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2 SYNOPSIS

Name of Sponsor/Company: Johnson & Johnson Consumer Inc., McNeil Consumer Healthcare Division	**Individual Study Table Referring to Part of the Dossier**	***(For National Authority Use Only)***
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Title of Study:

A Randomized, Single-Dose, Four-Treatment Crossover Bioequivalence and Food Effect Study of Test Formulation of Cetirizine 10 mg Chewable Tablets Versus Two Marketed Cetirizine 10 mg Immediate Release Tablets.

Protocol No: CCSURA000499 (*Altasciences Project No JHS-P3-176*)

Principal Investigator:

Eric Sicard, MD, Clinical Principal Investigator

Study center(s):

Altasciences Company Inc., 1200 Beaumont Ave., Mount-Royal, Quebec, Canada, H3P 3P1

Publication (reference):

None

Study Period:		**Phase of Development:**
Study Initiation Date:	11-December-2018	Phase I
Scheduled Study Completion Date:	03-February-2019	

Objectives:

The objectives were:

- To evaluate cetirizine bioequivalence from chewable tablet, 10 mg, with and without water relative to 2 commercially available Immediate-Release (IR) cetirizine tablets (Part 1),
- To evaluate cetirizine bioequivalence between 2 commercially available IR cetirizine tablets (Part 1),
- To evaluate the effect of food on cetirizine bioavailability from the chewable tablet with water (Part 2),
- To assess subject's sensory experience and ease of swallowing of the test product,
- To evaluate the safety of test and reference formulations of cetirizine tablets.

Methodology:

This was a randomized, single-dose, 4-treatment crossover bioequivalence and food effect study. The study was conducted in 2 parts. Part 1 of the study had a randomized, 4-way crossover study design in which 40 healthy subjects, aged 18 to 55 years, were randomized to 4 sequences of Treatments A, B, D and E over consecutive periods. No less than approximately 40% of either gender was to be represented

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in the study population. Part 2 of the study assessed a potential food effect in which all subjects were administered Treatment C in the fifth period.

Number of subjects (planned and analyzed):

Planned for inclusion: 40

Included: 40

Subjects discontinued: 2

Analyzed: 40

Considered in the pharmacokinetic analysis and at least one statistical comparison: 40

Considered in all statistical comparisons: 38

Considered in the safety analysis: 40

Diagnosis and main criteria for inclusion:

Healthy male or female subject between the ages of 18 and 55 years, inclusive.

Test product, dose and mode of administration, batch number:

Test (Treatments A, B and C):

Name: Cetirizine 10 mg tablet

Dosage form/Route of administration: Chewable tablet / Oral

Regimen for Treatment A: Single dose of 10 mg cetirizine as a chewable tablet, administered orally after a 10 hour overnight fast and followed with 240 mL ambient water. Subjects were instructed to chew the tablet completely before swallowing.

Regimen for Treatment B: Single dose of 10 mg cetirizine as a chewable tablet, administered orally after a 10 hour overnight fast without water. Subjects were instructed to chew the tablet completely before swallowing.

Regimen for Treatment C: Single dose of 10 mg cetirizine as a chewable tablet, administered orally after a 10 hour overnight fast and 30 minutes after the start of the standard high-fat breakfast and followed with 240 mL ambient water. Subjects were instructed to chew the tablet completely before swallowing.

Batch no.: [redacted]

Manufacturer: [redacted]

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Reference Products, Dose and Mode of Administration, Batch Number:

Reference-1 (Treatment D):

Name: Zyrtec® IR (cetirizine hydrochloride) 10 mg tablet

Dosage form/Route of administration: IR tablet / Oral

Regimen for Treatment D: (US marketed product): Single dose of currently marketed US 10 mg cetirizine as IR tablet (Zyrtec®), administered orally after a 10-hour overnight fast and followed with 240 mL ambient water.

Batch no.: [redacted]

Manufacturer: [redacted]

Reference-2 (Treatment E):

Name: Reactine® (cetirizine dihydrochloride) 10 mg film-coated tablet

Dosage form/Route of administration: Film-coated tablet / Oral

Regimen for Treatment E: (EU/Australian marketed product): Single dose of currently marketed EU/Australian 10 mg cetirizine film coated tablet (Reactine®) administered orally after a 10 hour overnight fast and followed with 240 mL ambient water.

Batch no.: [redacted]

Manufacturer: [redacted]

Treatment Periods:

Period 1: 05-January-2019

Period 2: 12-January-2019

Period 3: 19-January-2019

Period 4: 26-January-2019

Period 5: 02-February-2019

Duration of treatment:

A single 10 mg oral dose of cetirizine was administered under fasting conditions (Treatment A, B, D and E) or fed conditions (Treatment C) in each study period. The drug administrations were separated by a wash-out of 7 calendar days.

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Blood Sampling Points:

In each study period, 16 blood samples for PK measurements were taken before dosing and at 0.25, 0.5, 0.75, 1, 1.25, 1.5, 2, 3, 4, 6, 8, 12, 24, 28 and 32 hours after drug administration. Plasma was harvested and quantified for cetirizine using a validated analytical method.

Criteria for Evaluation:

Pharmacokinetics:

Part 1:

Statistical inference of cetirizine was based on a bioequivalence approach using the following standards:

For evaluation of bioequivalence in accordance with regulatory standards for the US:

The ratios of geometric Least-Squares means (LSmeans) with corresponding 90% confidence intervals, calculated from the exponential of the difference between the Test and Reference products for the ln-transformed parameters C_{max}, AUC_{0-T} and $AUC_{0-\infty}$, were all to be within the 80.00 to 125.00% bioequivalence range comparing Treatment A vs D and B vs D.

For evaluation of bioequivalence in accordance with regulatory standards for Australia:

The ratios of geometric LSmeans with corresponding 90% confidence intervals, calculated from the exponential of the difference between the Test and Reference products for the ln-transformed parameters C_{max} and AUC_{0-T}, were both to be within the 80.00 to 125.00% bioequivalence range comparing Treatment A vs D, A vs E, B vs D, B vs E and D vs E, respectively.

Part 2:

Statistical inference of food effects on cetirizine bioavailability used the following regulatory standards for the US:

The ratios of geometric LSmeans with corresponding 90% confidence intervals, calculated from the exponential of the difference between the Test and Reference products for the ln-transformed parameters C_{max}, AUC_{0-T} and $AUC_{0-\infty}$, were all to be within the 80.00 to 125.00% range comparing Treatment C vs A.

Safety:

Safety was evaluated through assessment of adverse events (AEs) clinical laboratory test results, vital signs and ECG findings.

Pharmacodynamics:

Product Acceptability:

Subjects completed a product sensory questionnaire within 15 minutes following the administrations of Treatment A, Treatment B and Treatment C to assess subject's sensory experience and perceived ease of swallowing of the test product.

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Statistical methods:

Mathematical Model and Statistical Methods of Pharmacokinetic Parameters

The main absorption and disposition parameters were calculated using a non-compartmental approach with a log-linear terminal phase assumption. The trapezoidal rule was used to estimate area under the curve. The terminal phase estimation was based on maximizing the coefficient of determination. The pharmacokinetic parameters of this trial were C_{max}, T_{max}, AUC_{0-T}, $AUC_{0-\infty}$, $AUC_{\%Extrap}$, λ_Z and T_{half}.

The statistical analyses of C_{max}, AUC_{0-T} and $AUC_{0-\infty}$ were based on parametric ANOVA models of the ln-transformed pharmacokinetic parameters; the two-sided 90% confidence intervals of the ratios of geometric means were, in each case, based on the fitted model and calculated through exponentiation.

ANOVA model

For evaluation of bioequivalence in accordance with regulatory standards for the US:

- Fixed factors: sequence, period, treatment
- Random factor: subject (nested within sequence)
- Mixed-effect analysis-of-variance model including all evaluable data from treatments A, B, D and E

For evaluation of bioequivalence in accordance with regulatory standards for Australia:

- Fixed factors: sequence, period, treatment, subject (nested within sequence)
- Separately fitted analysis-of-variance models that included evaluable data only from the two treatments involved in the specific comparison and restricted to subjects providing evaluable data for both treatments involved

For evaluation of the food effect in accordance with regulatory standards for the US:

- Fixed factors: sequence, treatment
- Random factor: subject (nested within sequence)
- Mixed-effect analysis-of-variance model including all evaluable data from Treatments A and C

Summary - Conclusions

Pharmacokinetics Results:

A single center, randomized, single dose, laboratory-blinded, four-way, crossover comparative bioavailability and food effect study in 40 healthy male and female subjects. The rate and extent of absorption of cetirizine were assessed and compared following a single dose (1 x 10 mg) of the Test and the Reference formulations. The bioavailability of cetirizine was equivalent across all Test and Reference comparisons under fasting conditions. There was a food effect observed for cetirizine C_{max}

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however, no significant food effect was observed for AUC_{0-T} or $AUC_{0-\infty}$. The results from evaluable data from 40 subjects are presented in the summary tables on pages 10 and 11.

Safety Results:

A total of 40 subjects entered the study:

- 39 subjects (97.5%) received Treatment A,
- All 40 subjects received Treatments B,
- 38 subjects (95.0%) received Treatment C,
- All 40 subjects received Treatment D,
- All 40 subjects received Treatment E.

No deaths or SAEs were reported for any of the subjects enrolled in this study. No subject was withdrawn by the Investigator due to a Treatment-Emergent Adverse Event (TEAE).

During the study, 1 pregnancy test with inconclusive test results was observed that due to the limited amount of information available and following multiple failed attempts at contacting the subject was considered the subject as lost to follow-up and 1 pregnant partner who refused to consent for follow-up was reported.

The proportion of subjects with at least one TEAE was similar between the 5 treatments (5.1% for Treatment A, 12.5% for Treatment B, 7.9% for Treatment C, 2.5% for Treatment D and 7.5% for Treatment E). Treatment-related TEAEs were only reported following administration of Treatment B (2.5%) and Treatment C (7.9%).

Twenty TEAEs were reported in 11 of the 40 subjects (27.5%) who participated in this study. Of these events, 2 occurred after administration of Treatment A, 8 after administration of Treatment B, 4 after administration of Treatment C, 1 after administration of Treatment D, and 5 after administration of Treatment E.

The TEAEs experienced during the study were of mild (18/20; 90.0%) or moderate (2/20; 10.0%) severity. No severe TEAE was reported by any of the subjects participating in this study.

Of the 20 TEAEs, 5 (25.0%) were considered related to treatment administration and 15 (75.0%) were considered not related; all 5 related events were assessed as possibly related.

The most frequent TEAEs were reported within the SOC nervous system disorders, and included: headache (2.6% for Treatments A, 5.0% for Treatment B, 2.6% for Treatment C and 2.5% for Treatment E) and dizziness (2.6% for Treatment C only). Other TEAEs reported less frequently included oropharyngeal pain (5.0% for Treatment B only), rhinorrhea (5.0% for Treatment B only), vessel puncture site pain (2.6% for Treatment A and 2.5% for Treatment E) and cough (2.5% for each Treatment B and D). Other TEAEs reported by only one subject (2.5-2.6%) included fatigue, peripheral

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swelling, nasal congestion, abdominal distension, and skin fissures.

Abnormalities in the vital signs assessments of the subjects who participated in this study were considered not clinically significant.

Conclusion

The results presented show that the criteria used to assess bioequivalence between the Test and Reference formulations under fasted conditions were all fulfilled, for both the US and the Australian submissions. The Test to Reference estimated ratios of geometric LSmeans and corresponding 90% confidence intervals for C_{max}, AUC_{0-T} and $AUC_{0-\infty}$ were all within the bioequivalence acceptance range of 80.00 to 125.00%:

Cetirizine Chewable Tablet, Fasted With Water (Treatment A) vs Zyrtec® IR tablet US Reference Fasted with Water (Treatment D)

US Submission:

The C_{max} and AUC distributions were similar between Treatment A and Treatment D, with estimated geometric mean ratios and 90% CIs of 102.12% (98.02-106.40%), 100.67% (98.23%-103.17%) and 100.79% (98.26-103.38%) for C_{max}, AUC_{0-T} and $AUC_{0-\infty}$, respectively. Hence, cetirizine chewable tablet with water (Treatment A) was judged to be bioequivalent to Zyrtec® tablet US reference (Treatment D), under fasting conditions.

Australian Submission:

The C_{max} and AUC distributions were similar between Treatment A and Treatment D, with estimated geometric mean ratios and 90% CIs of 102.16% (98.63-105.81%) and 100.67% (98.49%-102.90%) for C_{max} and AUC_{0-T} respectively. Hence, cetirizine chewable tablet with water (Treatment A) was judged to be bioequivalent to Zyrtec® tablet US reference (Treatment D), under fasting conditions.

Cetirizine Chewable Tablet, Fasted With Water (Treatment A) vs Reactine® IR tablet Australian Reference Fasted with Water (Treatment E)

Australian Submission:

The C_{max} and AUC distributions were similar between Treatment A and Treatment E, with estimated geometric mean ratios and 90% CIs of 99.72% (95.55-104.07%) and100.06% (97.19%-103.01%) for C_{max} and AUC_{0-T} respectively. Hence, cetirizine chewable tablet with water (Treatment A) was judged to be bioequivalent to Reactine® tablet EU and Australian reference (Treatment E), under fasting conditions.

Cetirizine Chewable Tablet, Fasted Without Water (Treatment B) vs Zyrtec® IR tablet US Reference Fasted with Water (Treatment D)

US Submission:

The C_{max} and AUC distributions were similar between Treatment B and Treatment D, with estimated

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geometric mean ratios and 90% CIs of 100.59% (96.58-104.77%), 101.96% (99.51%-104.47%) and 102.02% (99.48-104.63%) for C_{max}, AUC_{0-T} and $AUC_{0-\infty}$, respectively. Hence, cetirizine chewable tablet without water (Treatment B) was judged to be bioequivalent to Zyrtec® tablet US reference (Treatment D), under fasting conditions.

Australian Submission:

The C_{max} and AUC distributions were similar between Treatment B and Treatment D, with estimated geometric mean ratios and 90% CIs of 100.59% (96.08-105.32%) and 101.96% (99.77%-104.20%) for C_{max} and AUC_{0-T}, respectively. Hence, cetirizine chewable tablet without water (Treatment B) was judged to be bioequivalent to Zyrtec® tablet US reference (Treatment D), under fasting conditions.

Cetirizine Chewable Tablet, Fasted Without Water (Treatment B) vs Reactine® IR tablet Australian Reference Fasted with Water (Treatment E)

Australian Submission:

The C_{max} and AUC distributions were similar between Treatment B and Treatment E, with estimated geometric mean ratios and 90% CIs of 98.10% (94.31%-102.05%) and 101.33% (98.82%-103.90%) for C_{max} and AUC_{0-T}, respectively. Hence, cetirizine chewable tablet without water (Treatment B) was judged to be bioequivalent to Reactine® tablet EU and Australian reference (Treatment E), under fasting conditions.

Zyrtec® IR tablet US Reference Fasted with Water (Treatment D) vs Reactine® IR tablet Australian Reference Fasted with Water (Treatment E)

Australian Submission:

The C_{max} and AUC distributions were similar between Treatment D and Treatment E with estimated geometric mean ratios and 90% CIs of 97.52% (93.25%-101.99%) and 99.38% (96.94%-101.88%) for C_{max} and AUC_{0-T} respectively. Hence, Zyrtec® IR tablet US Reference (Treatment D) was judged to be bioequivalent to Reactine® tablet Australian reference (Treatment E), under fasting conditions.

Cetirizine Chewable Tablet, Fed With Water (Treatment C) vs Cetirizine Chewable Tablet, Fasted With Water (Treatment A)

US Submission:

The C_{max} values were on average lower following Treatment C compared to Treatment A, with a estimated geometric mean ratio and 90% CI of 55.95% (53.63-58.38%). This difference was substantially less pronounced for the AUC values with estimated geometric mean ratios and 90% CIs of 90.25% (87.79%-92.78%) and 91.27% (88.60%-94.02%) for AUC_{0-T} and $AUC_{0-\infty}$, respectively. Therefore, a food effect was observed for cetirizine C_{max} while for AUC_{0-T} and $AUC_{0-\infty}$ the bioequivalence criterion was fulfilled, when cetirizine chewable tablet was administered following a high-fat breakfast with water.

The majority of subjects rated agreement (i.e. “strongly agree”, “agree”, or “agree somewhat”) that the

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Test product taken in Treatment A, B and C had an acceptable taste, had an acceptable mouth feel while chewing, did not leave an unacceptable aftertaste, and was easy to chew and to swallow. For the statement "this product has an acceptable taste", the majority of subjects rated agreement (i.e. "strongly agree", "agree", or "agree somewhat") following the administration of Treatment A (97.4%), Treatment B (92.5%), and Treatment C (89.5%). For the statement "this product has an acceptable mouth feel while chewing", the majority of subjects rated agreement (i.e. "strongly agree", "agree", or "agree somewhat") following the administration of Treatment A (92.3%), Treatment B (95.0%), and Treatment C (86.8%). For the statement "this product does not leave an unacceptable aftertaste", the majority of subjects rated agreement (i.e. "strongly agree", "agree", or "agree somewhat") following the administration of Treatment A (92.3%), Treatment B (87.5%), and Treatment C (89.5%). For the statement "this product is easy to chew", all subjects rated agreement (i.e. "strongly agree", "agree", or "agree somewhat") following the administration of Treatment A (100.0%), Treatment B (100.0%), and Treatment C (100.0%). For the statement "this product is easy to swallow", the majority of subjects rated agreement (i.e. "strongly agree", "agree", or "agree somewhat") following the administration of Treatment A (100.0%), Treatment B (97.5%), and Treatment C (100.0%). Overall, the tested drugs were generally safe and well tolerated by the subjects included in this study.		
Date of the Report: 3-June-2019		

Pharmacokinetic Parameters

CETIRIZINE

PARAMETER	Treatment A (n=39)		Treatment B (n=40)		Treatment C (n=38)		Treatment D (n=40)		Treatment E (n=40)	
	MEAN	**C.V. (%)**	**MEAN**	**C.V. (%)**	**MEAN**	**C.V. (%)**	**MEAN**	**C.V. (%)**	**MEAN**	**C.V. (%)**
C_{max} (ng/mL)	330.26	(20.9)	326.17	(21.1)	183.69	(16.6)	325.54	(22.0)	331.76	(19.0)
T_{max} (hours)[a]	0.75	(0.50-1.50)	1.25	(0.50-3.00)	4.00	(1.03-6.00)	1.00	(0.50-2.02)	0.75	(0.50-1.55)
AUC_{0-T} (ng·h/mL)	2561.99	(16.6)	2592.22	(17.4)	2312.50	(19.6)	2546.89	(18.1)	2559.48	(17.9)
$AUC_{0-\infty}$ (ng·h/mL)	2689.14	(17.7)	2716.42	(18.1)	2454.32	(21.2)	2671.01	(19.8)	2679.15	(19.1)
$AUC_{\%Extrap}$(%)	4.49	(60.9)	4.38	(62.0)	5.41	(56.0)	4.31	(70.1)	4.22	(63.2)
λ_Z (hours^{-1})	0.1028	(19.5)	0.1057	(19.2)	0.1029	(19.9)	0.1070	(20.3)	0.1070	(21.0)
T_{half} (hours)	7.01	(20.9)	6.82	(21.2)	7.00	(20.6)	6.78	(23.6)	6.77	(22.4)

[a] Median and range are presented

Summary of Statistical Analysis of Cetirizine for Bioequivalence and Food Effect

COMPARISON	REGULATORY SUBMISSION	PARAMETER	INTRA-SUBJECT C.V. (%)	GEOMETRIC LSMEANS[a]		RATIO (%)	90% CONFIDENCE LIMITS (%)	
				TEST	REFERENCE		LOWER	UPPER
Treatment A vs D	US	C_{max}	11.0	324.59	317.84	102.12	98.02	106.40
		AUC_{0-T}	6.6	2520.60	2503.91	100.67	98.23	103.17
		$AUC_{0-\infty}$	6.8	2638.68	2618.07	100.79	98.26	103.38
	Australian	C_{max}	9.2	323.96	317.13	102.16	98.63	105.81
		AUC_{0-T}	5.7	2527.32	2510.44	100.67	98.49	102.90
		$AUC_{0-\infty}$	5.8	2647.51	2626.83	100.79	98.59	103.03
Treatment A vs E	Australian	C_{max}	11.2	323.95	324.87	99.72	95.55	104.07
		AUC_{0-T}	7.6	2526.74	2525.27	100.06	97.19	103.01
		$AUC_{0-\infty}$	7.9	2646.91	2639.31	100.29	97.31	103.36
Treatment B vs D	US	C_{max}	11.0	319.72	317.84	100.59	96.58	104.77
		AUC_{0-T}	6.6	2552.99	2503.91	101.96	99.51	104.47
		$AUC_{0-\infty}$	6.8	2671.04	2618.07	102.02	99.48	104.63
	Australian	C_{max}	12.2	319.72	317.84	100.59	96.08	105.32
		AUC_{0-T}	5.8	2552.99	2503.91	101.96	99.77	104.20
		$AUC_{0-\infty}$	5.9	2671.04	2618.07	102.02	99.80	104.30
Treatment B vs E	Australian	C_{max}	10.5	319.72	325.91	98.10	94.31	102.05
		AUC_{0-T}	6.6	2552.99	2519.50	101.33	98.82	103.90
		$AUC_{0-\infty}$	7.1	2671.04	2631.66	101.50	98.82	104.25
Treatment D vs E	Australian	C_{max}	11.9	317.84	325.91	97.52	93.25	101.99
		AUC_{0-T}	6.6	2503.91	2519.50	99.38	96.94	101.88
		$AUC_{0-\infty}$	7.0	2618.07	2631.66	99.48	96.89	102.15
Treatment C vs A	US	C_{max}	11.0	181.26	323.94	55.95	53.63	58.38
		AUC_{0-T}	7.2	2281.21	2527.59	90.25	87.79	92.78
		$AUC_{0-\infty}$	7.7	2416.75	2647.83	91.27	88.60	94.02

[a] units are ng/mL for C_{max} and ng·h/mL for AUC_{0-T} and $AUC_{0-\infty}$

Note Treatment A is considered Reference for the purpose of the food effect comparison only