



SAMPLE REQUIREMENTS FOR JMHLW BIOCOMPATIBILITY TESTING

The sample sizes provided reflect the *optimal* amount of sample, depending on the test being performed.

Turnaround times for GLP testing are shown in brackets with each test listing. For non-GLP testing, turnaround times would be approximately 7 days shorter.

If you have questions, before submitting samples, contact Client Services at WuXi AppTec's St. Paul facility: 651-675-2000 or 888-794-0077.

TESTS PERFORMED USING EXTRACTION RATIOS

	< 0.5mm thickness (120cm ² /20mL ratio) <i>[film, sheet, tubing wall]</i>	≥ 0.5mm thickness (60cm ² /20mL ratio) <i>[tubing wall, slab, molded items]</i>	Irregularly Shaped (4g/20mL ratio) <i>[powder, pellets, foam, non-absorbent molded items]</i>
Extract Colony by Elution – JMHLW [31 days]	120cm ²	120cm ²	2g
Hemolytic Toxicity – JMHLW [32 days]	3 x 90cm ²	3 x 45cm ²	3 x 3g
Intracutaneous Reactivity – JMHLW [29 days]	2 x 36cm ²	2 x 18cm ²	2 x 1.2g
Material Mediated Rabbit Pyrogen – JMHLW [26 days]	900cm ²	450cm ²	30g
Acute Systemic Test – JMHLW [27 days]	2 x 48cm ²	2 x 24cm ²	2 x 1.6g
Subacute (28 Day) Intravenous Toxicity Study in Rats (28 Repeat Dose Exposure) [105 days]	28 x 186cm ²	28 x 93cm ²	28 x 6.2g

TESTS PERFORMED USING EXHAUSTIVE EXTRACTION METHODS

	Pretest	Method 1	Method 2
Bacterial Reverse Mutation – JMHLW [40 days]	2g	<i>To Be Determined*</i>	1g
<i>In Vitro</i> Chromosome Aberration – JMHLW [62 days]	<i>The pretest result can be used for any one or all of these tests.</i>	<i>To Be Determined*</i>	2g
Maximization Sensitization – JMHLW [81 days]		<i>To Be Determined*</i>	15g

* During the pretest, the test article is extracted with methanol and acetone. The extracts are then rotary evaporated to a residue. The extract solvent that produces a greater residue (by weight, without degradation) is used for the extraction for the main study (Method 1). If neither solvent produces a sufficient evaporation residue, then Method 2 (extraction) will be used. In either case, the sample requirements – based on the amount of residue obtained in the pretest – will be communicated to the client by a WuXi AppTec representative.

IMPLANTATION TESTS

Intramuscular Implantation – JMHLW [42 days]	Sufficient material to produce 15 implants, approx. 10mm x 3mm each
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Note: TAT is in addition to implant duration.