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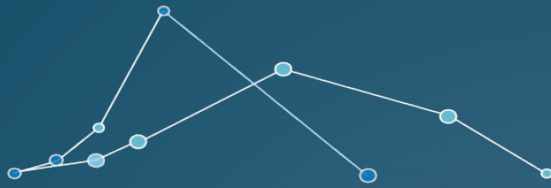
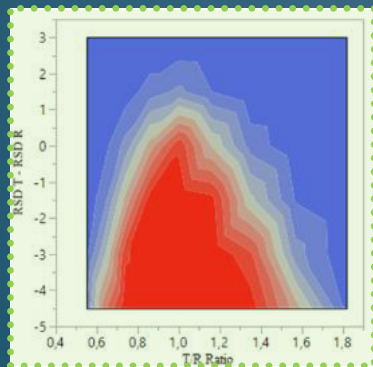


Table AX.Y. Particle Size Distribution of the API in the Suspension on IN-VITRO BIOEQUIVALENCE TESTING FOR THE COMPARISON OF CHARACTERISTICS BETWEEN TEST PRODUCT (MANUFACTURER, Test) and REFERENCE PRODUCT (MANUFACTURER, Reference) Protocol XYZ.

Population Bioequivalence (PBE) Results

PARAMETER	GEOMETRIC MEANS		GEOMETRIC MEAN RATIO (T/R)%	95% UPPER CONFIDENCE BOUND FOR LINEARIZED CRITERIA				BIOEQUIVALENT (YES/NO)
	TEST	REFERENCE		REF Variance	Upper CL if REF Var=< Var_T0	Upper CL if REF Var> Var_T0	Upper 95% CL	
D ₅₀ (µm)	2.000	1.968	101.6	0.0002	-0.031	-0.001	-0.031	YES
Span	1.797	1.886	95.3	0.0002	-0.028	0.004	-0.028	YES

Average BE limit = 1.11, variance term offset = 0.01, scaling variance (Var_T0) = 0.01
In-vitro bioequivalence limit (theta=2.089) is computed as square of the average BE limit in natural log scale plus the variance term offset.
This result is then divided by the scaling variance.
BOLD FONT indicates that Upper 95% Confidence Limit > 0



Experience with Regulatory Agencies/ Countries:

- US (FDA)
- EU (EMA)
- Canada (Health Canada)
- Brazil
- Mexico
- China
- Japan (PMDA)
- S.Africa
- Taiwan
- Saudi Arabia
- Malaysia
- Australia
- Thailand

Special Benefits We Offer

- Discount for new customers
- Urgent turn-around times
- Consultation services geared to the client's level of expertise
- Individual communications and Q/A sessions (written and oral with client and agencies)
- Tailored training in statistics

IN-VITRO BIOEQUIVALENCE STUDIES

Regulatory Statistical Analyses

- Average Bioequivalence
- Population Bioequivalence
- Profile Test to RLD Comparison (Earth Mover's Distance and PBE)
- Dissolution Profile Test to RLD Comparison (model dependent MSD, model independent MSD, f_2 bootstrap methods, etc.)

Statistical Report Writing

Ad-hoc Statistical Analysis

- Simulation studies for estimating the values of PBE constants, estimating power/type I error, examining test properties under various conditions, testing
- Outlier Studies
- Other Studies