Sample Name :-</b>               | Shut                                                                                                 | <b>AR. No. :-</b>                           | D2404181193              |
| <b>Sample Number :-</b>             | 26                                                                                                   | <b>Instrument Method :-</b>                 | Shut method _HPLC 05 new |
| <b>Sample Type :-</b>               | Unknown                                                                                              | <b>Instrument Method Created By :-</b>      | Santosh K Padmere        |
| <b>Injection Volume :-</b>          | 30.00 µL                                                                                             | <b>Instrument Method Created On :-</b>      | 25-04-2017 16:43:57      |
| <b>Vial Position :-</b>             | Vial:1                                                                                               | <b>Processing Method :-</b>                 | Ramithiazide_RS_PR       |
| <b>Column No. :-</b>                | QbD/LC/COL/128                                                                                       | <b>Processing Method Last Updated By :-</b> | Gauri Rane               |
| <b>Instrument ID. :-</b>            | QbD-INST-HPLC-05                                                                                     | <b>Processing Method Last Updated On :-</b> | 27-11-2018 11:11:44      |
| <b>Injection Date &amp; Time :-</b> | 28-11-2018 05:46:53                                                                                  | <b>Experiment Name:-</b>                    | Intermediate precision   |
| <b>Analyst :-</b>                   | Gauri Rane                                                                                           | <b>Wavelength:-</b>                         | n.a.                     |
| <b>Sequence Path :-</b>             | Method Validation\Generic Healthcare\Ramithiazide Tablet\Related Substances\HPLC-05_27-Nov-18_A1.seq |                                             |                          |

Channel DAD\_Signal\_A is not available for injection #26 - Shut.

| Peak No. | Peak Name | Ret. Time min | Area n.a. | Area % | Asymmetry (EP/USP) | Plates (USP) | Manipulated | Resolution (USP) |
|----------|-----------|---------------|-----------|--------|--------------------|--------------|-------------|------------------|
|----------|-----------|---------------|-----------|--------|--------------------|--------------|-------------|------------------|