SAMPLE REQUIREMENTS FOR BIOCOMPATIBILITY TESTING

This chart is designed as a convenient quick guide for some of our most commonly ordered tests (and does not list all available tests).
The sample sizes provided reflect the *optimal* amount of sample, depending on the test being performed.
For liquid samples, contact Client Services.
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 *[film, sheet, tubing wall]*	**≥ 0.5mm thickness** *[tubing wall, slab, molded items]*	**Irregularly Shaped** *[powder, pellets, foam, non-absorbent molded items]*	**Membranes** *[low-density materials]*
CYTOTOXICITY				
MEM Elution Using L-929 Mouse Fibroblast Cells – ISO/USP *[18 days]*	1 x 30cm²	1 x 15cm²	1 x 1g	1 x 0.5g
MTT Cytotoxicity Assay with L-929 Mouse Fibroblast Cells *[26 days]*	1 x 36cm²	1 x 18cm²	1 x 1.2g	1 x 0.8g
GENOTOXICITY				
Bacterial Mutagenicity (Ames) *[28 days]*	2 x 24cm²	2 x 12cm²	2 x 0.8g	2 x 0.4g
In Vitro Chromosome Aberration *[62 days]*	2 x 42cm²	2 x 21cm²	2 x 1.4g	2 x 0.7g
In Vitro Mouse Lymphoma *[39 days]*	2 x 42cm²	2 x 21cm²	2 x 1.4g	2 x 0.7g
In Vivo Mouse Micronucleus *[55 days]*	2 x 120cm²	2 x 60cm²	2 x 4g	2 x 2g
IRRITATION				
Intracutaneous Reactivity – ISO/USP *[29 days]*	2 x 36cm²	2 x 18cm²	2 x 1.2g	2 x 0.6g
Vaginal Mucosal Irritation – ISO *[54 days]*	10 x 60cm²	10 x 30cm²	10 x 2g	10 x 1g
PYROGENICITY				
Material Mediated Rabbit Pyrogen – ISO *[26 days]*	900cm²	450cm²	30g	15g
SENSITIZATION				
Maximization Sensitization (Guinea Pig) – ISO *[54 days]*	6 x 60cm²	6 x 30cm²	6 x 2g	6 x 1g
Murine Local Lymph Node Assay (LLNA) *[32 days]*	6 x 30cm²	6 x 15cm²	6 x 1g	6 x 0.5g
SYSTEMIC TOXICITY				
Acute Systemic Test – ISO/USP *[27 days]*	2 x 48cm²	2 x 24cm²	2 x 1.6g	2 x 0.8g
Subacute/Subchronic Toxicity (Mice) – 5 Dose Exposure *[89 days]*	5 x 30cm²	5 x 15cm²	5 x 1g	5 x 0.5g
Subacute/Subchronic Toxicity (Mice) – 14 Dose Exposure *[89 days]*	14 x 30cm²	14 x 15cm²	14 x 1g	14 x 0.5g

HEMOCOMPATIBILITY / BLOOD COMPATIBILITY TESTS

	< 0.5mm thickness *[film, sheet, tubing wall]*	**= 0.5mm thickness** *[sheet, tubing wall, slab, molded items]*	**> 0.5mm thickness** *[tubing wall, slab, molded items]*	**Irregularly Shaped** *[powder, pellets, foam, non-absorbent molded items]*
Complement Activation C3a and SC5b-9 *[25 days]*	6cm² *	3cm² *	3cm² *	0.1g *
Hemolysis: ASTM – Direct Contact *[21 days]*	3 x 42cm²	3 x 42cm²	3 x 21cm²	3 x 1.4g
Hemolysis: ASTM – Extract *[21 days]*	3 x 60cm²	3 x 60cm²	3 x 30cm²	3 x 2g
In Vitro Hemocompatibility *[25 days]*	3 x 12cm² *			
Partial Thromboplastin Time *[25 days]*	3 x 4cm² *			
Platelet and Leukocyte Count *[25 days]*	3 x 12cm² *			
Thrombosis (*In Vivo*) – 2 Dog *[28 days]* *Other animal models available.*	Length: 8-15cm • Maximum Diameter: ≤ 3mm [2 test samples *and* 2 comparison samples]			

*****Concurrent testing of sponsor-supplied comparison product is recommended. (Required for thrombosis studies.) Sample size of the comparison product should be the same as that of the test article.*

TESTS PERFORMED USING THE PATCH METHOD (SKIN CONTACTING)

Agarose Overlay Using L-929 Cells – ISO/USP *[14 days]*	Sufficient material to produce 3 patches, 1cm x 1cm each
Primary Skin Irritation – ISO *[30 days]*	Sufficient material to produce 7 patches, 2.5cm x 2.5cm each
Repeated Patch Dermal Sensitization Test – Buehler *[57 days]*	Sufficient material to produce 105 patches, 2.5cm x 2.5cm each

IMPLANTATION STUDIES

Intramuscular/Subcutaneous Implantation (3 Rabbit) – ISO *[42 days]*	Sufficient material to produce 15 implants, approx. 10mm x 3mm each
Intramuscular/Subcutaneous Implantation (5 Rabbit) – ISO *[49 days]*	Sufficient material to produce 25 implants, approx. 10mm x 3mm each
Intramuscular Implantation – USP *[21 days]*	Sufficient material to produce 12 implants, approx. 10mm x 3mm each

Note: TAT is in addition to implant duration.

CHEMISTRY

FTIR *[7 days]*	5g
Physicochemical Test for Plastics – USP *[7 days]*	10g or 600cm²

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