

Antiasthmatic Drugs – ISR Pass Rates for Different Clinical Trials

2011

Fluticasone Propionate 95.0 % (2238 study samples)

Fluticasone Propionate 99.7 % (5266 study samples)

Salmeterol 94.0 % (3040 study samples)

Salmeterol 98.9 % (6319 study samples)

Cortisol 100.0 % (3700 study samples)

2012

Fluticasone Propionate 98.6 % (5542 study samples)

Salmeterol 87.8 % (6236 study samples)

2013

Budesonide 91.2 % (5117 study samples)

Formoterol 85.6 % (6478 study samples)

2014

Formoterol 99.0 % (1724 study samples), new method

2015

Budesonide 99.4 % (5580 study samples)

Formoterol 99.8 (6629 study samples)

Calibration Ranges and Volume Used

Fluticasone Propionate 3.00-1,000 pg/mL, 0.25 mL

Fluticasone Propionate 0.250-50.0 pg/mL, 1.0 mL

Formoterol 0.400-100 pg/mL, 0.25 mL

Budesonide 5.00-1000 pg/mL, 0.25 mL

Salmeterol 2.00-600 pg/mL, 0.25 mL

Cortisol 1.50-500 ng/mL, 0.1 mL (plasma,serum,urine)

ANTIASTHMATICS/INHALATION PUBLICATIONS

Effect of Particle Deposition Density of Dry Powders on the Results Produced by an In Vitro Test System Simulating Dissolution – and Absorption Rates in the Lungs

Author: Maria Malmlöf, Mattias Nowenwik, Kristof Meelich, Iwona Radberg, Ewa Selg, John Burns, Hermann Mascher, Per Gerde

Publisher: European Journal of Pharmaceutics and Biopharmaceutics, 2019, 139, 213-223

A FIM Study to Assess Safety and Exposure of Inhaled Single Doses of AP301-A Specific ENaC Channel Activator for the Treatment of Acute Lung Injury

Author: R. Schwameis, S. Eder, H. Pietschmann, B. Fischer, H. Mascher, S. Tzotzos, H. Fischer, R. Lucas, M. Zeitlinger, R. Hermann

Publisher: J of Clin. Pharm., 2013, 54(3), 341-350

Sensitive Determination of the Peptide AP301 - A Motif of TNF- α – from Human Plasma using HPLC-MS/MS.

Author: Daniel Mascher, Werner Tscherwenka, Bernhard Fischer, Hermann Mascher

Publisher: J Chromatogr. B, 2012, 908, 18-22

Dose Escalation Study in Healthy Male Subjects to Investigate Safety, Tolerability and Systemic Exposure of Orally Inhaled Single-Doses of AP301.

Author: H. Pietschmann, H. Fischer, S. Tzotzos, B. Fischer, M. Zeitlinger, R. Lucas, R. Hermann, Hermann Mascher, (Vienna, Austria, Augusta, USA).

Poster: European Respiratory Society - Annual Congress, 09/12, Vienna

Bioavailability and Disposition of Azelastine and Fluticasone Propionate when Delivered by MP29-02, a Novel Aqueous Nasal Spray.

Author: Hartmut Derendorf, Ullrich Munzel, Ursula Petzold, Joachim Maus, Hermann Mascher, Robert Hermann, Jean Bousquet

Publisher: Br J Clin Pharmacol, 2012, 74, 125-133

Pulmonary pharmacokinetics and safety of nebulized duramycin in healthy male volunteers

Author: Ilka Steiner, Peter Errhalt, Klaus Kubesch, Marianne Hubner, Marion Holy, Martin Bauer, Markus Müller, Sabine Hinterberger, Rudolf Widmann, Daniel Mascher, Michael Freissmuth, Meinhard Kneussl

Publisher: Naunyn-Schmiedeberg's Arch Pharmacol, 2008, 378, 323-333

Sensitive simultaneous determination of Ciclesonide, Ciclesonide-M1-metabolite and Fluticasone Propionate in Human Serum by HPLC-MS/MS with APPI ionization

Author: H.J. Mascher, K. Zech, D.G. Mascher

Publisher: J Chromatogr. B, 2008, 869, 84-92

Anti-asthmatic drugs in plasma/serum - a real analytical challenge

Author: D.G. Mascher, K.M. Kubesch, H.J. Mascher

Publisher: LC-GC AdS, September 2007

Ultra-sensitive determination of Formoterol in human serum by high performance liquid chromatography and electrospray tandem mass spectrometry

Author: D.G. Mascher, K. Zech, R. Nave, K.M. Kubesch, H.J. Mascher

Publisher: J Chromatogr. B 2006, 830, 25-34