

## Pharmacokinetic/Statistical Work Sheet

### Product information:

Product Information	Example
Name of drug product/metabolite	MOH-Remarkable (MOH Inc.)
Name of submitted product (Test)	Remarkable (Brand Y Inc.) Lot number: Expiry date:
Name of original product (Reference)	Remarkable (Brand Y Inc.) Lot number: Expiry date:
Strength/dosage form	5mg USP tablets

### Reviewer:

AUC (0-T)	Test Product (Name/Strength/Dosage Form)	Reference Product (Name/Strength/Dosage Form)
Mean	20.12	19.04
Standard Deviation	14.04	13.21
Coefficient of Variation	69.80	69.38
Ratio of Means	105%	-
Mean of Ratios	107%	-
90% Confidence Interval (potency corrected)	95-115%	-

ANOVA (S/NS)	Subject	[S]	Treatment	[N/S]	Sequence	Sequence	[N/S]
Distribution of individual ratios (# Subjects test vs. ref.)	<0.7	0.7-0.8	0.8-0.9	0.9-1.1	1.1-1.2	1.2-1.3	>1.3
Distribution of individual ratios (# Subjects test vs. ref.)	2	0	2	6	4	2	2

<b>AUC (0-4)</b>	<b>Test Product</b> (Name/Strength/ Dosage Form)	<b>Reference Product</b> (Name/Strength/ Dosage Form)
Mean	21.54	20.39
Standard Deviation	14.24	13.37
Coefficient of Variation	66.11	65.57
Ratio of Means	105%	-
Mean of Ratios	107%	-
90% Confidence Interval (potency corrected)	96-115%	-

ANOVA (S/NS)	Subject	[S]	Treatment	[N/S]	Sequence	Sequence	[N/S]
Distribution of individual ratios (# Subjects test vs. ref.)	<0.7	0.7-0.8	0.8-0.9	0.9-1.1	1.1-1.2	1.2-1.3	>1.3
Distribution of individual ratios (# Subjects test vs. ref.)	2	0	1	6	5	2	2

<b>Cmax</b>	<b>Test Product</b> (Name/Strength/Dosage Form)	<b>Reference Product</b> (Name/Strength/Dosage Form)
Mean	12.16	11.55
Standard Deviation	7.85	8.68
Coefficient of Variation	64.56	75.13
Ratio of Means	103%	-
Mean of Ratios	110%	-
90% Confidence Interval (potency corrected)	89-120%	-

ANOVA (S/NS)	Subject	[S]	Treatment	[N/S]	Sequence	Sequence	[N/S]
Distribution of individual ratios (# Subjects test vs. ref.)	<0.7	0.7-0.8	0.8-0.9	0.9-1.1	1.1-1.2	1.2-1.3	>1.3
Distribution of individual ratios (# Subjects test vs. ref.)	3	0	3	4	2	1	5

<b>Tmax</b>	<b>Test Product</b> (Name/Strength/Dosage Form)	<b>Reference Product</b> (Name/Strength/Dosage Form)
Mean	0.58	0.50
Standard Deviation	0.25	0.27
Coefficient of Variation	41.05	41.26