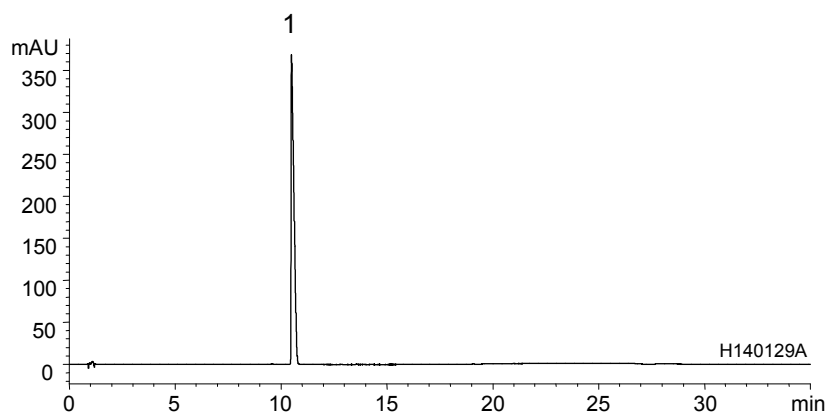


アリピプラゾール (米国薬局方記載条件)  
Aripiprazole (The United States Pharmacopeia)

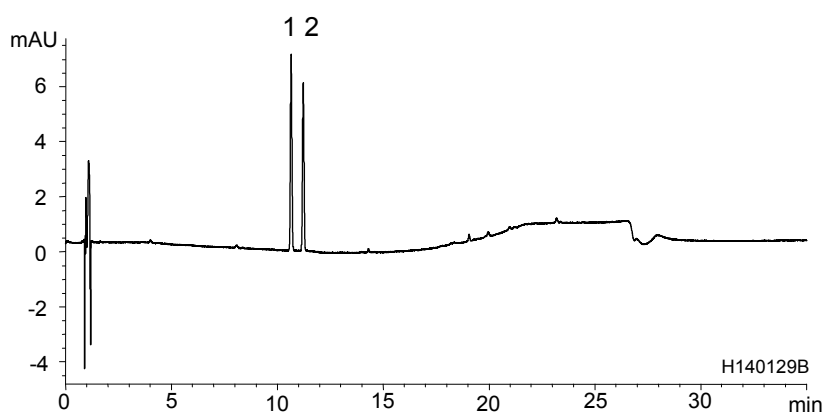
H140204A

(A) Standard solution<sup>\*1</sup>, Sample solution<sup>\*1</sup>  
(0.1 mg/mL Aripiprazole)

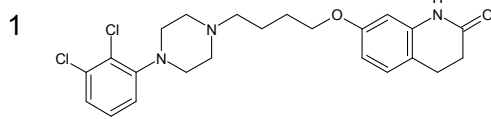


|   | System suitability requirement | Result |
|---|--------------------------------|--------|
| Relative standard deviation of the peak area (Aripiprazole) | ≤ 1.0%                         | 0.13%  |

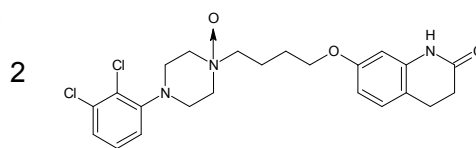
(B) System suitability solution<sup>\*1</sup>  
(1.0 μg/mL Aripiprazole, 1.0 μg/mL Aripiprazole related compound F)



|                               | System suitability requirement | Result |
|-------------------------------|--------------------------------|--------|
| Tailing factor (Aripiprazole) | ≤ 1.5                          | 1.03   |
| Resolution (1,2)              | ≥ 2.0                          | 4.49   |



Aripiprazole



Aripiprazole related compound F

|             |   |
|-------------|---|
| Column      | : YMC-Pack ODS-A (3 μm, 12 nm)<br>100 X 4.6 mmI.D.  |
| Eluent      | : A) acetonitrile/0.05 % TFA (10/90)<br>B) acetonitrile/0.05 % TFA (90/10)<br>20%B (0-2 min), 20-35%B (2-10 min), 35-90%B (10-20 min), 90%B (20-25 min),<br>90-20%B (25-26 min), 20%B (26-35 min) |
| Flow rate   | : 1.2 mL/min  |
| Temperature | : 25°C  |
| Detection   | : UV at 254 nm  |
| Injection   | : 20 μL   |

(The United States Pharmacopeia 36th; Assay, Impurities)

<sup>\*1</sup> All solutions were prepared from aripiprazole and aripiprazole related compound F supplied as a reagent for laboratory use.