

شرکت تحقیقاتی بیوفارماسی پارس (سهامی خاص) ثبت شده به شماره –۱۰۰۷۷۲ دارای پروانه تحقیق شماره ۶۰۰۰۱–۸۱۵۸۶

| Sequence, single dose, hosequivalence study of Montelukast 10mg tablet of MSD, in 24 healthy adult subjects under fasting conditions | Title: | A randomized, open label, two treatment, two period, two |
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| sponsor: Investigational Products: Project Code: R.ZAUMS.REC.1398.225 Principle Investigator: Ladan Tayebi Executive Colleagues: Habib Ghaznavi; Gh. Komeili; M.M. Vahedi; S.A. Ebrahimi; A. Behmanesh; M. Hadizadeh; A. Alipour Clinical: Core Research Lab. of Zahedan University of Medical Sciences Bio-Analytical Pharmacok. & Statistics: Number of Subjects: Regimen & Duration of Treatment: Blood Sampling Points: Criteria for Evaluation: Criteria for Bioequivalence: Conclusion: Conclusion: tablet of MSD, in 24 healthy adult subject – Amin Pharm Co. - Singulai Iong tablet – Amin Pharm Co Singulair 10mg tablet – Amin Pharmacoka (A. Alipour Core Research Co Singulair 10mg tablet – Amin Pharmacoka (A. Alipour | | sequence, single dose, bioequivalence study of <i>Montelukast</i> |
| Conditions | | tablet of MSD, in 24 healthy adult subjects under fasting |
| Amin Pharm Co., IRAN - Montelukast 10mg tablet - Amin Pharm Co. | | |
| Investigational Products: | Sponsor: | |
| - Singulair 10mg tablet – MSD Project Code: IR.ZAUMS.REC.1398.225 Principle Investigator: Ladan Tayebi Executive Colleagues: Habib Ghaznavi; Gh. Komeili; M.M. Vahedi; S.A. Ebrahimi; A. Behmanesh; M. Hadizadeh; A. Alipour Clinical: Core Research Lab. of Zahedan University of Medical Sciences Bio-Analytical Pharmacok. & Statistics: Number of Subjects: 23 healthy adult subjects Regimen & Duration of Treatment: - Single dose of 2*10 mg Montelukast tablet - Washout period: At least 7 days Before and at 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 8.0, 10.0 & 24.0 hours post-dose. Criteria for Evaluation: - Efficacy: AUC (0.24), AUC (0.24), AUC (0.24), AUC (0.24), AUC (0.24) and T1/2 - Safety: Adverse events - The mean ratios of the test to reference product (T/R) of montelukast were respectively 99.7% for AUC (0.24) and 110.2% for C _{max} values were within the limits of 80 – 125%. The 90% confidence intervals calculated for AUC (0.24) and C _{max} values were within the limits of 80 – 125%. The 1000 | | - Montelukast 10mg tablet – Amin Pharm Co. |
| Executive Colleagues: Habib Ghaznavi; Gh. Komeili; M.M. Vahedi; S.A. Ebrahimi; A. Behmanesh; M. Hadizadeh; A. Alipour | | |
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| Clinical: Bio-Analytical Pharmacok. & Statistics: Number of Subjects: Regimen & Duration of Treatment: Blood Sampling Points: Criteria for Evaluation: Criteria for Bioequivalence: Doct. Confidence Intervals of the ratio (T/R) - Both formulations had no Serious Adverse Events - The mean ratios of the test to reference product (T/R) of montelukast were respectively 99.7% for AUC (0.24) and 110.2% for Cmax. - The 90% confidence intervals calculated for AUC (0.24) and Cmax values were within the limits of 80 – 125%. Criteria for Bioequivalence: The 90% confidence intervals calculated for AUC (0.24) and Cmax values were within the limits of 80 – 125%. Time (hr.) | Executive Colleagues: | Habib Ghaznavi; Gh. Komeili; M.M. Vahedi; S.A. Ebrahimi; |
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| Treatment: Blood Sampling Points: Before and at 0.5, 1.0, 1.5, 2.0, 2.5, 3.0, 3.5, 4.0, 5.0, 6.0, 8.0, 10.0 & 24.0 hours post-dose. Criteria for Evaluation: - Efficacy: AUC (0-24), AUC (0-∞, C _{max} , T _{max} , K _e and T _{1/2} - Safety: Adverse events Criteria for Bioequivalence: Onclusion: - Both formulations had no Serious Adverse Events - The mean ratios of the test to reference product (T/R) of montelukast were respectively 99.7% for AUC (0-24) and 110.2% for C _{max} The 90% confidence intervals calculated for AUC (0-24) and C _{max} values were within the limits of 80 − 125%. The serious Adverse Events - The mean ratios of the test to reference product (T/R) of montelukast were respectively 99.7% for AUC (0-24) and 110.2% for C _{max} The 90% confidence intervals calculated for AUC (0-24) and C _{max} values were within the limits of 80 − 125%. The serious Adverse Events - The mean ratios of the test to reference product (T/R) of montelukast were respectively 99.7% for AUC (0-24) and 110.2% for C _{max} The 90% confidence intervals calculated for AUC (0-24) and C _{max} values were within the limits of 80 − 125%. The serious Adverse Events - The mean ratios of the test to reference product (T/R) of montelukast were respectively 99.7% for AUC (0-24) and 110.2% for C _{max} The 90% confidence intervals calculated for AUC (0-24) and C _{max} values were within the limits of 80 − 125%. The serious Adverse Events - The mean ratios of the test to reference product (T/R) of montelukast were respectively 99.7% for AUC (0-24) and 110.2% for C _{max} The 90% confidence intervals calculated for AUC (0-24) and 110.2% for C _{max} The 90% confidence intervals calculated for AUC (0-24) and 110.2% for C _{max} The 90% confidence intervals calculated for AUC (0-24) and 110.2% for C _{max} . | Number of Subjects: | · |
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| Time (hr.) 110.2% for C_{max} . - The 90% confidence intervals calculated for AUC (0-24) and C_{max} values were within the limits of $80-125\%$. Final Report Date: Dec. 2021 | | |
| - The 90% confidence intervals calculated for AUC $_{(0-24)}$ and $_{C_{max}}$ values were within the limits of $80-125\%$. 1000 | | |
| C _{max} values were within the limits of 80 – 125%. 1000 | | |
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| This study was approved by Itali Pood and Drug Administration | | |