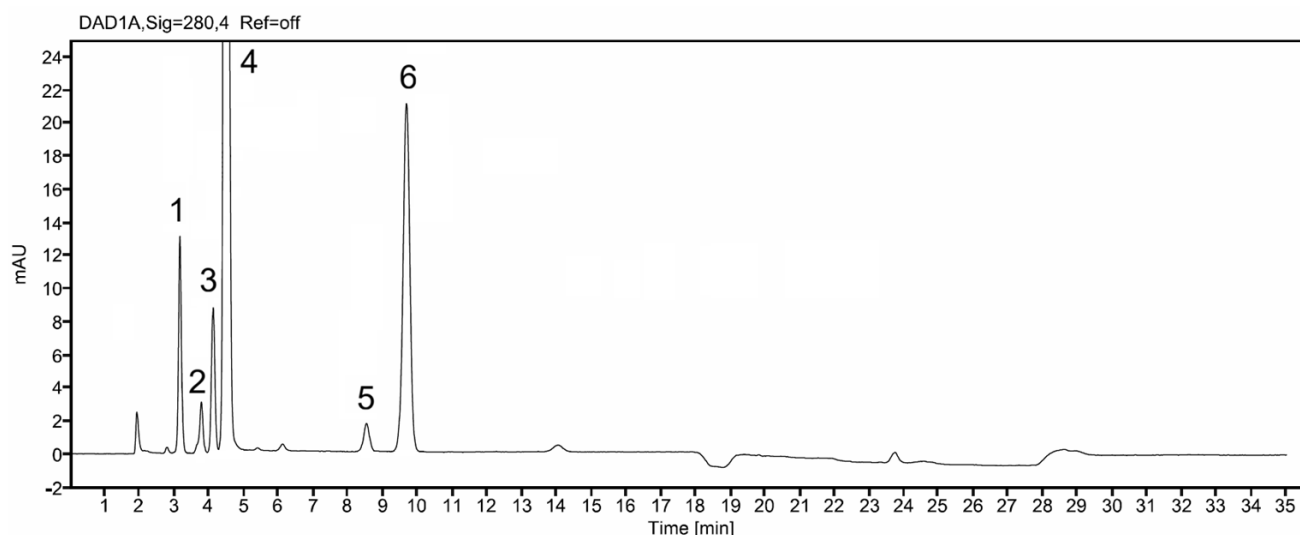




Co-careldopa Prolonged-release Tablets – BP 2027

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 Co-careldopa Prolonged-release Tablets as published in BP 2027.

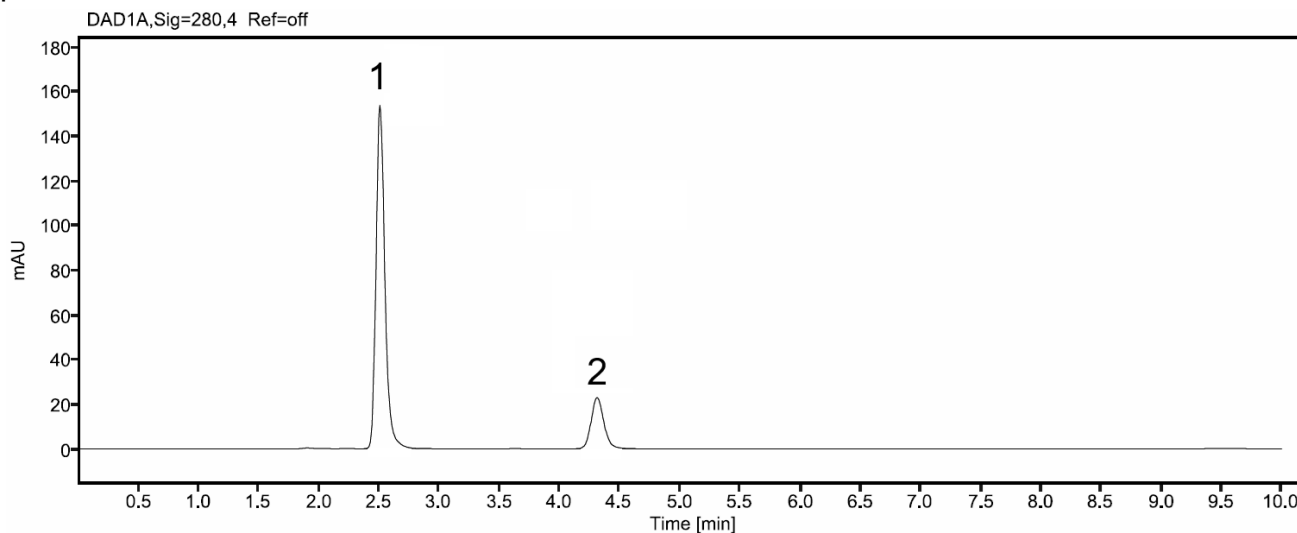


Peak ID: 1: Levodopa Impurity B. 2: Carbidopa Impurity A. 3: Levodopa Impurity C. 4: Carbidopa. 5: Carbidopa Impurity 1. 6: Carbidopa Impurity G.

Column	YMC Pack ODS-A C18 (150 mm x 4.6 mm, 5 µm)
Method Ref.	Related Substances for the Co-careldopa Tablets monograph from BP 2027
Buffer	0.05M anhydrous sodium dihydrogen orthophosphate adjusted to pH 2.2 with orthophosphoric acid
Mobile Phase A	Ethanol (96%): buffer (5:95, v/v)
Mobile Phase B	Ethanol (96%)
Diluent	Mobile phase A

Flow rate	1.0 mL/min		
Column Temp	25°C		
Injection Volume	20 µL		
Detection	280 nm		
Gradient			
Time (minutes)	Mobile phase A (% v/v)	Mobile phase B (% v/v)	Comment
0 – 15	100	0	isocratic
15 – 16	100 → 90	0 → 10	linear gradient
16 – 25	90	10	isocratic
25 – 26	90 → 100	10 → 0	linear gradient
26 - 35	100	0	re-equilibration

Typical chromatogram for solution (3) from the Assay test for Co-careldopa Tablets as published in BP 2027.

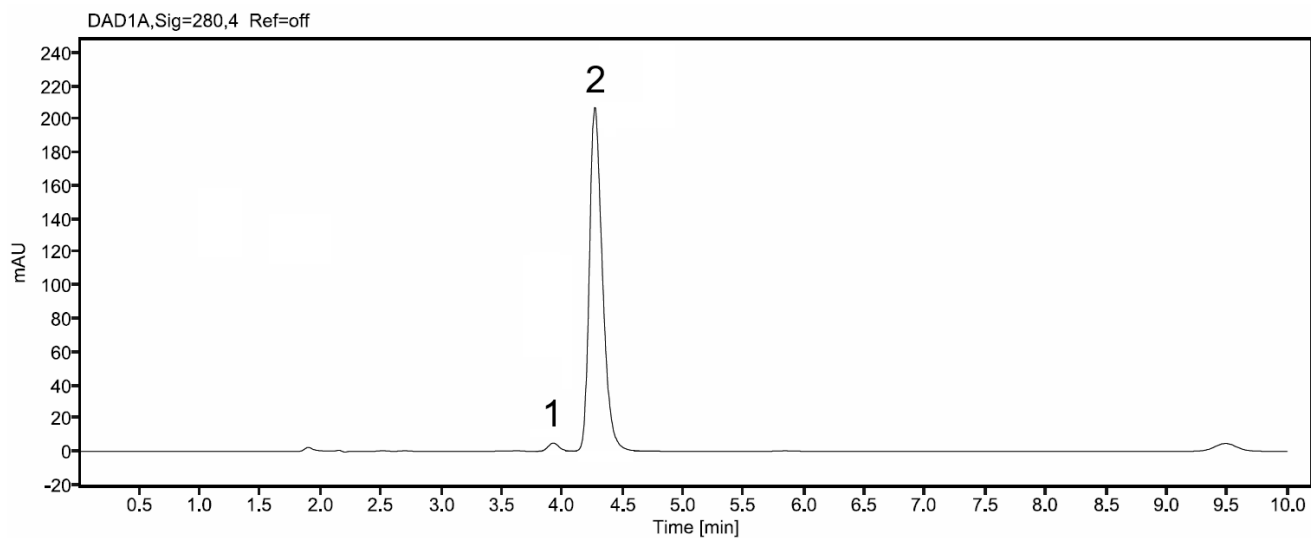


Peak ID: 1: Levodopa. 2: Carbidopa.

Column	YMC Pack ODS-A C18 (150 mm x 4.6 mm, 5 µm)
Method Ref.	Assay for the Co-careldopa Tablets monograph from BP 2027
Buffer	0.05M anhydrous sodium dihydrogen orthophosphate adjusted to pH 2.2 with orthophosphoric acid

Mobile Phase	Ethanol: buffer (5:95, v/v)
Diluent	Mobile phase
Flow rate	1.0 mL/min
Column Temp	25°C
Injection Volume	20 µL
Detection	280 nm

Typical chromatogram for solution (4) from the Assay test for Co-careldopa Tablets as published in BP 2027.

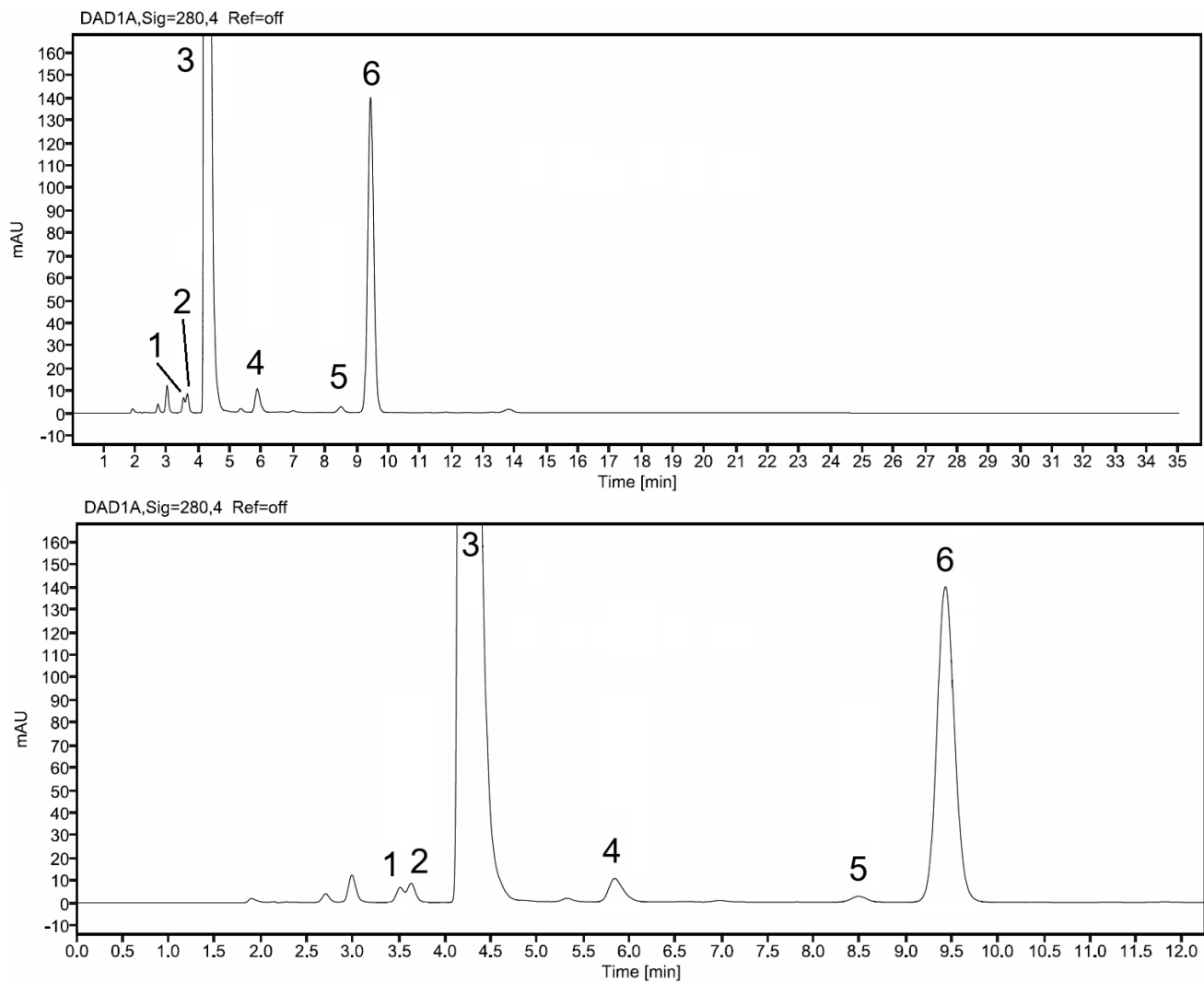


Peak ID: 1: Levodopa Impurity C. 2: Carbidopa.

Column	YMC Pack ODS-A C18 (150 mm x 4.6 mm, 5 µm)
Method Ref.	Assay for the Co-careldopa Tablets monograph from BP 2027
Buffer	0.05M anhydrous sodium dihydrogen orthophosphate adjusted to pH 2.2 with orthophosphoric acid
Mobile Phase	Ethanol: buffer (5:95, v/v)
Diluent	Mobile phase
Flow rate	1.0 mL/min
Column Temp	25°C
Injection Volume	20 µL
Detection	280 nm

The following chromatograms were generated under the described conditions to aid in the assignment of unknown impurity peaks to either the Carbidopa or Levodopa drug substance. The solutions described below do not correspond to a numbered solution in the monograph.

Typical chromatogram of a 0.1% w/v solution of Carbidopa after being stored at ambient temperature for 4 weeks.

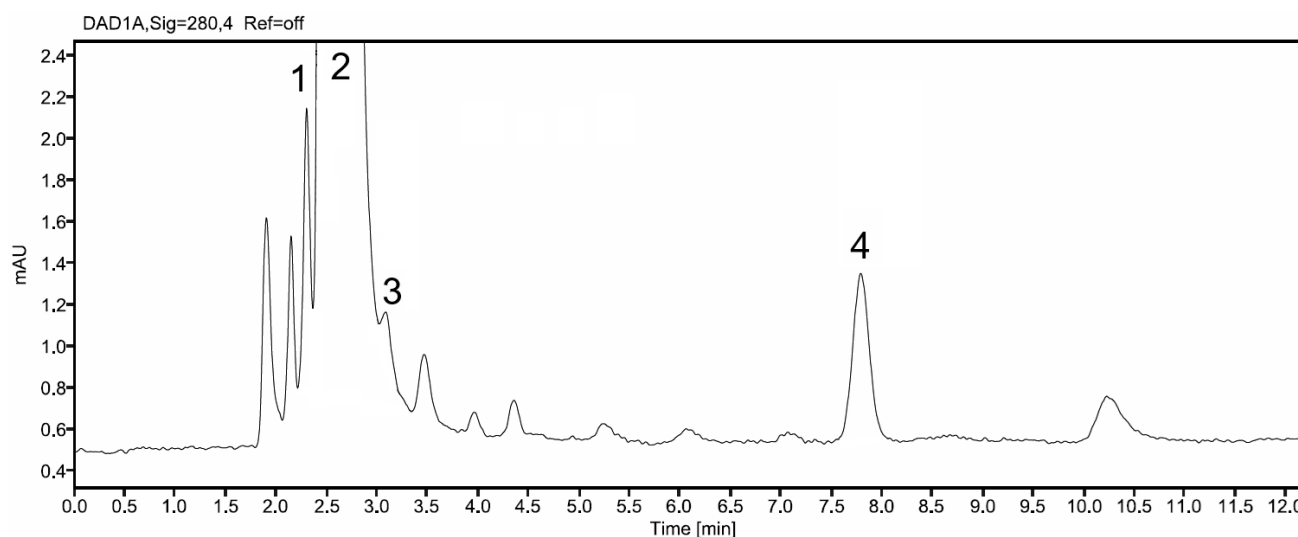
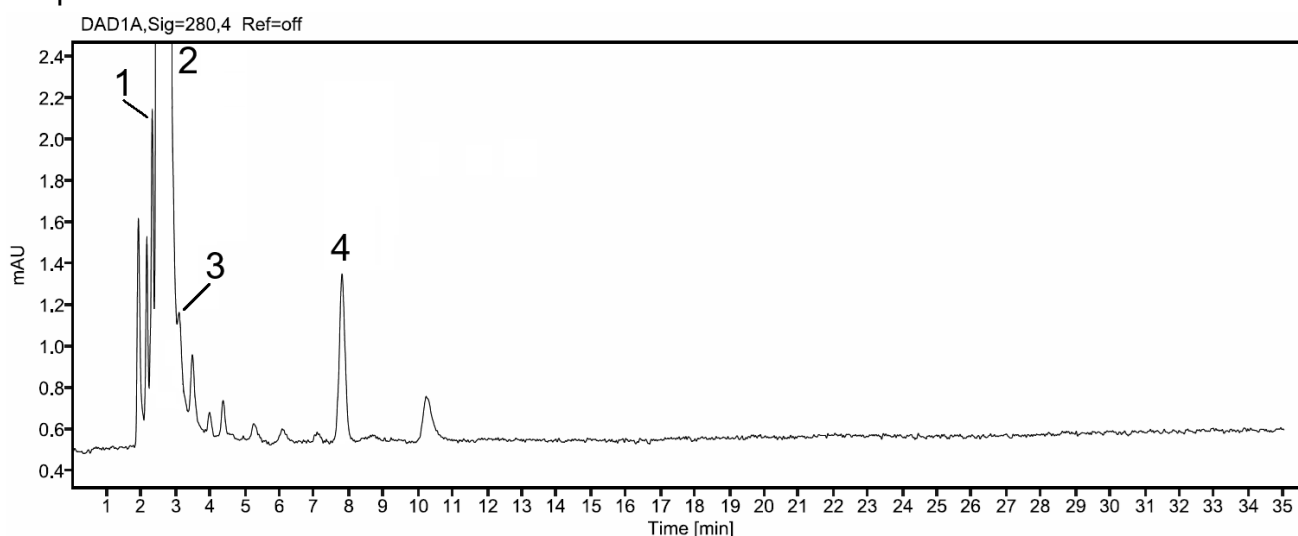


Peak ID: 1: Carbidopa Impurity A. 2: Carbidopa Unknown 1. 3: Carbidopa. 4: Carbidopa Unknown 2. 5: Carbidopa Unknown 3. 6: Carbidopa Impurity G.

Column	YMC Pack ODS-A C18 (150 mm x 4.6 mm, 5 µm)
Method Ref.	Related Substances for the Co-careldopa Tablets monograph from BP 2027
Buffer	0.05M anhydrous sodium dihydrogen orthophosphate adjusted to pH 2.2 with orthophosphoric acid
Mobile Phase	Ethanol: buffer (5:95, v/v)

Diluent	Mobile phase
Flow rate	1.0 mL/min
Column Temp	25°C
Injection Volume	20 µL
Detection	280 nm

Typical chromatogram of a 0.1% w/v solution of Levodopa after being stored at ambient temperature for 4 weeks.

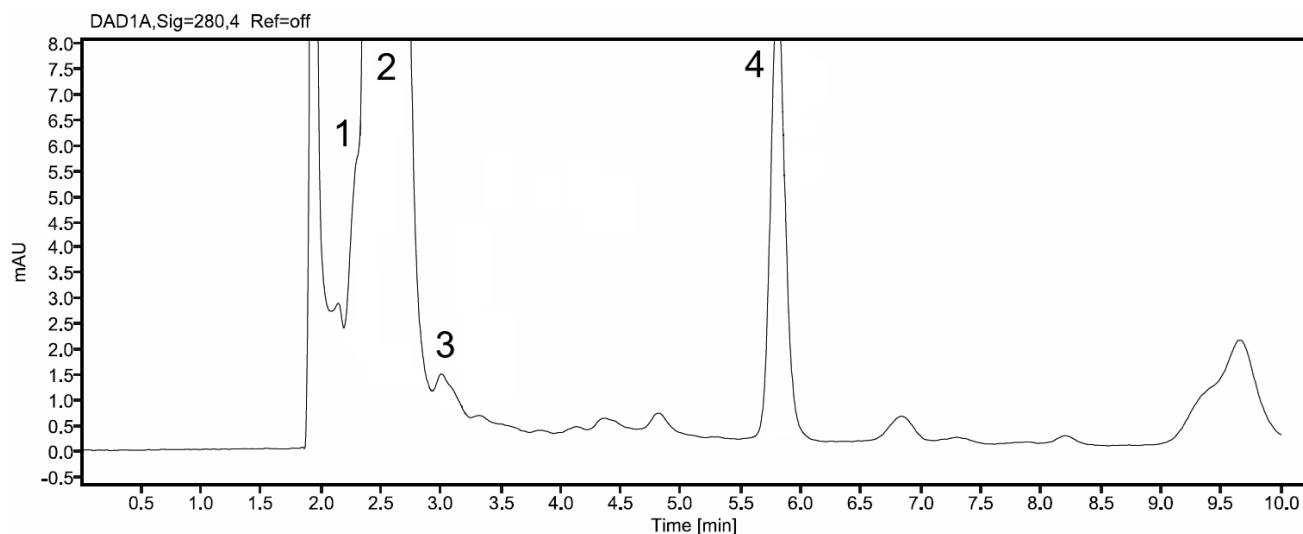


Peak ID: 1: Levodopa Impurity A. 2: Levodopa. 3: Levodopa Unknown 1. 4: Levodopa Unknown 3.

Column	YMC Pack ODS-A C18 (150 mm x 4.6 mm, 5 µm)
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Method Ref.	Related Substances for the Co-careldopa Tablets monograph from BP 2027
Buffer	0.05M anhydrous sodium dihydrogen orthophosphate adjusted to pH 2.2 with orthophosphoric acid
Mobile Phase	Ethanol: buffer (5:95, v/v)
Diluent	Mobile phase
Flow rate	1.0 mL/min
Column Temp	25°C
Injection Volume	20 µL
Detection	280 nm

Typical chromatogram of a 0.1% w/v solution of Levodopa after being treated with 100 µL of 1M sodium hydroxide solution and allowed to stand for 30 minutes.



Peak ID: 1: Levodopa Impurity A. 2: Levodopa. 3: Levodopa Unknown 1. 4: Levodopa Unknown 2

Column	YMC Pack ODS-A C18 (150 mm x 4.6 mm, 5 µm)
Method Ref.	Related Substances for the Co-careldopa Tablets monograph from BP 2027
Buffer	0.05M anhydrous sodium dihydrogen orthophosphate adjusted to pH 2.2 with orthophosphoric acid
Mobile Phase	Ethanol: buffer (5:95, v/v)
Diluent	Mobile phase
Flow rate	1.0 mL/min
Column Temp	25°C
Injection Volume	20 µL
Detection	280 nm