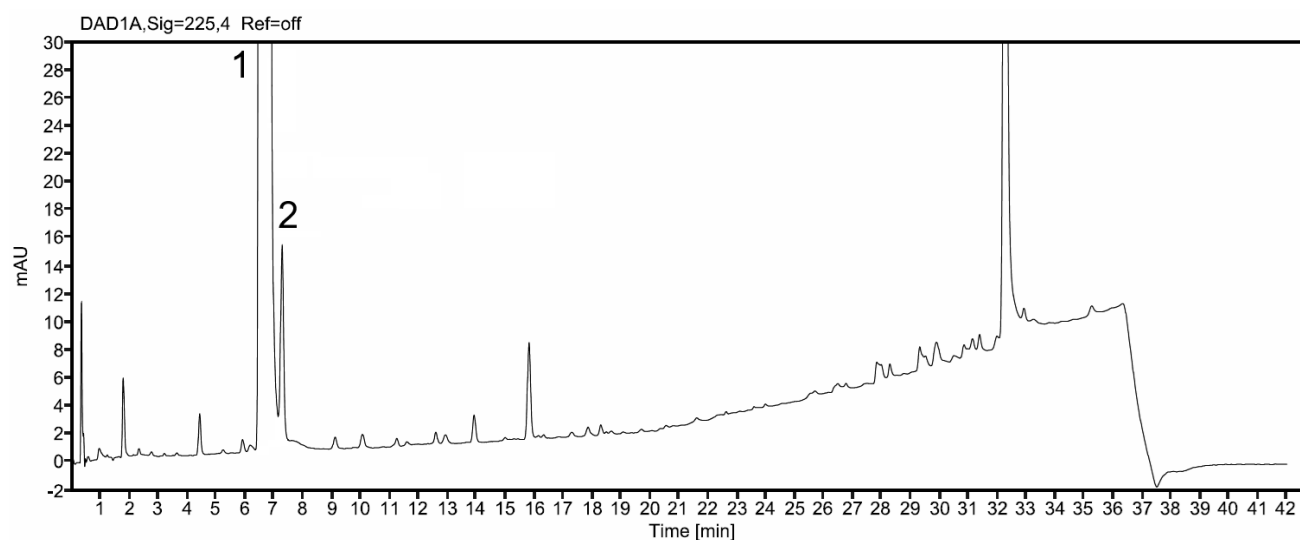




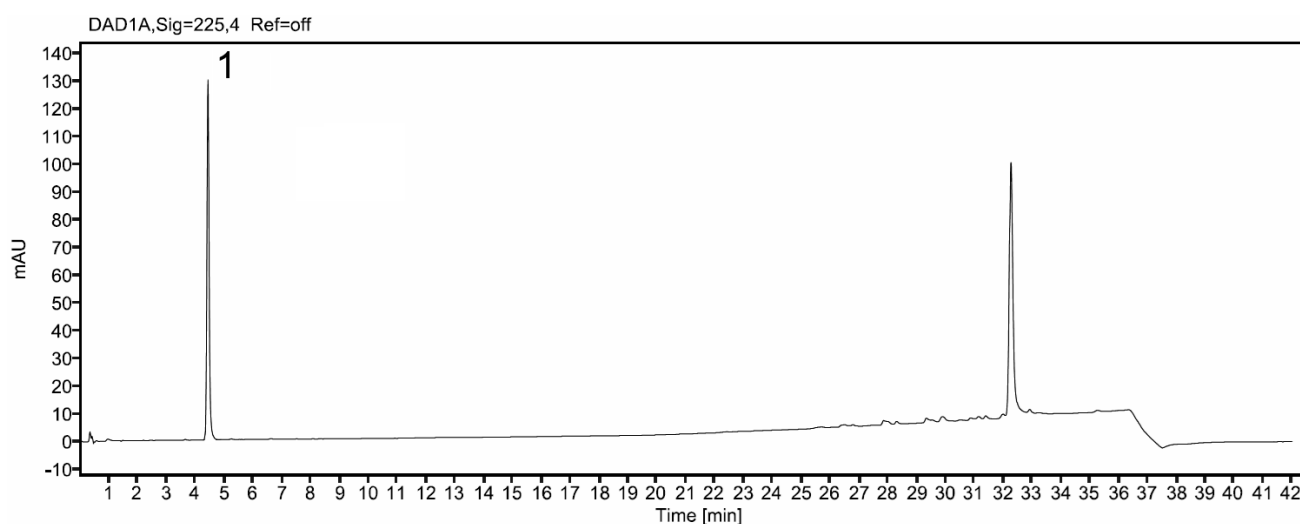
## Melatonin Capsules – BP 2027

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.

Typical chromatogram for solution (3) from the Related Substances test for Melatonin Capsules as published in BP 2027.



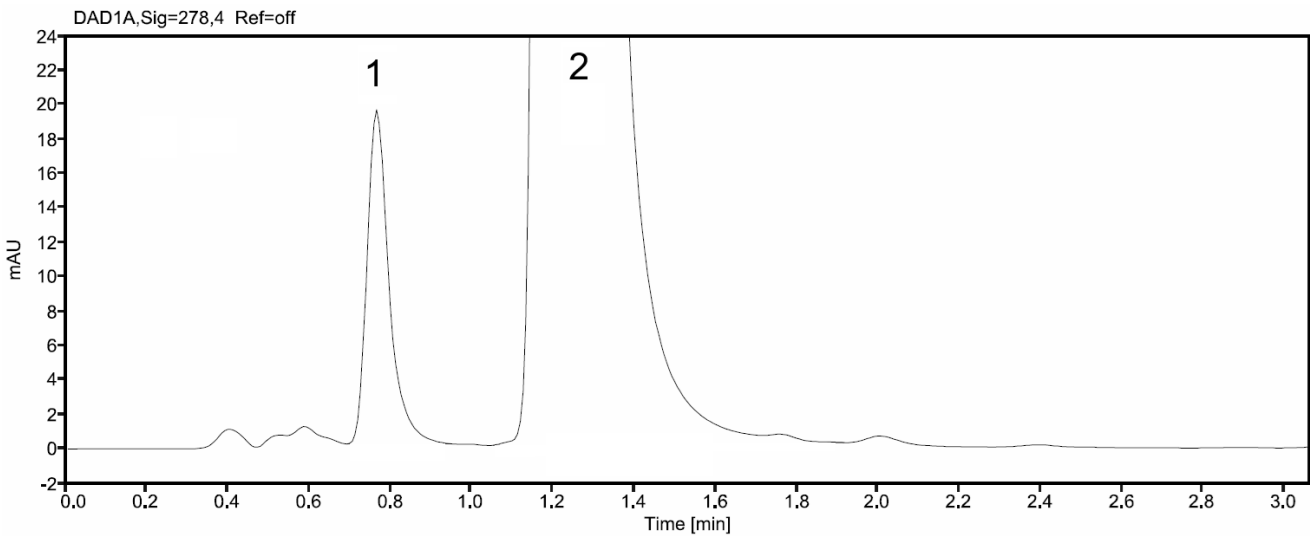
Peak ID: 1: Melatonin. 2: Impurity D.



Peak ID: 1: AFMK.

|                  |                                                                                               |                        |                  |
|------------------|-----------------------------------------------------------------------------------------------|------------------------|------------------|
| Column           | Eclipse Plus C18 (50 mm x 4.6 mm, 1.8 μm)                                                     |                        |                  |
| Method Ref.      | Related Substances for the Melatonin Capsules monograph from BP 2027                          |                        |                  |
| Buffer           | 2.45 g/L potassium dihydrogen orthophosphate adjusted to pH 3.0 with 85% orthophosphoric acid |                        |                  |
| Mobile Phase A   | Acetonitrile: buffer (80:20, v/v)                                                             |                        |                  |
| Mobile Phase B   | Buffer                                                                                        |                        |                  |
| Diluent          | Acetonitrile: water (20:80, v/v)                                                              |                        |                  |
| Flow rate        | 1.5 mL/min                                                                                    |                        |                  |
| Column Temp      | 25°C                                                                                          |                        |                  |
| Injection Volume | 10 μL                                                                                         |                        |                  |
| Detection        | 225 nm                                                                                        |                        |                  |
| Gradient         |                                                                                               |                        |                  |
| Time (minutes)   | Mobile phase A (% v/v)                                                                        | Mobile phase B (% v/v) | Comment          |
| 0 – 20           | 12.5 → 37.5                                                                                   | 87.5 → 62.5            | linear gradient  |
| 20 – 36          | 37.5 → 87.5                                                                                   | 62.5 → 12.5            | linear gradient  |
| 36 – 39          | 87.5 → 12.5                                                                                   | 12.5 → 87.5            | linear gradient  |
| 39 – 42          | 12.5                                                                                          | 87.5                   | re-equilibration |

Typical chromatogram for solution (3) from the Assay test for Melatonin Capsules as published in BP 2027.



Peak ID: 1: AFMK. 2: Melatonin.

|                  |                                                                                          |
|------------------|------------------------------------------------------------------------------------------|
| Column           | XBridge C18 (50 mm x 3.0 mm, 2.5 µm)                                                     |
| Method Ref.      | Assay for the Melatonin Capsules monograph from BP 2027                                  |
| Buffer           | 0.5 g/L potassium dihydrogen orthophosphate adjusted to pH 3.5 with orthophosphoric acid |
| Mobile Phase     | Acetonitrile: buffer (25:75, v/v)                                                        |
| Diluent          | Mobile phase                                                                             |
| Flow rate        | 0.6 mL/min                                                                               |
| Column Temp      | 25°C                                                                                     |
| Injection Volume | 10 µL                                                                                    |
| Detection        | 278 nm                                                                                   |