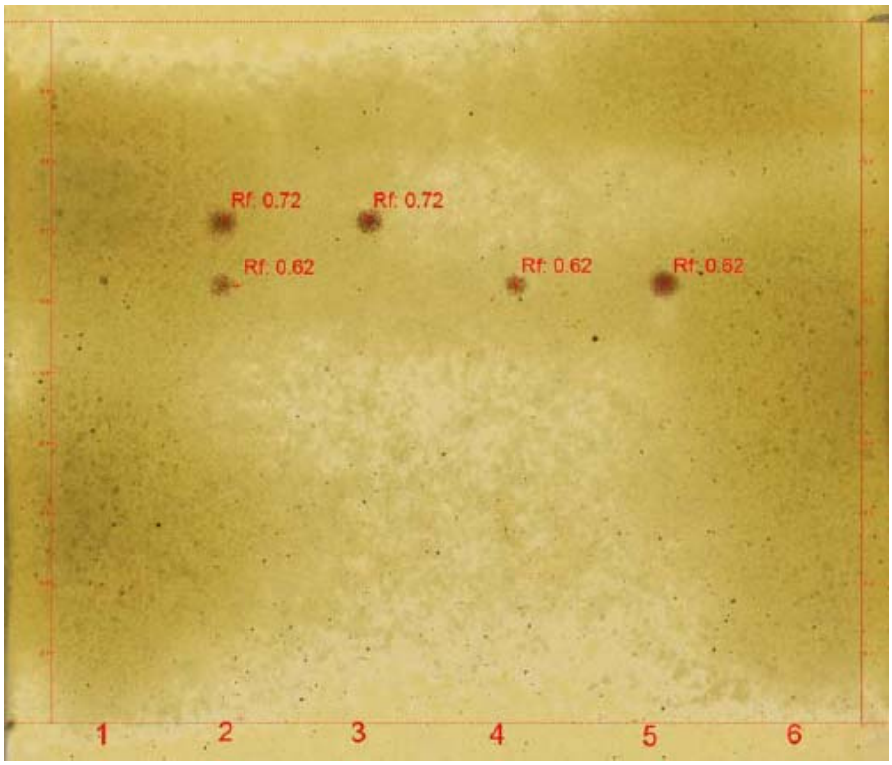
Nitrazepam Oral Suspension – BP 2017

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

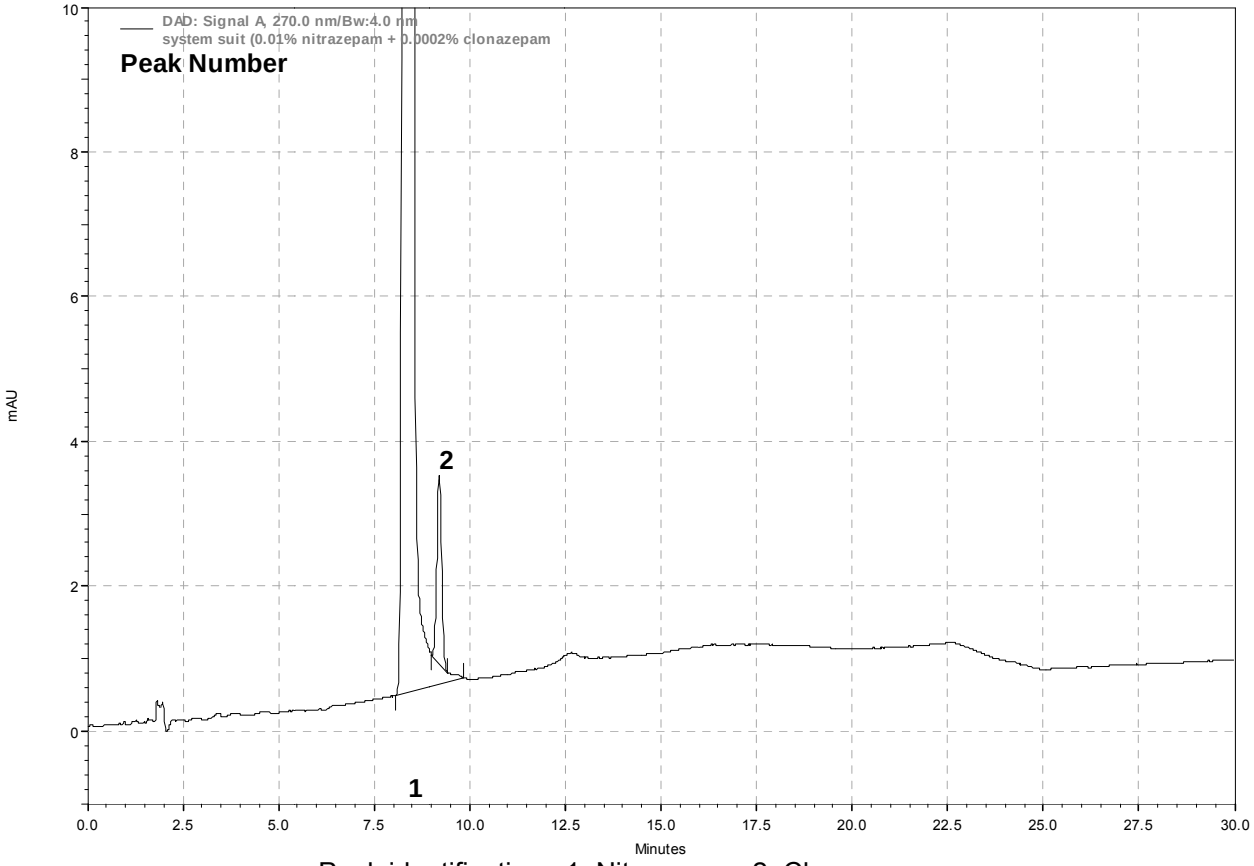
Example chromatogram for Identification in Nitrazepam Oral Suspension as published in BP 2017.

1. Blank
2. System suitability solution, 0.025% w/v of both nitrazepam and diazepam (solution 3)
3. 0.025 % w/v diazepam
4. 0.025 % w/v nitrazepam (solution 2)
5. 0.025% w/v nitrazepam in oral suspension sample (solution 1)
6. 0.025 % w/v nitrazepam



HPTLC Plate	: Merck TLC silica gel 60 F254 Plate, 20 cm × 20 cm
Mobile Phase	: Conc. ammonia : methanol : ethyl acetate (5:10:85 v/v/v)
Diluent	: Standard preparations – methanol, sample preparations - acetonitrile
Application	: 10 µL with a 3mm band size
Development	: 150 mm
Development time	: 40 minutes
Drying time	: 10 minutes
Derivatisation	: Sprayed with potassium iodobismuthate
Detection	: Post-derivatisation under white light

Typical chromatogram for solution (3) in the Related substances test for Nitrazepam Oral Suspension as published in BP 2017.



Peak identification : 1: Nitrazepam, 2: Clonazepam

Column : Lichrospher C8 RP Select B (250 mm × 4. mm, 5 µm)
Mobile phase A : 0.05 M sodium dihydrogen orthophosphate adjusted to pH 3.0 with orthophosphoric acid.
Mobile phase B : Mobile phase A: acetonitrile (20: 80 v/v)
Diluent : Acetonitrile
Flow Rate : 1.0 mL/min
Column Temp : 40 °C
Injection Volume : 20 µL
Detection : 270 nm
Gradient

Time (mins)	Mobile phase A (% v/v)	Mobile phase B (% v/v)
0	55	45
3-10	55-37	45-63
10-20	37	63
20-22	37-55	63-45
22-30	55	45