



Search here...

Login

Register

Cart 0

## Current Pharmaceutical Analysis

Editor-in-Chief &gt;&gt;

ISSN (Print): 1573-4129

ISSN (Online): 1875-676X

Back

Journal ▾

Subscribe

Research Article

## A New Short Validated U-HPLC Method for the Determination of Recombinant Human Insulin in Microspheres

**Author(s):** [Pravin Wakte](#), [Gauravkumar Agrawal\\*](#) and [Santosh Shelke](#)

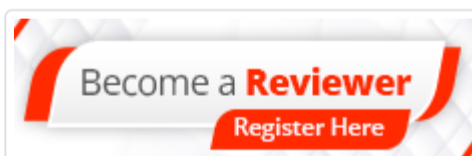
Volume 14, Issue 5, 2018

Page: [501 - 512]

Pages: 12

DOI: [10.2174/1573412913666170704150803](https://doi.org/10.2174/1573412913666170704150803)

Price: \$65



### Abstract

**Background:** The objective of present research work was to develop and validate rapid UHPLC method with short run time for the detection and quantification of recombinant human insulin content in microsphere formulations. Validation emphasizes mainly on studying the effects of the flow rate, wavelengths, column temperature, pH and organic content of the mobile phase and of presence of other additives on the method's accuracy.

**Methods:** Chromatographic separation was achieved using YMC Triart C-18 column and the mobile phase was composed of the mixture (aqueous solution of 0.2M anhydrous sodium sulphate, pH 2.3 and acetonitrile) in a ratio 73:27 (%v/v). The column temperature and flow rate was 40°C and 0.613 mL/min respectively whereas, UV detection was performed at 214 nm. All the method procedures were validated according to international

conference on harmonization (ICH) guidelines. The retention time of recombinant human insulin was about 3.0 min with very short run time of just 5 min. Fluctuations in analytical conditions or presence of additives and impurities or insulin related analogs did not show any significant effect on the specificity and accuracy of the method.

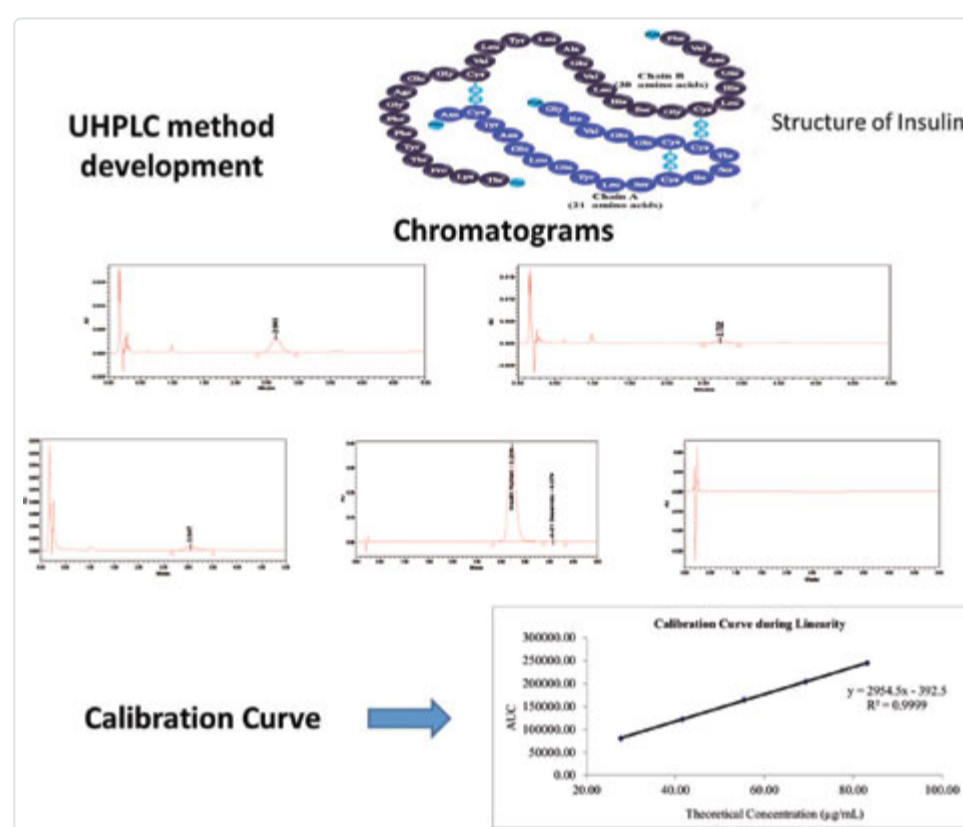
Results: The assay is reproducible with acceptable %RSD value (0.87%). Linearity was confirmed by correlation coefficient of 0.9999 over the range of 26.84-81.23 µg/mL. The accuracy of the method and % recovery of insulin content were found to be in between 98.02 and 99.71% while RSD ranged from 0.01 to 0.88%. The specificity of the method proved that no interferences occurred with RT of insulin peak.

Conclusion: This new short validated method can be applied during development studies in research laboratories for high throughput testing as well as for quality control procedures of lot release testing, in-process quality control and finished product analysis.

**Keywords:** [U-HPLC](#), [human insulin](#), [method validation](#), [microspheres](#), [chromatographic](#), [acetonitrile](#).

[« Previous](#)
[Next »](#)

## Graphical Abstract


[Mark Item](#)
[Purchase PDF](#)
[Rights & Permissions](#)
[Print](#)
[Cite](#)

Article Metrics



PDF

27



HTML

1



ePUB

1

PRC

1

**FIND YOUR INSTITUTION**

### Journal Information

> [About Journal](#)

> [Editorial Board](#)

> [Current Issue](#)

> [Volumes /Issues](#)

[For Authors](#)[For Editors](#)[For Reviewers](#)[Explore Articles](#)[Open Access](#)[For Visitors](#)

## Related Articles

**FGF10 and FGF21 as Regulators in Adipocyte Development and Metabolism**

*Endocrine, Metabolic & Immune Disorders - Drug Targets*

**Mast Cell Chymase and Tryptase as Targets for Cardiovascular and Metabolic Diseases**

*Current Pharmaceutical Design*

**Hemostatic Factors and the Metabolic Syndrome**

*Current Vascular Pharmacology*

**Serum Pro-oxidant-antioxidant Balance in Subjects with Type 2 Diabetes Mellitus**

*Combinatorial Chemistry & High Throughput Screening*

**New Pharmacological Approaches to the Prevention of Myocardial Ischemia- Reperfusion Injury**

*Current Drug Targets*

**Low Molecular Weight Compounds with Transition Metals as Free Radical Scavengers and Novel Therapeutic Agents**

*Cardiovascular & Hematological Agents in Medicinal Chemistry*

**Nutrition and Bone Health: Its Relationship to Osteoporosis**

*Current Nutrition & Food Science*

**Epigenetics and the Environmental Regulation of the Brain's Genome and its Function**

*Current Psychiatry Reviews*

**Primary and Secondary Insomnia: Prevalence, Causes and Current Therapeutics**

*Current Medicinal Chemistry - Central Nervous System Agents*

**Neurotrophic Factors for Retinal Ganglion Cell Neuropathy - With a Special Reference to Diabetic Neuropathy in the Retina**

*Current Diabetes Reviews*

**Computer Aided Drug Design Strategies Used in the Discovery of Fructose 1, 6-Bisphosphatase Inhibitors**

*Current Pharmaceutical Design*

**Alstrom Syndrome: Genetics and Clinical Overview**

*Current Genomics*

**Vascular Consequences of Aldosterone Excess and Mineralocorticoid Receptor Antagonism**

*Current Hypertension Reviews*

**Editorial**

*Current Diabetes Reviews*

**Determination of Phytochemicals by GC-MS in Two Fractions (17 and 21) of Methanol Extract of Loranthus Micranthus and their Antioxidant and Anti-Inflammatory Activity**

*The Natural Products Journal*

Cytokine Polymorphisms in Chronic Inflammatory Diseases with Reference to Occupational Diseases

*Current Molecular Medicine*

Is Atherothromboaspiration a Possible Solution for the Prevention of No-Reflow Phenomenon in Acute Coronary Syndromes? Single Centre Experience and Review of the Literature

*Current Vascular Pharmacology*

Non Invasive Indexes for the Assessment of Patients with Non-alcoholic Fatty Liver Disease

*Current Pharmaceutical Design*

Pharmacological Evaluation of Jambrushila Tablet on Animal Model of Type-2 Diabetes

*The Natural Products Journal*

Peripheral Arterial Disease: The Magnitude of the Problem and its Socioeconomic Impact

*Current Drug Targets - Cardiovascular & Hematological Disorders*

