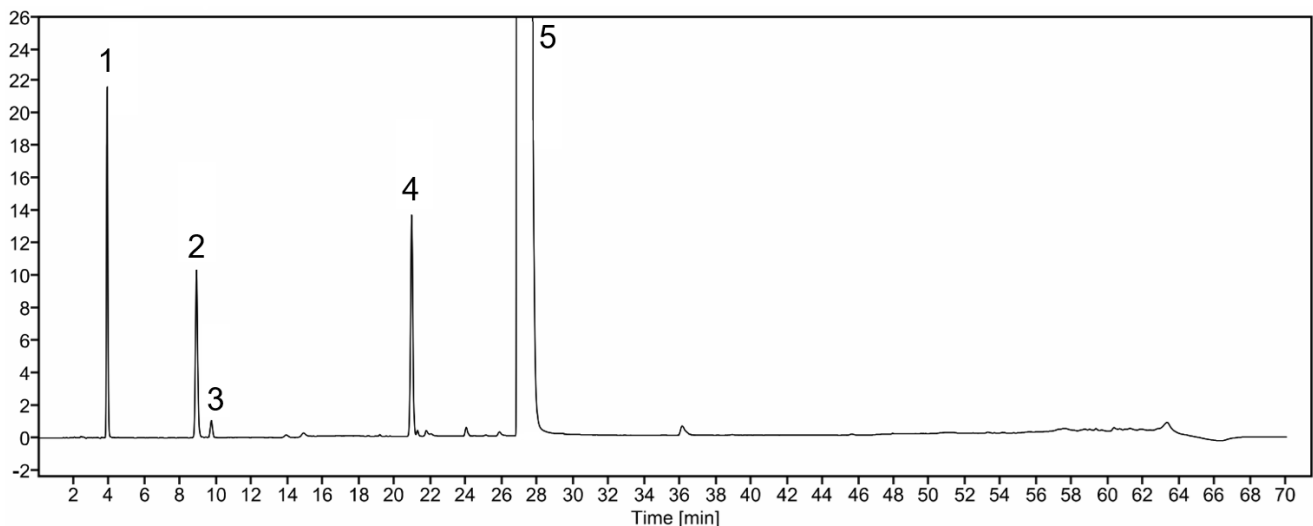


## Chlorhexidine Gluconate Dental Gel – BP 2024

These chromatograms are provided for information only as an aid to analysts and are intended as guidance for the interpretation and application of BP monographs.

Example chromatogram for solution (4) during method development (without impurity H) illustrating SST requirements in the Related Substances test for Chlorhexidine Gluconate Dental Gel as published in BP 2024.

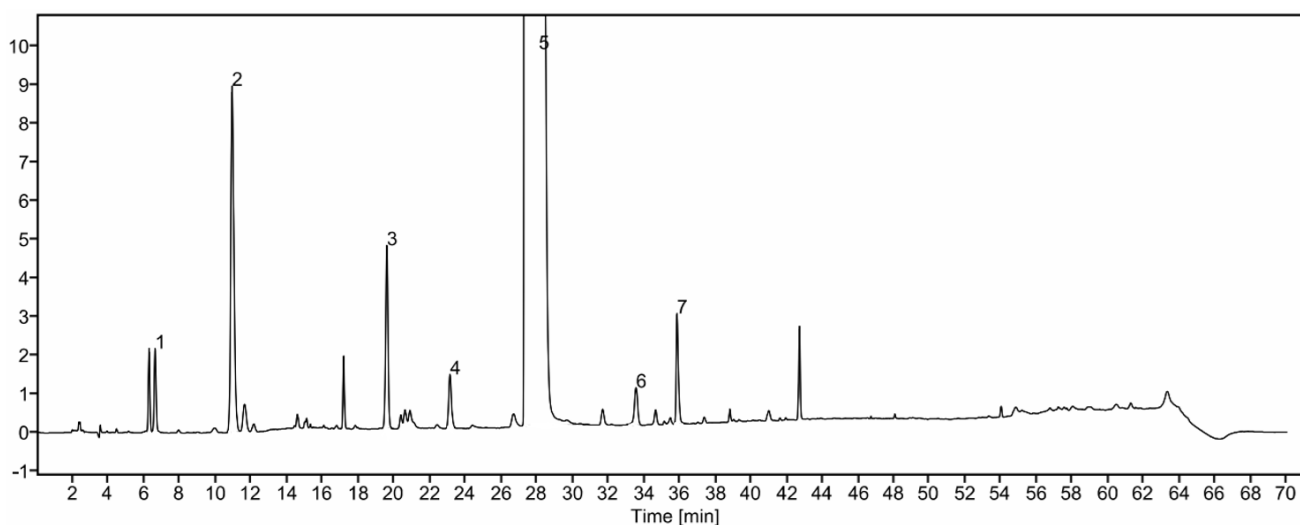


Peak ID: 1: Impurity 1; 2: Impurity 2; 3: Impurity P; 4: Impurity F; 5: Chlorhexidine

|                       |                                                                                      |
|-----------------------|--------------------------------------------------------------------------------------|
| <b>Column</b>         | Dr. Maisch, ReproSil-Pur Basic C18 (250 mm x 4.6 mm, 5 µm)                           |
| <b>Method Ref.</b>    | Related Substances for the Chlorhexidine Gluconate Dental Gel monograph from BP 2024 |
| <b>Buffer</b>         | 10% v/v Trifluoroacetic acid in acetonitrile                                         |
| <b>Mobile Phase A</b> | Buffer: acetonitrile: water (1.9:180:820, v/v)                                       |
| <b>Mobile Phase B</b> | Buffer: water: acetonitrile (0.2:200:800, v/v/v)                                     |
| <b>Diluent</b>        | Mobile phase A                                                                       |

|                         |                       |                               |                               |                  |
|-------------------------|-----------------------|-------------------------------|-------------------------------|------------------|
| <b>Flow rate</b>        | 1.0 mL/min            |                               |                               |                  |
| <b>Column Temp</b>      | 40 °C                 |                               |                               |                  |
| <b>Injection Volume</b> | 25 µL                 |                               |                               |                  |
| <b>Detection</b>        | 250 nm                |                               |                               |                  |
| <b>Gradient</b>         | <b>Time (minutes)</b> | <b>Mobile phase A (% v/v)</b> | <b>Mobile phase B (% v/v)</b> | <b>Comment</b>   |
|                         | 0 – 10                | 100                           | 0                             | isocratic        |
|                         | 10 – 14               | 100 → 85                      | 0 → 15                        | linear gradient  |
|                         | 14 – 43               | 85 → 75                       | 15 → 25                       | linear gradient  |
|                         | 43 – 54               | 75 → 0                        | 25 → 100                      | linear gradient  |
|                         | 54 – 60               | 0                             | 100                           | isocratic        |
|                         | 60 – 62               | 0 → 100                       | 100 → 0                       | linear gradient  |
|                         | 62 – 70               | 100                           | 0                             | re-equilibration |

Typical chromatogram for solution (5) in the Related Substances test for Chlorhexidine Gluconate Dental Gel as published in BP 2024.



Peak ID: 1: Impurity G; 2: Impurity N; 3: Impurity F; 4: Impurity O; 5: Chlorhexidine; 6: Impurity J; 7: Impurity K

|                         |                                                                                      |                               |                               |                  |
|-------------------------|--------------------------------------------------------------------------------------|-------------------------------|-------------------------------|------------------|
| <b>Column</b>           | Dr. Maisch, ReproSil-Pur Basic C18 (250 mm x 4.6 mm, 5 µm)                           |                               |                               |                  |
| <b>Method Ref.</b>      | Related Substances for the Chlorhexidine Gluconate Dental Gel monograph from BP 2024 |                               |                               |                  |
| <b>Buffer</b>           | 10% v/v Trifluoroacetic acid in acetonitrile                                         |                               |                               |                  |
| <b>Mobile Phase A</b>   | Buffer: acetonitrile: water (1.9:180:820, v/v)                                       |                               |                               |                  |
| <b>Mobile Phase B</b>   | Buffer: water: acetonitrile (0.2:200:800, v/v/v)                                     |                               |                               |                  |
| <b>Diluent</b>          | Mobile phase A                                                                       |                               |                               |                  |
| <b>Flow rate</b>        | 1.0 mL/min                                                                           |                               |                               |                  |
| <b>Column Temp</b>      | 40 °C                                                                                |                               |                               |                  |
| <b>Injection Volume</b> | 25 µL                                                                                |                               |                               |                  |
| <b>Detection</b>        | 250 nm                                                                               |                               |                               |                  |
| <b>Gradient</b>         | <b>Time (minutes)</b>                                                                | <b>Mobile phase A (% v/v)</b> | <b>Mobile phase B (% v/v)</b> | <b>Comment</b>   |
|                         | 0 – 10                                                                               | 100                           | 0                             | isocratic        |
|                         | 10 – 14                                                                              | 100 → 85                      | 0 → 15                        | linear gradient  |
|                         | 14 – 43                                                                              | 85 → 75                       | 15 → 25                       | linear gradient  |
|                         | 43 – 54                                                                              | 75 → 0                        | 25 → 100                      | linear gradient  |
|                         | 54 – 60                                                                              | 0                             | 100                           | isocratic        |
|                         | 60 – 62                                                                              | 0 → 100                       | 100 → 0                       | linear gradient  |
|                         | 62 – 70                                                                              | 100                           | 0                             | re-equilibration |