Irbesartan Related Substances Method per IP Monograph

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Overview

Irbesartan is a potent selective angiotensin II type 1 (AT1) receptor antagonist and is used in the treatment of hypertensive patients and diabetic nephropathy. The development of a quick and efficient analysis of Irbesartan and its related substances is of interest for India generic drug manufacturers. In this application note, we report the separation of Irbesartan and its related substances using a Luna™ 5 µm C18(2) column according to the Indian Pharmacopoeia (IP) Monograph for Irbesartan, which references use of a 25 cm x 4.0 mm stainless-steel column packed with octadecylsilane bonded to porous silica (5 µm).

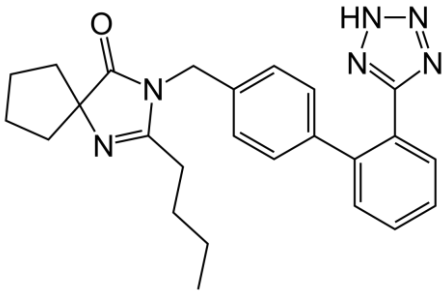
System suitability per IP Monograph for the Irbesartan Related Substances is resolution of not less than (NLT) 3.0 between Irbesartan and Irbesartan Impurity A.

The results clearly show that the system suitability criteria (resolution) met and surpassed the minimum requirement. This illustrates that the Luna 5 µm C18(2) meet all requirements for system suitability as outlined in the Indian Pharmacopoeia monograph for Irbesartan.

All solutions were prepared as indicated in the IP Monograph for Irbesartan. The following certified reference standards (CRS) were purchased from the European Directorate for the Quality of Medicines & HealthCare (EDQM) – Council of Europe; Postal address: Allee Kastner CS 30026 F - 67081 Strasbourg (France):

- Y0001166, Irbesartan CRS
- Y0001156, Irbesartan Impurity A CRS

Figure 1. Irbesartan



LC-UV Conditions

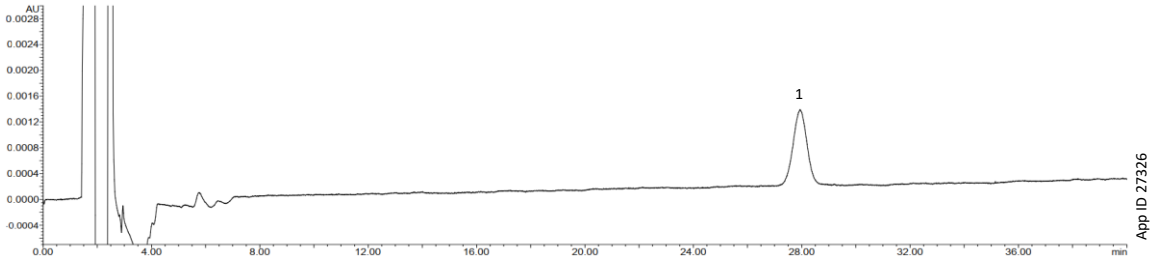
Column: Luna 5 µm C18(2)
Dimensions: 250 x 4.0 mm
Part No.: 00G-4252-D0
Mobile Phase: A mixture of 67 volumes of buffer solution prepared by diluting 5.5 mL of Orthophosphoric Acid in 950 mL of Water, adjusted to pH 3.2 with Triethylamine and 33 volumes of Acetonitrile.
Flow Rate: 1 mL/min (Isocratic)
Injection Volume: 10 µL
Temperature: 25 °C
Detector: UV @ 220 nm
System: Waters® ACQUITY Arc® HPLC

Table 1. Preparation of Solutions

Solution	Composition
Test Solution	Dissolved 50 mg of Irbesartan RS in Methanol, dilute to 50.0 ml with Methanol.
Reference Solution (a)	Diluted 1.0 ml of the Test Solution to 20.0 ml with Methanol. Diluted 1.0 ml of this solution to 50.0 ml with Methanol.
Reference Solution (b)	Dissolved 5 mg of Irbesartan RS and 5 mg of Irbesartan impurity A CRS in Methanol and diluted to 10 mL with the same solvent. Diluted 1 mL of the solution to 10 mL with Methanol.

Figure 2. Reference Solution (a)

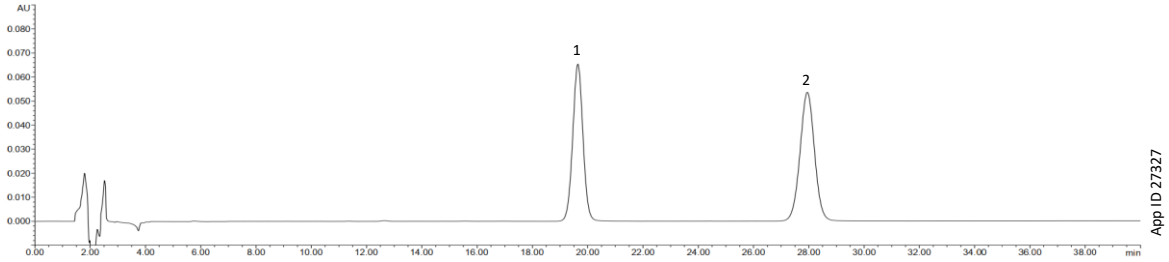
Luna™ 5 µm C18(2) Column



Peak No.	Analyte	Retention Time (min)	Area	Area %RSD	Tailing Factor	Theoretical Plates
1	Irbesartan	27.94	42876	0.65	1.02	13282
N = 6 Injections						

Figure 3. Reference Solution (b)

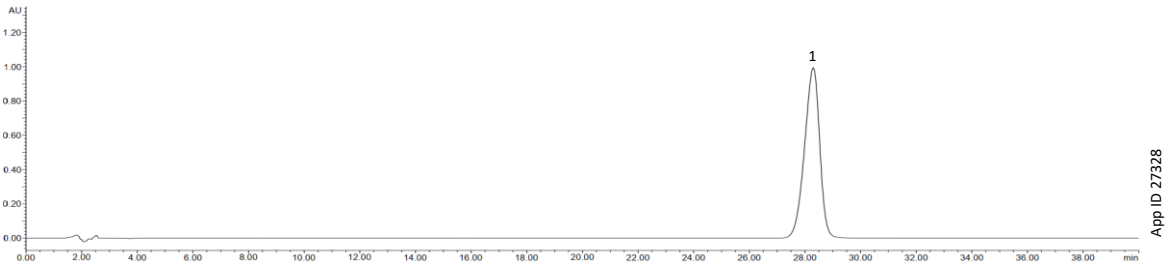
Luna 5 µm C18(2) Column



Peak No.	Analyte	Retention Time (min)	Relative Retention Time	Area	Area %RSD	Resolution
1	Irbesartan Impurity A	19.66	0.7	1706526	0.49	10.07
2	Irbesartan	27.97	1.0	1972656	0.53	
N = 6 Injections						

Figure 3. Test Solution

Luna 5 µm C18(2) Column



Peak No.	Analyte	Retention Time (min)	Area	Height	Tailing Factor	Theoretical Plates
1	Irbesartan	28.30	37770240	993899	0.88	12614
N = 6 Injections						

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