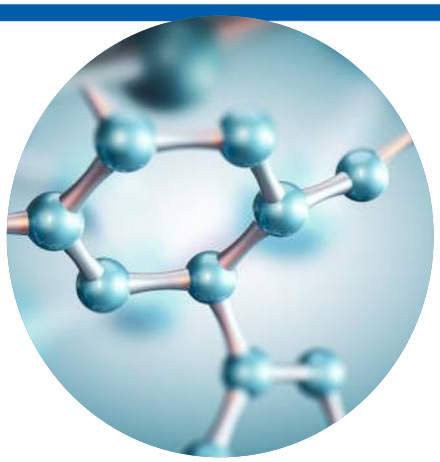

Limit of Valsartan Related Compound A per USP Monograph for Amlodipine, Valsartan, and Hydrochlorothiazide Tablets

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Overview

Amlodipine, Valsartan, and Hydrochlorothiazide tablets contain a combination of drugs used to treat high blood pressure. Amlodipine is a calcium channel blocker (CCB) that affects calcium movement into the cells of the heart and blood vessels, Valsartan is an angiotensin II receptor blocker (ARB) that relaxes blood vessels, and Hydrochlorothiazide is a thiazide diuretic that reduces the amount of water in the body by increasing the flow of urine and lowering blood pressure. In this application note, we report the limit of Valsartan Related Compound A using a Lux 5 µm Cellulose-1 column compared with a CHIRALCEL 5 µm OD-H column according to the USP monograph for Amlodipine, Valsartan, and Hydrochlorothiazide tablets, which specifies a column containing L40 (Cellulose tris-(3,5-dimethylphenylcarbamate)) packing with dimensions of 250 x 4.6 mm.

System suitability per USP monograph for Amlodipine, Valsartan, and Hydrochlorothiazide tablets is resolution no less than (NLT) 2.0 between Valsartan and Valsartan related compound A and a percent relative standard deviation (%RSD) of no more than (NMT) 5 % for Valsartan related compound A. All system suitability requirements for the Limit of Valsartan Related Compound A were met by both the Lux Cellulose-1 and CHIRALCEL OD-H.

The Lux Cellulose-1 column is a suitable substitute for the CHIRALCEL OD-H column for the USP monograph for Amlodipine, Valsartan, and Hydrochlorothiazide tablets Limit of Valsartan Related Compound A method.

All solutions were prepared as indicated in the USP monograph for Amlodipine, Valsartan, and Hydrochlorothiazide tablets. USP Valsartan RS (Catalog No. 1708762) and USP Valsartan Related Compound A RS (Catalog No. 1708773) were purchased from USP.

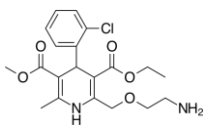
LC-UV Conditions

Columns: Lux™ 5 µm Cellulose-1 (00G-4459-E0)
CHIRALCEL® 5 µm OD-H
Dimensions: 250 x 4.6 mm
Mobile Phase: N-Hexane / 2-Propanol / Trifluoroacetic Acid (850:150:1, v/v/v)
Flow Rate: 0.8 mL/min (Isocratic)
Injection Volume: 20 µL
Temperature: 30 °C
LC System: Agilent® 1260
Detection: UV @ 230 nm

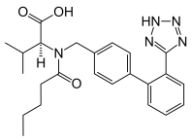
Table 1. Preparation of Test Solutions

Solution	Composition
Standard Solution	0.001 mg/mL of *USP Valsartan Related Compound A RS* in Mobile Phase.
System Suitability Solution	0.04 mg/mL each of *USP Valsartan Related Compound A* and *USP Valsartan RS* in Mobile Phase.

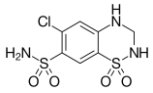
Figure 1. Drug Structures.



Amlodipine



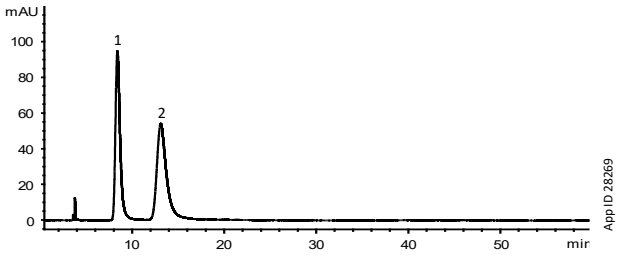
Valsartan



Hydrochlorothiazide

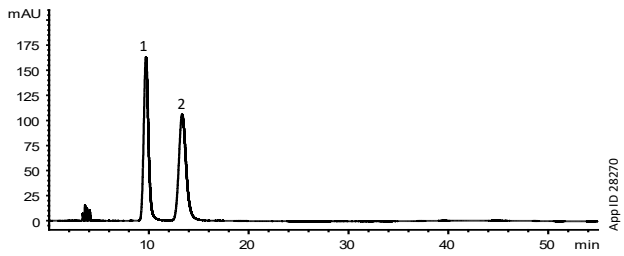
Figure 2. System Suitability Solution.

CHIRALCEL® 5 µm OD-H® Column



Peak No.	Analyte	Retention Time (min)	Area	Resolution
1	Valsartan Related Compound A	8.40	3225.7	3.51
2	Valsartan	13.11	3570.6	
N=5 Injections				

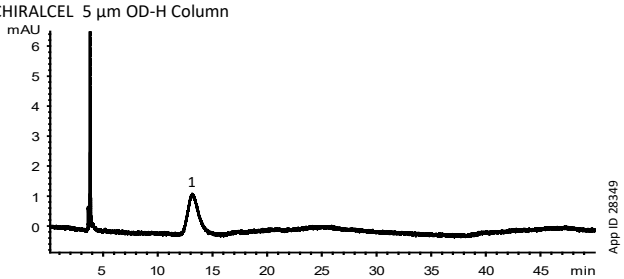
Lux™ 5 µm Cellulose-1 Column



Peak No.	Analyte	Retention Time (min)	Area	Resolution
1	Valsartan Related Compound A	9.81	5349.74	3.60
2	Valsartan	13.94	5290.46	
N=5 Injections				

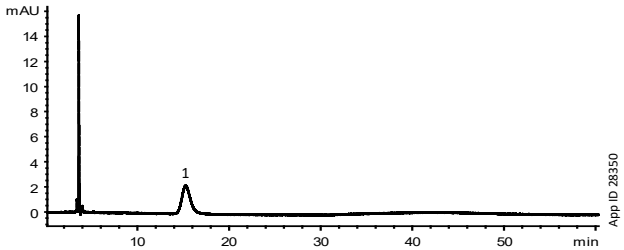
Figure 3. Standard Solution.

CHIRALCEL 5 µm OD-H Column



Peak No.	Analyte	Retention Time (min)	Area	%RSD
1	Valsartan	13.13	101.50	3.55
N=6 Injections				

Lux 5 µm Cellulose-1 Column



Peak No.	Analyte	Retention Time (min)	Area	%RSD
1	Valsartan	15.26	153.15	1.19
N=6 Injections				

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