USP Dexamethasone Assay and Organic Impurities by LC-UV using the Kinetex® 1.7 µm C18 Core-Shell UHPLC Column

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Overview

Dexamethasone is a corticosteroid widely used for its anti-inflammatory and immunosuppressant effects. This application note for the LC-UV assay and organic impurities for Dexamethasone is based on the official USP method. We compare the results obtained utilizing a Kinetex 1.7 µm C18 100 x 2.1 mm core-shell LC column with the original Waters® ACQUITY® BEH™ 1.7 µm C18 column indicated in the USP Chromatographic Columns[1]. The standard and system suitability solutions for the assay and organic impurities were prepared in accordance with the USP monograph.

Both columns met the system suitability requirements for the assay: peak symmetry for Dexamethasone NMT 2.0, RSD NMT 0.73 % for Dexamethasone, and resolution NLT 1.5 between Betamethasone and Dexamethasone. Both columns also met the system suitability requirements for the organic impurities: RSD NMT 5.0 % for Dexamethasone and each of the three impurities, and resolution NLT 1.5 between Betamethasone and Dexamethasone.

LC-UV Conditions

Column: Kinetex 1.7 µm C18 (00D-4475-AN)
Waters ACQUITY UPLC BEH 1.7 µm C18
Dimension: 100 x 2.1 mm
Mobile Phase: A = 3.4 g/L of monobasic potassium phosphate in water. Adjust with phosphoric acid to a pH of 3.0
B = Acetonitrile

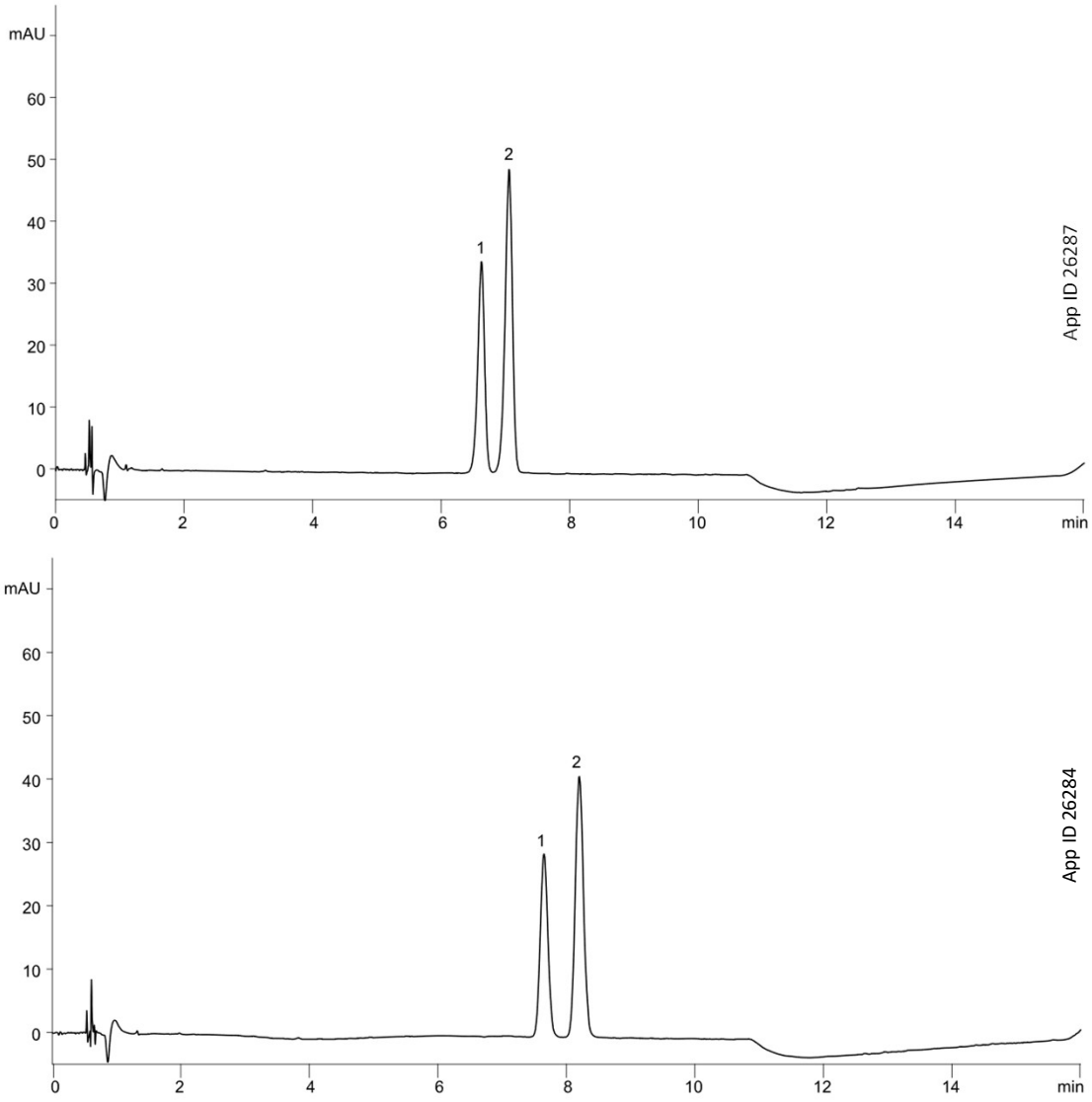
Gradient:

Time (min)	% B
0	24
10	24
15	55
16	90
16.1	24
20	24

Flow Rate: 0.4 mL/min
Temperature: 35 °C
Detector: UV @ 240 nm
Injection: 2 µL
System: Agilent 1290 Infinity (binary)
Sample: As indicated in each chromatogram

1. USP Chromatographic Columns (https://www.uspchromcolumns.com/chrom/display).

Figure 1: System Suitability Solution (same for Assay and Organic Impurities) on Kinetex® 1.7 µm C18 (top) and Waters® ACQUITY ® BEH™ 1.7 µm C18 (bottom)

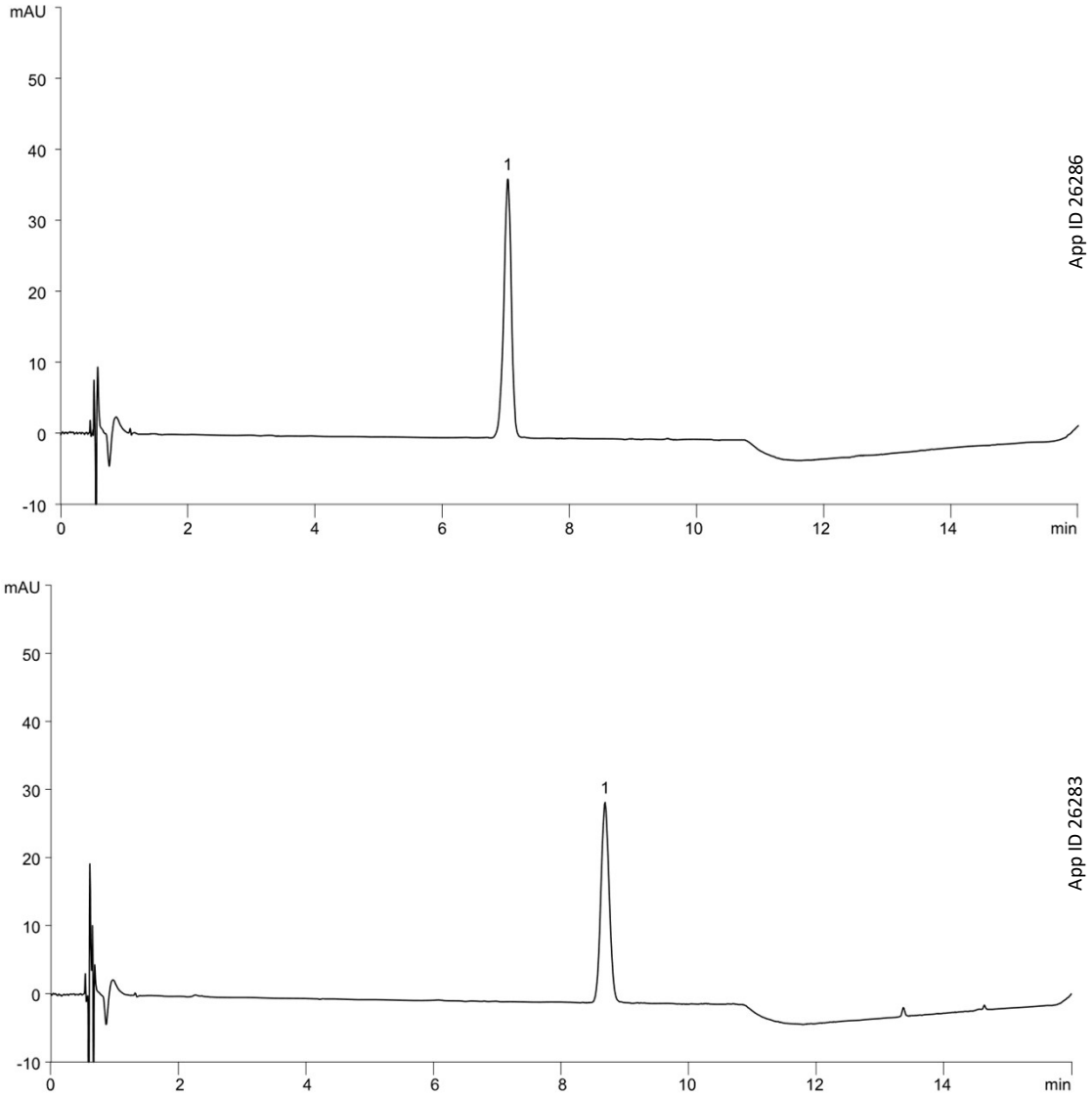


Sample: 1. Betamethasone
2. Dexamethasone

Results – System Suitability Solution (Assay and Organic Impurities)

	Kinetex 1.7 µm C18		ACQUITY BEH 1.7 µm C18	
Analyte	Retention Time, min	Resolution, NLT 1.5	Retention Time, min	Resolution, NLT 1.5
Betamethasone	6.63		8.16	
Dexamethasone	7.06	2.18	8.71	2.40

Figure 2: Standard Solution (Assay) on Kinetex® 1.7 µm C18 (top) and Waters® ACQUITY® BEH™ 1.7 µm C18 (bottom)

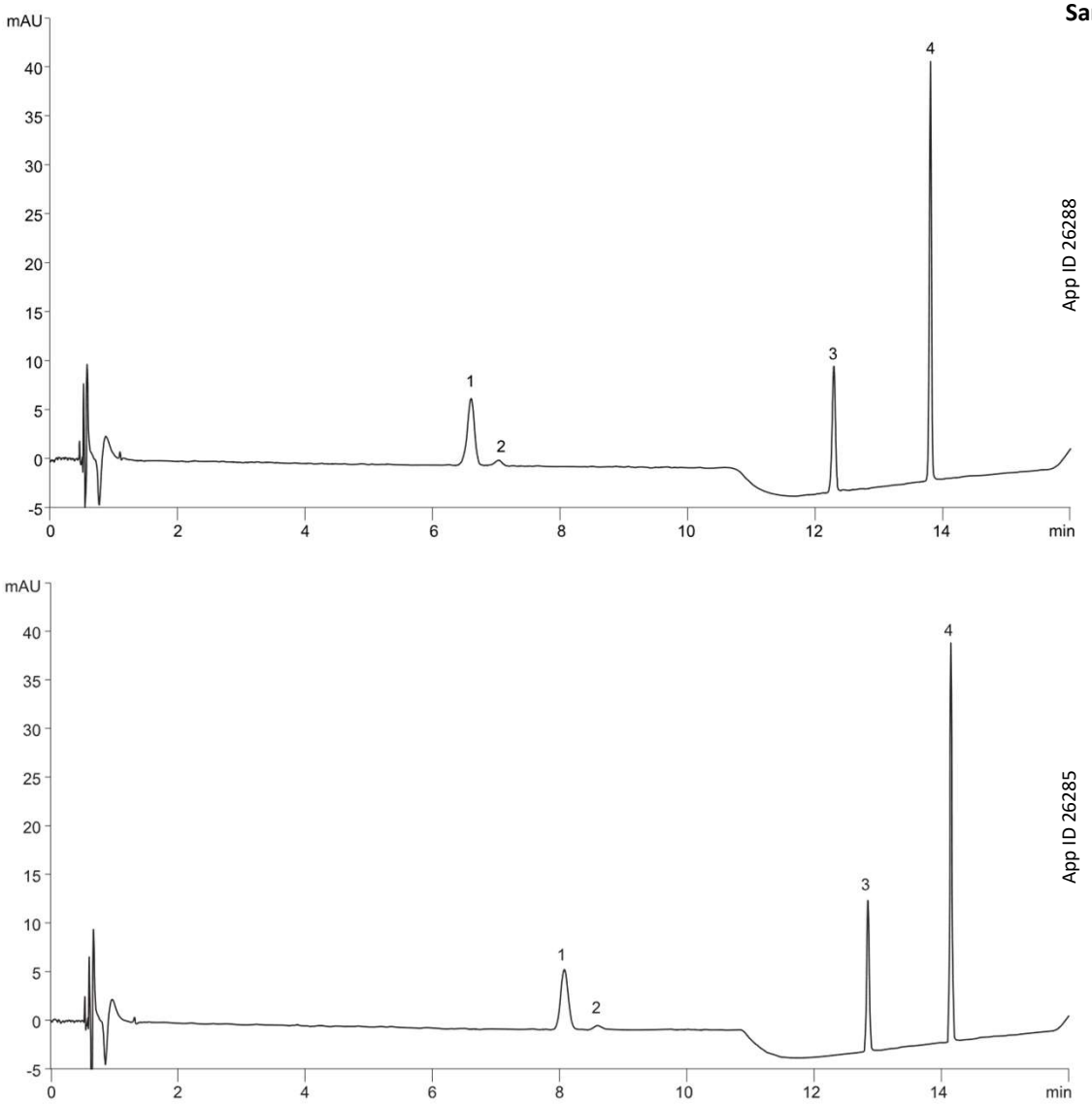


Sample: 1. Dexamethasone

Results – Standard Solution, Assay

	Kinetex 1.7 µm C18		ACQUITY BEH 1.7 µm C18	
Analyte	Retention Time, min	RSD, NMT 0.73 %	Retention Time, min	RSD, MNT 0.73 %
Dexamethasone	7.04	0.53 %	8.69	0.43 %

Figure 3: Standard Solution (Organic Impurities) on Kinetex® 1.7 µm C18 (top) and Waters® ACQUITY® BEH™ 1.7 µm C18 (bottom)



Sample: 1. Betamethasone
2. Dexamethasone
3. Desoximetasone
4. Dexamethasone Acetate

Results – Standard Solution, Organic Impurities

	Kinetex 1.7 µm C18		ACQUITY BEH 1.7 µm C18	
Analyte	Retention Time, min	RSD, NMT 5.0%	Retention Time, min	RSD, MNT 5.0%
Betamethasone	6.62	1.35%	8.15	1.80%
Dexamethasone	7.05	3.98%	8.70	4.15%
Desoximetasone	12.30	1.09%	12.87	0.62%
Dexamethasone Acetate	13.81	1.15%	14.16	0.33%

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