

Appendix 15 Hematology (Preliminary study)

B130235

Sex: Male Day(s) Relative to Start Date

Group: 1	Hematology													
	Reticulocyte	Reticulocyte	Reticulocyte	Reticulocyte	Reticulocyte	Reticulocyte	Reticulocyte	Reticulocyte	Reticulocyte	Reticulocyte	PT	PT	PT	PT
	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(sec)	(sec)	(sec)	(sec)
	1	2	5	6	8	9	12	13	20	21	1	2	5	6
29001	0.96	1.06	0.80	0.94	1.59	1.77	2.39	3.18	4.33	5.04	9.2	9.7	9.0	9.5

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Sex: Male Day(s) Relative to Start Date

Group: 1	Hematology													
	PT	PT	PT	PT	PT	PT	APTT	APTT	APTT	APTT	APTT	APTT	APTT	APTT
	(sec)	(sec)	(sec)	(sec)	(sec)	(sec)	(sec)	(sec)	(sec)	(sec)	(sec)	(sec)	(sec)	(sec)
	8	9	12	13	20	21	1	2	5	6	8	9	12	13
29001	9.0	8.8	9.3	9.1	8.8	8.9	22.1	21.7	20.9	21.0	20.5	20.6	20.9	20.8

Sex: Male Day(s) Relative to Start Date

Group: 1	Hematology													
	APTT (sec)	APTT (sec)	White Blood Cell Count (10 ³ /μL)	White Blood Cell Count (10 ³ /μL)	White Blood Cell Count (10 ³ /μL)	White Blood Cell Count (10 ³ /μL)	White Blood Cell Count (10 ³ /μL)	White Blood Cell Count (10 ³ /μL)	White Blood Cell Count (10 ³ /μL)	White Blood Cell Count (10 ³ /μL)	White Blood Cell Count (10 ³ /μL)	White Blood Cell Count (10 ³ /μL)	Lymphocyte (%)	Lymphocyte (%)
	20	21	1	2	5	6	8	9	12	13	20	21	1	2
29001	20.8	24.7	5.87	7.39	5.75	7.73	5.95	9.47	6.90	8.74	6.63	11.04	38.5	46.0

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Sex: Male Day(s) Relative to Start Date

Group: 1	Hematology													
	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte	Neutrophil	Neutrophil	Neutrophil	Neutrophil	Neutrophil	Neutrophil
	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
	5	6	8	9	12	13	20	21	1	2	5	6	8	9
29001	29.2	25.2	30.9	21.5	38.8	25.9	30.8	21.4	56.4	48.3	66.9	69.6	65.3	73.3

Appendix 15 Hematology (Preliminary study)

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Sex: Male Day(s) Relative to Start Date

Group: 1	Hematology													
	Neutrophil	Neutrophil	Neutrophil	Neutrophil	Eosinophil	Eosinophil	Eosinophil	Eosinophil	Eosinophil	Eosinophil	Eosinophil	Eosinophil	Eosinophil	Eosinophil
	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
	12	13	20	21	1	2	5	6	8	9	12	13	20	21
29001	55.7	68.8	64.8	74.9	0.3	0.3	0.2	0.3	0.3	0.0	0.1	0.0	0.0	0.0

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Sex: Male Day(s) Relative to Start Date

Group: 1	Hematology													
	Basophil	Basophil	Basophil	Basophil	Basophil	Basophil	Basophil	Basophil	Basophil	Basophil	Monocyte	Monocyte	Monocyte	Monocyte
	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)	(%)
	1	2	5	6	8	9	12	13	20	21	1	2	5	6
29001	0.0	0.1	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	4.8	5.3	3.7	4.9

Appendix 15 Hematology (Preliminary study)

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Sex: Male Day(s) Relative to Start Date

Group: 1	Hematology													
	Monocyte	Monocyte	Monocyte	Monocyte	Monocyte	Monocyte	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte	Lymphocyte
	(%)	(%)	(%)	(%)	(%)	(%)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)
	8	9	12	13	20	21	1	2	5	6	8	9	12	13
29001	3.5	5.2	5.4	5.3	4.4	3.7	2.26	3.40	1.68	1.95	1.84	2.04	2.68	2.26

Appendix 15 Hematology (Preliminary study)

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Sex: Male Day(s) Relative to Start Date

Group: 1	Hematology													
	Lymphocyte	Lymphocyte	Neutrophil	Neutrophil	Neutrophil	Neutrophil	Neutrophil	Neutrophil	Neutrophil	Neutrophil	Neutrophil	Neutrophil	Eosinophil	Eosinophil
	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)	(10 ³ /μL)
	20	21	1	2	5	6	8	9	12	13	20	21	1	2
29001	2.04	2.36	3.31	3.57	3.85	5.38	3.88	6.94	3.84	6.02	4.30	8.27	0.02	0.02

Appendix 15 Hematology (Preliminary study)

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Sex: Male Day(s) Relative to Start Date

Group: 1	Hematology													
	Eosinophil (10 ³ /μL)	Eosinophil (10 ³ /μL)	Eosinophil (10 ³ /μL)	Eosinophil (10 ³ /μL)	Eosinophil (10 ³ /μL)	Eosinophil (10 ³ /μL)	Eosinophil (10 ³ /μL)	Eosinophil (10 ³ /μL)	Basophil (10 ³ /μL)	Basophil (10 ³ /μL)	Basophil (10 ³ /μL)	Basophil (10 ³ /μL)	Basophil (10 ³ /μL)	Basophil (10 ³ /μL)
	5	6	8	9	12	13	20	21	1	2	5	6	8	9
29001	0.01	0.02	0.02	0.00	0.01	0.00	0.00	0.00	0.00	0.01	0.00	0.00	0.00	0.00

Appendix 15 Hematology (Preliminary study)

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Sex: Male Day(s) Relative to Start Date

Group: 1	Hematology													
	Basophil (10 ³ /μL)	Basophil (10 ³ /μL)	Basophil (10 ³ /μL)	Basophil (10 ³ /μL)	Monocyte (10 ³ /μL)	Monocyte (10 ³ /μL)	Monocyte (10 ³ /μL)	Monocyte (10 ³ /μL)	Monocyte (10 ³ /μL)	Monocyte (10 ³ /μL)	Monocyte (10 ³ /μL)	Monocyte (10 ³ /μL)	Monocyte (10 ³ /μL)	Monocyte (10 ³ /μL)
	12	13	20	21	1	2	5	6	8	9	12	13	20	21
29001	0.00	0.00	0.00	0.00	0.28	0.39	0.21	0.38	0.21	0.49	0.37	0.46	0.29	0.41

Sex: Male Day(s) Relative to Start Date

Group: 1	Blood Chemistry													
	ASAT	ASAT	ASAT	ASAT	ASAT	ASAT	ASAT	ASAT	ASAT	ASAT	ALAT	ALAT	ALAT	ALAT
	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)
	1	2	5	6	8	9	12	13	20	21	1	2	5	6
29001	39	99	50	74	56	81	51	95	55	266	59	75	67	67

Appendix 16 Blood Chemistry (Preliminary study)

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Sex: Male Day(s) Relative to Start Date

Group: 1	Blood Chemistry													
	ALAT	ALAT	ALAT	ALAT	ALAT	ALAT	LDH	LDH	LDH	LDH	LDH	LDH	LDH	LDH
	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)	(U/L)
	8	9	12	13	20	21	1	2	5	6	8	9	12	13
29001	65	68	63	70	71	99	220	358	305	388	350	436	369	508

Sex: Male Day(s) Relative to Start Date

Group: 1	Blood Chemistry													
	LDH (U/L)	LDH (U/L)	Creatine Kinase (U/L)	Creatine Kinase (U/L)	Creatine Kinase (U/L)	Creatine Kinase (U/L)	Creatine Kinase (U/L)	Creatine Kinase (U/L)	Creatine Kinase (U/L)	Creatine Kinase (U/L)	Creatine Kinase (U/L)	Creatine Kinase (U/L)	Total Bilirubin (mg/dL)	Total Bilirubin (mg/dL)
	20	21	1	2	5	6	8	9	12	13	20	21	1	2
29001	357	2115	175	303	35	198	110	126	150	421	154	6930	0.1	0.1

Appendix 16 Blood Chemistry (Preliminary study)

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Sex: Male Day(s) Relative to Start Date

Group: 1	Blood Chemistry							
	Total Bilirubin (mg/dL)	Total Bilirubin (mg/dL)	Total Bilirubin (mg/dL)	Total Bilirubin (mg/dL)	Total Bilirubin (mg/dL)	Total Bilirubin (mg/dL)	Total Bilirubin (mg/dL)	Total Bilirubin (mg/dL)
	5	6	8	9	12	13	20	21
29001	0.1	0.2	0.1	0.2	0.1	0.3	0.1	0.7

11. $[^{14}\text{C}]$ P092 マレイン酸塩の
ラットにおける単回投与後の
薬物動態予備試験

本写しは原本と相違ありません
（株）LSIメディエンス 鹿島研究所
2014年7月8日
試験責任者 牧之段太志



最終報告書

[¹⁴C]P092・マレイン酸塩のラットにおける単回投与後の薬物動態予備試験

(試験番号：B140398)

株式会社LSIメディエンス

1. 陳述書

表題： [^{14}C]P092・マレイン酸塩のラットにおける単回投与後の薬物動態予備試験

試験番号： B140398

本最終報告書は試験結果を正しく反映したものである。

試験責任者：

2014 年 7 月 8 日

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