

Ibuprofen and Paracetamol Tablets – Assay and Related Substances Method as per IP Monograph

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Overview

The combination of Paracetamol and Ibuprofen has been found to be efficacious in a variety of acute pain states, including postoperative pain, dysmenorrhea and musculoskeletal pain. The Paracetamol / Ibuprofen combination is known to provide improved pain relief compared to either drug alone and is usually offered as a substitute to codeine-based analgesics for short-term management of pain.

This application note highlights the use of the Phenomenex Luna[®] C8(2) column for the identification of Ibuprofen and Paracetamol tablets as per Indian Pharmacopoeia (IP). The requirements to meet system suitability for the assay is a percent relative standard deviation (%RSD) no more than (NMT) 2 % for each peak, and for related substances a resolution of no less than (NLT) 10 and a %RSD NMT 2 % for each of the principal peaks. The method meets the system suitability requirements as per the monograph when analyzing this drug product sample and demonstrates excellent precision over multiple injections.

Sample Preparation

Transfer powdered sample (approximate weight 0.384 g) of Paracetamol and Ibuprofen tablet which contains 0.16 g Ibuprofen in 100 mL volumetric flask, dissolve and dilute with the diluent (mobile phase) and filter the solution using CLARIFY-NY 13 mm Syringe Filters ([AF8-7707-12](#)). Take 10 mL of the above solution in 100 mL volumetric flask and dilute with the diluent.

NOTE: Average tablet weight: 0.963 g / tab
Strength of Ibuprofen: 400 mg
Strength of Paracetamol: 325 mg

LC-UV Conditions – Assay Method

Column: Luna[®] 5 µm C8(2)

Dimension: 250 x 4.6 mm

Part No.: [00G-4249-E0](#)

Mobile Phase: Buffer/Acetonitrile/Methanol (75:24.5:0.5, v/v/v)

Buffer: 3.9 g of Sodium dihydrogen phosphate dihydrate (25 mM) and 8.9 g of Disodium hydrogen phosphate dihydrate (50 mM) are dissolved in 1000 mL water and adjust pH to 7.0 with Orthophosphoric acid

Flow Rate: 1.5 mL/min (Isocratic)

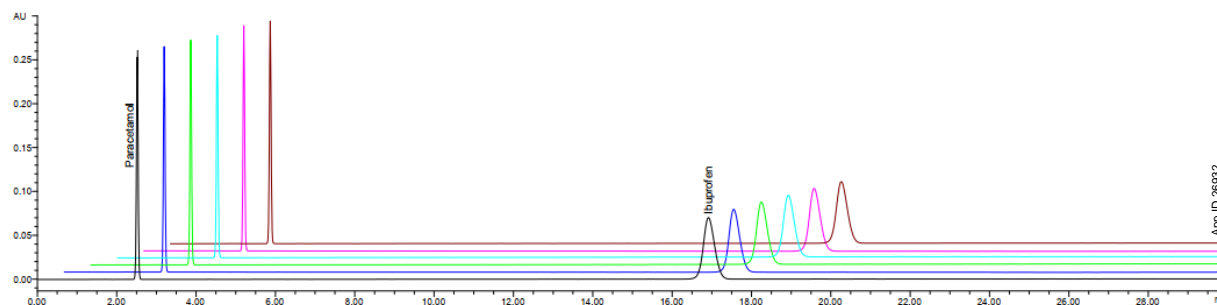
Injection Volume: 5 µL

Temperature: 35 °C

Detection: UV @ 220 nm

LC System: Waters[®] ACQUITY[®] H-Class HPLC

Figure 1. Overlay Chromatogram of Six Injections of Paracetamol and Ibuprofen Test Solution for Assay on Luna 5 µm C8(2)



Compound (Precision, N=6)	Retention Time (min)	Retention Time %RSD	Area	Area %RSD	Symmetry Factor	Resolution
Paracetamol	2.53	0.08	767341	0.18	1.02	-
Ibuprofen	16.91	0.09	1381303	0.11	1.13	48.4



Sample Preparation

Transfer powdered sample (approximate weight 0.241 g) of Paracetamol and Ibuprofen tablet which contains 0.1 g Ibuprofen in 50 mL volumetric flask, add 30 mL of diluent (see below) sonicate for 10 minutes. Cool the solution, add diluent up to volume with diluent, and filter the solution CLARIFY-NY 13 mm Syringe Filters ([AF8-7707-12](#)).

Diluent: Solution A/Methanol (40:60, v/v)

Solution A: 6.8 g of Monobasic potassium phosphate in 1000 mL water and pH adjusted to 3.0 with Orthophosphoric acid.

LC-UV Conditions – Related Substances Method

Column: Luna® 5 µm C8(2)

Dimension: 250 x 4.6 mm

Part No.: [00G-4249-E0](#)

Mobile Phase: A: 6.8 g of Monobasic potassium phosphate in 1000 mL water (pH adjusted to 3.0 with Orthophosphoric acid) with 0.25 g Hexane 1-sulphonic acid sodium salt
B: Acetonitrile

Gradient:	Time (min)	%B
	0	2
	6	2
	16	20
	22	35
	55	40
	63	55
	63.1	2
	70	2

Flow Rate: 1.5 mL/min

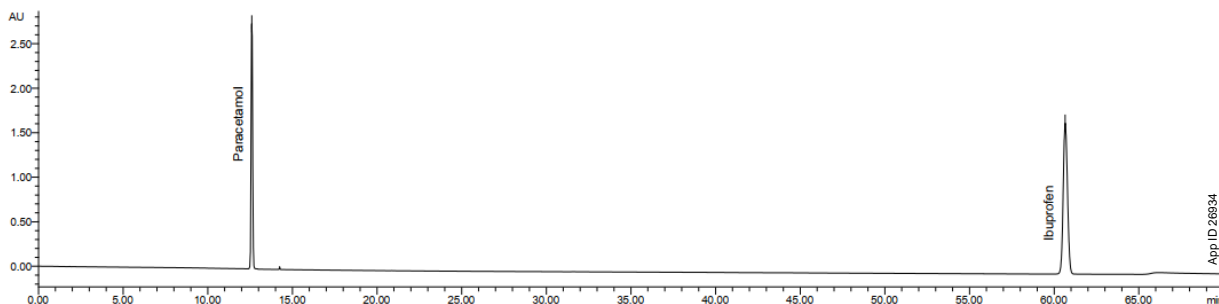
Injection Volume: 10 µL

Temperature: 25 °C

Detection: UV @ 214 nm

LC System: Waters® ACQUITY® H-Class HPLC

Figure 2. Paracetamol and Ibuprofen Test Solution for Related Substances on Luna 5 µm C8(2)



Compound	Retention Time (min)	Area	Theoretical Plates	Symmetry Factor	Resolution
Paracetamol	12.60	17747139	106396	1.12	-
Ibuprofen	60.65	29994847	267055	1.09	154.02



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