ASTM-Hemolysis Complete

ASTM-Hemolysis Direct

ASTM-Hemolysis Indirect

AAMI-Bacterial Endotoxins Test-Gel Clot-GLP

AAMI-Bacterial Endotoxins Test-Gel Clot-GLP-Validation

AAMI-Bacterial Endotoxins Test-Gel Clot-GMP

AAMI-Bacterial Endotoxins Test-Gel Clot-GMP-Validation

AAMI-Bacteriostasis and Fungistasis by Membrane Filtration-GMP

AAMI-Bioburden Assay-GMP

AAMI-Bioburden Validation-Spore Inoculation

AAMI-Biological Indicator Sterility-GMP

AAMI-Sterility Assay by Membrane Filtration Method-GMP

AAMI-Sterility-Membrane Filtration or Direct Transfer-GMP

AMMI-Bacteriostasis and Fungistasis by Membrane Filtration or Direct Transfer-GMP

CFDA-Primary Skin

USP-Physicochemical Test for Plastics

USP-Physicochemical Test for Plastics-Non-Volatile Residue

USP-Rubber Articles Intended 4 Repeated Use

EP 2.6.8-Pyrogen

EP 2.6.8-Pyrogen-Direct Exposure

ISO-14-Day Repeat Dose IV Tox in Mice

ISO-14-Day Repeat Dose IV Tox in Rats-Abridged

ISO-21 Day Ocular Safety Study in Rabbit

ISO-26 Week Toxicity (Chronic Tox) via Subcutaneous Implant-Abridged

ISO-26-Day Systemic Tox in Rats Via Muscle Implant-Abridged

ISO-26-Day Systemic Tox in Rats Via Muscle Implant-Abridged

ISO-28-Day Repeat Dose IV Tox in Rats-Abridged

ISO-28-Day Systemic Tox in Rats via Muscle Implant-Abridged

ISO-28-Day Systemic Tox in Rats Via Muscle Implant-Compliance

ISO-28-Day Systemic Tox in Rats via Subcutaneous Implant-Abridged

ISO-28-Day Systemic Tox in Rats Via Subcutaneous Implant-Compliance

ISO-90-Day Systemic Tox in Rabbits Via Subcutaneous Implant-Abridged

ISO-90-Day Systemic Tox in Rabbits via Subcutaneous Implant-Compliance

ISO-90-Day Systemic Tox in Rats Via Muscle Implant-Abridged

ISO-90-Day Systemic Tox in Rats Via Muscle Implant-Compliance

ISO-90-Day Systemic Tox in Rats Via Subcutaneous Implant-Abridged

ISO-90-Day Systemic Tox in Rats Via Subcutaneous Implant-Compliance

ISO-90-Day Tox in Rats via Bone Implant

ISO-Hemolysis-Human Blood (Direct)

ISO-Hemolysis-Human Blood (Indirect)

ISO-Hemolysis-Rabbit Blood (Direct)

ISO-Hemolysis-Rabbit Blood (Indirect)

ISO-L929 Direct Contact

ISO-L929 MTT Test (1 Concentrations)

ISO-L929 MTT Test (4 Concentrations)

ISO-L929 Neutral Red Uptake (1 Concentration)

ISO-L929 Neutral Red Uptake (4 Concentrations)

ISO-L929 Qualitative Evaluation (1 Concentration)

ISO-L929 Qualitative Evaluation (4 Concentration)

ISO-L929 XTT Test (1 Concentration)

ISO-L929 XTT Test (4 Concentrations)

ISO-Acute Oral Extraction Method

ISO-Agar Diffusion-Direct

ISO-Agar Diffusion-Indirect

ISO-Ames

ISO-Bladder Irritation

ISO-Bladder Irritation-Direct

ISO-Bone Implant

ISO-Brain Implant

ISO-Buccal Irritation (Oral)

ISO-Buccal Irritation (Oral)-Direct

ISO-Buehler-Direct Contact

ISO-Chromosomal Abberration Assay in Human Lymphocytes With confirmation

ISO-Chromosomal Abberration Assay in Human Lymphocytes WITHOUT confirmation

ISO-Chromosomal Abberration-with confirmation-200 Metaphases

ISO-Chromosomal Abberration-with confirmation-300 Metaphases

ISO-Chromosomal Abberration-WITHOUT confirmation-200 Metaphases

ISO-Complement Activation Assay (Direct)

ISO-Complement Activation Assay (Indirect)

ISO-Direct Contact Cytotoxicity-SK-N-MC

ISO-Elution Test-S-K-N-MC

ISO-Elution Vero Cell

ISO-Elution

ISO-In Vitro Hemocompatibility (Direct)

ISO-In Vitro Hemocompatibility (Indirect)

ISO-Intracutaneous Injection Test

ISO-Intracutaneous Injection Test-Direct

ISO-Kligman Maximization Test

ISO-Kligman Maximization Test-Direct

ISO-Lee and White Coagulation Direct Contact Test

ISO-Lee and White Coagulation Indirect Contact Test

ISO-Local Lymph Nodes Assay (LLNA)

ISO-Micronucleus-Rodent Blood-Double Dose

ISO-Micronucleus-Rodent Blood-Single Dose

ISO-Mouse Lymphoma With Confirmation

ISO-Mouse Lymphoma WITHOUT Confirmation

ISO-Muscle Implant

ISO-Platelet Aggregation-Direct

ISO-Platelet Aggregation-Indirect

ISO-Primary Ocular Irritation

ISO-Primary Ocular Irritation-Direct

ISO-Primary Penile Irritation-Repeat Exposure

ISO-Primary Penile Irritation-Repeat Exposure-Direct

ISO-Primary Rectal Irritation-Repeat Exposure

ISO-Primary Rectal Irritation-Repeat Exposure-Direct

ISO-Primary Skin-Direct

ISO-Primary Skin-Indirect

ISO-Primary Vaginal Irritation Repeat Exposure

ISO-Primary Vaginal Irritation Repeat Exposure-Direct

ISO-Prothrombin Time-Direct

ISO-Prothrombin Time-Indirect

ISO-Pyrogen

ISO-Pyrogen-Direct-Exposure

ISO-Quantitative Evaluation (NRU) (1 Concentration)

ISO-Quantitative Evaluation (NRU) (4 Concentrations)

ISO-UPTT-Direct

ISO-UPTT-Indirect

ISO-V79-Indirect

ISO-Subcutaneous Implant

ISO-Systemic Injection

ISO-Systemic Injection-Direct

ISO-Thrombin Anti Thrombin (TAT)(Direct)

ISO-Thrombin Anti Thrombin (TAT)(Indirect)

ISO-Thrombogenicity

ISO and USP-Class V

ISO and USP-Class VI

ISO and USP-Intracutaneous Injection Test

ISO and USP-Systemic Injection Test

JP XVI-Acute Systemic Toxicity

JP XVI-Pyrogen

MHLW-14-Day Repeat Dose IV Tox in Mice

MHLW-28-Day Repeat Dose IV Tox in Rats

MHLW-Acute Systemic Toxicity

MHLW-Ames

MHLW-Chromosomal Aberration

MHLW-GENE-Extraction Rate Determination

MHLW-Hemolysis Rabbit Blood (Indirect)

MHLW-Intracutaneous

MHLW-Primary Skin-Direct

MHLW-Primary Skin-Indirect

MHLW-Pyrogen

MHLW-Skin Sensitization-Kligman

MHLW-V79-Direct

MHLW-V79-Indirect

OECD 404-Acute Dermal Irritation

OECD 405-Ocular Irritation Corrosion

OECD 402-Acute Dermal Toxicity

OECD 406-Buehler

OECD 420-Acute Oral Toxicity Test-Fixed Dose Procedure (FDP)

OECD 425-Acute Oral-Up and Down Procedure

OECD 429-Local Lymph Nodes

OECD 429-Local Lymph Nodes-REDUCED

OECD 437-BCOP

OECD 439-In Vitro Skin Irritation

OECD 471-Ames

OECD 473-DRAFT Chromosomal Aberration

OECD 474-DRAFT Rodent Blood Micronucleus Repeat Dose

OECD-Kligman-39 Animals

USP Class VI

USP-Agar Diffusion-Direct

USP-Agar Diffusion-Indirect

USP-Amoebocyte Lysate for Detection and Quantitation-Chromogenic-GMP

USP-Amoebocyte Lysate for Inhibition and Enhancement-Chromogenc Validation-GMP

USP-Bacterial Endotoxins Test(BET)-Gel Clot-GMP

USP-Bacterial Endotoxins Test(BET)-Gel Clot-Validation-GMP

USP-Bacteriostasis and Fungistasis by Membrane Filtration or Direct Transfer-GMP

USP-Elution

USP-Intracutaneous

USP-Mouse Safety

USP-Muscle Implant

USP-Pyrogen

USP-Pyrogen-Direct Exposure

USP-Sterility-Membrane Filtration or Direct Transfer-GMP

USP-Sterility-Membrane Filtration or Direct Transfer-GMP

USP-Systemic

Custom Template

Healing of Full Thickness Wounds After Irradiation in Swine (Non-G)

USP-Residue on Ignition

AAMI-Bioburden Validation Exhaustive Recovery-GMP

METHOD VALIDATION FOR THE QUANTITATIVE ANALYSIS OF \_\_\_\_\_\_\_\_\_\_\_ IN FORMULATION SAMPLES BY HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC)

OCULAR TOLERABILITY STUDY IN DUTCH BELTED RABBITS

Cleaning validation - TIHM

DETERMINATION OF THE EXTRACTABLE AMOUNT OF CHEMICAL COMPOUNDS, PRESENT IN AND ON A PROCESS FLOW KIT - Non-g

Intra-articular implant

Intra-articular Implant

MHLW 7 day Muscle Implant

MHLW-Muscle Implant

Determination of the Extractable Amount of Chemical Compounds Present in Metallic Device

Method Validation of Elisa analysis for RhoGam, WinRho, RhoPhylac

Method Validation for WinRhp

Method Validation for RhoPhylac

1. REUSABLE DEVICE LIFECYCLE STUDY  SPONSOR SPECIFIED TIHM NASAL MASK  10 CYCLES

2. REUSABLE DEVICE LIFECYCLE STUDY  SPONSOR SPECIFIED TIHM NASAL MASK  15 CYCLES

3. REUSABLE DEVICE LIFECYCLE STUDY  SPONSOR SPECIFIED TIHM NASAL MASK  20 CYCLES

REUSABLE DEVICE LIFECYCLE STUDY  SPONSOR SPECIFIED TIHM NASAL MASK  25 CYCLES

5. REUSABLE DEVICE LIFECYCLE STUDY  SPONSOR SPECIFIED TIHM NASAL MASK  30 CYCLES

ep 3.1.8 silicone lubricant oil

ethicon JP silicone oil

A 180-DAY REPEAT DOSE SUBCUTANEOUS TOXICITY AND TOXICOKINETIC STUDY OF PROLONG PEG-GCSF IN SPRAGUE DAWLEY RATS WITH A 30-DAY RECOVERY PERIOD

BACTERIAL ENDOTOXINS TEST (BET) FOR DETECTION AND QUALITATIVE MEASUREMENT OF ENDOTOXINS (GELCLOT METHOD)  USP FOR EMD MILLIPORE PRODUCTS MANUFACTURED BY SMC, LTD. AND VENTION MEDICAL

SHEEP THROMBOGENICITY

SS - CLEANING VALIDATION

DETERMINATION OF THE EXTRACTABLE AMOUNT OF CHEMICAL COMPOUNDS, PRESENT IN AND ON A PLATINUM CURED SILICONE TUBING

METHOD DEVELOPMENT AND VALIDATION FOR THE DETECTION AND QUANTITATION OF TARGET LEACHATES IN THE SPONSORS FINISHED PRODUCT

USP 788 Particular Analysis

USP 788 Particulate Analysis Light Obstruction

USP 661 Compedial Physiochemical Test Plastics

Tissue Evaluation (Non-GLP - Quote#15-08-27-0014)

VALIDATION OF DADE FIBRINOGEN DETERMINATION REAGENT IN CANINE AND PORCINE FIBRINOGEN FOR SYSMEX CA-1500

SS - CLEANING DISINFECTION WISP YOUTH TD3AND TD4

SS- NUANCE PRO GIGACEPT

SS - PICO TD1,2,3,4,5

SS - PICO - CIDEX,CIDEX OPA,WAVICIDE,ANIOXIDE 1000,GIGACEPT FF

SS - PICO - HOME CLEANING,MEDIZYME,ANIOSYME DD1,

SS -PICO - 20 CYCLE GIGACEPT

6 Month Repeat Dose Toxicity Study in Cynomolgous Macaques with 3 Month Interim Sacrifice and 1 Month Recovery

13 Week Repeat Dose Toxicity Study in Juvenile Rats with 4 Week Recovery

SS-GLP-MLLNA-ISO-Vistakon

SS - EXTRACTION - ICP-SVOC-VOS - SIMILAR TO P14-2272-00B

SS - ETHICON - EP

SS- ETHICON - JP

SS-BARD NVR

Thermal Tissue Evaluation (See Chris P)

A Single Dose Toxicity Study of Extracorporeal Mesenchymal Stromal Cell Therapy in Mongrel Dogs

Franck sent this to you yesterday

EFFECT OF TIME ON THE RELATIVE THROMBIN ACTIVITY OF THE THROMBIN COMPONENT OF FLOSEAL HEMOSTATIC MATRIX KIT – METHOD VALIDATION

RTA Time Validation 090951B or EFFECT OF TIME ON THE RELATIVE THROMBIN ACTIVITY OF THE THROMBIN COMPONENT OF FLOSEAL HEMOSTATIC MATRIX KIT – METHOD VALIDATION

SS-Chemical Characterization of Embolic Device

Pico – 30 Cycle gigacept life cycle conditioning

30/60 Day Implant of SNS in Dogs

SS-GIGACEPT 30 CYCLES CHBI WISP YOUTH 3 RINSES

SS-STERRAD NX AND 100 NX

SS- 100S STERRAD

BIOANALYTICAL METHOD VALIDATION FOR QUANTITATIVE ANALYSIS OF OLTIPRAZ IN MOUSE PLASMA BY HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) WITH TANDEM MASS SELECTIVE DETECTOR (LC/MS/MS)

Vistakon-SS-Non-GLP-Ocular-6 hour Lens Wear Study

Vistakon-SS-Non-GLP-Ocular-6 hour Lens Wear Study

Vistakon-SS-GLP-OECD 429-MLLNA

Extractable study of Polyproylene & PVDF

SS-CLEANING VALIDATION

Chemical Characterization of Embolic Device

Agar Diffusion-Direct

Buehler-Direct Contact

Primary Skin-Direct

STABILITY STUDY OF OLTIPRAZ IN MOUSE PLASMA

Non-GLP-Long Term-NRU (Franck Grall Study Director)

CHEMICAL CHARACTERIZATION - NEONATE

Efficacy in a Hypertonic Saline Injection Model of Glaucoma

Efficacy in a Hypertonic Saline Injection Model of Glaucoma

Extractable study for two Iterations of NexMed USA materials

SS- neuroderm extractable

SS- EXTRACTABLE

SS- CHEMICAL CHARACTERIZATION

Cleaning of Reusable Airway probe (441A) with Low level disinfection on combined organisms

Cleaning of Reusable Airway probe (402AC) with Low level disinfection on combined organisms

Cleaning of Reusable Airway probe (402) with Low level disinfection on combined organisms with

Cleaning of Reusable Airway probe (441A) with Low level disinfection on combined organisms with Steam Sterilization and Dry Time validation 50x life cycling and manual cleaning and disinfection validaion

Cleaning of Reusable Airway probe (402AC) with Low level disinfection on combined organisms with Steam Sterilization and Dry Time validation 50x life cycling and manual cleaning and disinfection validaion

Cleaning of Reusable Airway probe (402) with Low level disinfection on combined organisms with

Cleaning of Reusable Airway probe (441A) with Low level disinfection on combined organisms with Steam Sterilization and Dry Time validation 50x life cycling and manual cleaning and disinfection validaion

Cleaning of Reusable Airway probe (402AC) with Low level disinfection on combined organisms with Steam Sterilization and Dry Time validation 50x life cycling and manual cleaning and disinfection validaion

Manual Cleaning of Reusable Airway Probe 441A

50X Life Cycle Conditioning of Reusable Airway Probe 441A

Chemical Disinfection and Neutralization Validation of Reusable Airway Probe 441A

Steam Sterilization and Dry Time Validation of Reusable Airway Probe 441A

Manual Cleaning Validation of Reusable Temperature Probe 402AC

50X Life Cycle Conditioning of Reusable Temperature Probe 402AC

Chemical Disinfection and Neutralization Validation for Reusable Temperature Probe 402AC

Steam Sterilization and Dry Time Validation for Reusable Temperature Probe 402AC

50X Life Cycle Conditioning of Reusable Temperature Probe 402

Manual Cleaning and low level disinfection Validation of Reusable Temperature Probe 402AC with combined Gram + and - organism

Low Level Chemical Disinfection and Neutralization Validation of Reusable Temperature Probe 402 with combined +and - organisms

50X Life Cycle Conditioning of Reusable Temperature Probe 402

Manual Cleaning Validation of Reusable Temperature Probe 402

Chemical Disinfection (Low Level using combined organisms) and Neutralization Validation of Reusable Temperature Probe 402

USP Insulin Assay for Lispro

Related Compounds/Impurities

High Molecular Weight Proteins

EFFECT OF USING A DILUENT “FRESENIUS” COMPARED TO EXISTING BAXTER PRE-FILLED SYRINGE DILUENT ON THE RELATIVE THROMBIN ACTIVITY OF THE THROMBIN COMPONENT OF FLOSEAL HEMOSTATIC MATRIX KIT

EFFECT OF USING A NEW MALLEABLE TIP ON THE RELATIVE THROMBIN ACTIVITY OF THE THROMBIN COMPONENT OF FLOSEAL HEMOSTATIC MATRIX KIT

HPLC Method Validation for R-190

SUBCUTANEOUS IMPLANT TEST OF LEVONORGESTREL DRUG DELIVERY DEVICES IN NEW ZEALAND WHITE RABBITS

Single Dose Ocular Toxicity Study in Dutch Belted Rabbits

HPLC Method Validation

A 28-DAY REPEAT DOSE TOXICITY AND TOXICOKINETIC STUDY OF XXXX IN CYNOMOLGUS NON-HUMAN PRIMATES WITH A ONE-MONTH RECOVERY PERIOD

USP Preservative Effectiveness Test on Dry Material

Determination of the Extractable Amount of Chemical Compounds from Tubing Components used in the processing of Melphalan for Injection and its sterile diluent

USP 51 Preservative Effectiveness in a dry powder substance

Ni Elution Profile for Rail Sub Assembly by ICP-MS

Fentanyl Citrate leachable Study

Insulin Preservatives Method Suitability with USP Insulin Monograph

3 Month Toxicity Study in Rats

Lidocaine HCl 1% Sterilizung & Age Study

Analysis of Insulin Aspart per United States Pharmacopeia (USP) Monograph “Insulin Aspart Injection”

protocol request to update P15-0025-00B Analysis of Insulin Aspart per United States Pharmacopeia (USP) Monograph “Insulin Aspart Injection” Limit of High Molecular Weight Proteins by High Performance Liquid Chromatography

Oculart Biodistribution Study in Rats

5-Day Repeat Dose Toxicity Study

Mouse PK

Single Dose Tox in C57BL/6 Mice

USP-Elastomeric Closures for Injection

USP-Elastomeric Closures for Injection

Direct- Agar

Direct Buehler

Direct Primary Skin

Agar Direct

Buehler Direct

Primary Skin Direct

SS-Non-GLP-Extractables-Surgiform

SINGLE DOSE PHARMACOKINETICS (PK) STUDY IN BEAGLE DOGS

chemical characterization - ss

Ames

Chromosomal Aberration with Human Lymphocytes

Mouse micronucleus

DETERMINATION OF IDENTITIES AND ESTIMATED AMOUNTS OF EXTRACTABLE CHEMICAL ENTITIES PRESENT IN AND ON A SPONSOR DEVICE

SINGLE DOSE TOXICITY IN C57BL/6 MICE

SS-UVEITIS PILOT

BIOANALYTICAL METHOD VALIDATION FOR QUANTITATIVE ANALYSIS OF DEXAMETHASONE IN RABBIT PLASMA BY HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) WITH TANDEM MASS SELECTIVE DETECTOR (LC/MS/MS)

BIOANALYTICAL METHOD VALIDATION FOR QUANTITATIVE ANALYSIS OF DEXAMETHASONE IN RABBIT AQUEOUS HUMOR BY HIGH PERFORMANCE LIQUID CHROMATOGRAPHY (HPLC) WITH TANDEM MASS SELECTIVE DETECTOR (LC/MS/MS)

ss- gigacept

Extractable study for SPT 60L platinum silicone tubing

Extractable study for TYGON 3350 tubing

Extractable study for SaniPure BDF tubing

ss- copper ion release

Pilot-Efficacy of Tattoo Ink and Removal in Yucatan Swine (Non-GLP)

S--GIGACEPT - WISP

ss- gigacept - nuance pro

A 3 Month Repeat Dose Toxicity Study in Cynomolgous Maxaques with 1 Month Recovery

SS-EXTRACTABLE

Barrium Sulfate Extractable Study

30-Day Repeat dose Tolerability Study in Mice

Design Validation and Simulated Use Testing of Argyle™ Safety Fistula Cannula with Anti-Reflux Valve and Argyle™ Safety Fistula Cannula with Clamping Device (Non-GLP)

CROSSOVER PHARMACODYNAMIC (PD) STUDY IN BEAGLE DOGS

IMMUNOGENICITY STUDY IN NEW ZEALAND WHITE RABBITS AFTER TWO INTRAMUSCULAR INJECTIONS

SS-EXTRAXTABLE STUDY - STOPPERS

extraxctable - stoppers

Pilot-SC Implantation in Rats

SS- INTEGRA RAT PAW LICK STUDY

Cleaning and Disinfection Validation

DERMAL PHARMACOKINETICS (PK) STUDY IN HANFORD MINIATURE SWINE

HANMI - VALIDATION # 1

HANMI - VALIDATION # 2

HANMI VALIDATION # 3

FTIR by KBr method

Quantitation and Immunogenicity of Bevacizumab after Intravitreal Injection in Rabbits

Extractable & Leachables

Cleaning Validation

Disinfection Validation

Pilot Quantitation and Immunogenicity of Bevacizumab after Intravitreal Injection in Rabbits

Stability Study of Dexamethasone in Rabbit Plasma

Stability Study of Dexamethasone in Rabbit Aqueous Humor

Ocular Irritation Study in New Zealand White Rabbits

Compound Testing in an Experimental Dry Eye Model in Mice

SAMPLE Analysis for detection using GAS CHROMATOGRAPHY/MASS SPECTROMETRY (GC/MS)

Johnson and Johnson Visioncare-SS-Non-GLP-Ocular-Lens Wear Study-6 hour-repeat

Cleaning Validation

Extractables/Leachables Study

SS-modified Ames Assay

SS-Lenstec-Non-GLP-ISO 11979-5-Exhaustive Extraction (Annex A)

SS-Lenstec-Non-GLP-ISO 11979-5-Test for Leachables (Annex B)

SS-PharmRight-Non-GLP-Polypropylene Test per USP <661>

Life Cycle Conditioning - 402

Life Cycle Conditioning - 402-AC

Cleaning Validation - 402 & 402AC

Disinfection Validation - 402 & 402AC

Sterilization Validation - 402AC

EXTRACTABLE LEACHABLE - PART 1

EXTRACTABLE ELACHABLE - PART 2

Extractable Leachable Part 1 and Part 2

13 Week Intramuscular Implantation in Rabbits with Toxicity

Compound Testing in an Endotoxin Induced Uveitis (EIU) Model

IOP Lowering with Subconjunctival Implants in Beagle Dog

SS-MiRus-GLP-ISO-Bone Implantation

PLATELET AND LEUKOCYTES BINDING ASSAY-Method Validation (Non-GLP)

30-Day Systemic Tox in Rats via Subcutaneous Implant

Determination of Extractable Amount of Metals by ICP

GLP Pathology

SS-Medical Enterprises Distribution-GMP-Medical Device Cleaning Validation

SS-Medical Enterprises Distribution-GMP-Medical Device Sterilization Validation

Anti Adherance Study

123

USP-CLass I

Dose Escalating Oral Toxicity Study with Toxicokinetics in Beagle Dogs

Single Dose PK Study in Non-Naive Beagle Dogs

Single Dose Toxicity of MSC's in Mongrel Dogs

ISO and USP-Elution

SS - 180Day Ocular Implant

Test

Long Term Survival Option 2 (6 month Survival)

METHOD VALIDATION FOR QUANTITATIVE ANALYSIS OF R801 by HPLC

2 minute Challenge -

Determination of extractable amount of chemical compounds present in and on the sponsor's device in support of ISO 10993-18

extractable study for tubing sets

SS- TERUMO VALIDATION

BARD - SS NICKEL ELUTION

BIOBURDEN VALIDATION  SPORE INOCULATION  AAMI GUIDELINES

DOSE ESCALATING ORAL TOXICITY STUDY WITH TOXICOKINETICS IN BEAGLE DOGS

Point of Use Processing

Disassembly

Manual Pre-Cleaning

Ultrasonic Cleaning

Disinfection

Lubrication

Automatic Washer/Disinfector

Visual Inspection

human factors

Metals Validation (Non-GLP)

3 Month Repeat Dose Toxicity Study in Rats with 1 Month Recovery

3 Month Repeat Dose Toxicity Study in Rats with 1 Month Recovery

Full Thickness Excisonal Wound study in Pigs

Acute Pop-Out In Sheep Parenchyma

Acute Pop-Out In Sheep Parenchyma

USP Anti-Microbial Effectiveness

Leachables Testing for Metals Analysis for Metals by ICP/MS

ISO 10993-4 Hemocompatibility TestingModified ASTM Hemolysis (Sponsor-specified Direct only)

Leachables Testing for Metals Analysis for Metals by ICP/MS

ISO 10993-4 Hemocompatibility Testing Modified ASTM Hemolysis (Sponsor-specified Direct only)

Determination of Extractables

Determination of Extractables

Determination of Identities and Estimated Amount of Leachables from Aged Drug Product

Sample Analysis

ISO-Pyrogen

ISO-Kligman Maximization Test

ISO-Intracutaneous Injection Test

ISO-Ames

extractable study of HEALit dressing with Ag & Zn

Kligman Maximization Test-ISO

ISO-Ames with confirmation

ISO-Ames without confirmation

OECD-471-Ames

MHLW-Ames

Method Suitability with USP Epinephrine for Injection Monograph

USP Epinephrine for Injection Potency by HPLC

Class VI-USP

MHLW Systemic

SS-MHLW Systemic

SS-MHLW Systemic

Dog Efficacy

Extractable and Leachables

DOSE RANGE FINDING STUDY IN CByB6F1-Tg(HRAS)2Jic MICE (rasH2 mice)

ss-Residual life conditioning study

DETERMINATION OF THE EXTRACTABLE AMOUNT OF CHEMICAL COMPOUNDS PRESENT IN AND ON THE SPONSOR’S LYOPHILISATION TRAY

Extractable Protocol

Hydrolytic Degradation Study

B Thromboglobulin

B Thromboglobulin

ss- chemical characterization

SS-TERUMO HPLC SAMPLE ANALYSIS

ss- gore- chemical characterization

Needle Testing in Rabbits

mouse embryo

Chromosomal Aberration Assay with Human Lympocytes-OECD 473

Primary Rectal Irritation in Dogs

Visual Inspection Validation

Assembly and Disassembly Validation

SS-Keranetics-GLP-Dose-finding and efficacy study of KeraGenics Bone in a primate segmental bone defect model

28-Day Repeat Dose Toxicity Study in Rats with 14 Day Recovery

28-Day Repeat Dose Toxicity Study in Rats with 14 Day Recovery

Life cycle conditioning – 25 cycles

Life cycle conditioning – 10 cycles

Life cycle conditioning – 20 cycles

SS-MiMedx-Non-GLP-Evaluation of Dehydrated Human Amnion/Chorion Membrane Allograft (dHACM) for the Prevention of Fibrotic Adhesion Responses in a Rat Caecum/Abdominal Wall Adhesion Model

SS-United Therapeutics-Non-GLP-Leachables-Prelim-Risk Assessment Project

Residual testing for IPA/Gluteraldehyde in Heart Valves following rinse procedure

Physicochemical Plastics per USP 661

Physicochemical Plastics per USP 661

“EFFECT OF USING A NEW MALLEABLE TIP ON THE RELATIVE THROMBIN ACTIVITY OF THE THROMBIN COMPONENT OF FLOSEAL HEMOSTATIC MATRIX KIT”

This protocol would have both (non-heparin and heparin) per Chris Parker

This protocol would have call out the use of heparin.

Point of Use Notebook Study

Ultrasonic cleaning notebook study

Manual Pre-Cleaning Notebook Study

Lubrication Notebook Study

Disinfection Notebook Study

ss- chemical characterization

Scar Repair Study in Rabbit Ear Model

Metals Validation

Metals Validation for Lithium

Metals Validation for Mercury

Cleaning Validation Pilot Study

ss-glaucoma

SS-Mouse Micronucleus with Range Finding-OECD

Chromosomal Aberration with CHO cell w/ Confirmation

SS- OECD AMES w/ confirmation and range finding

cleaning and disinfection study see outline attached in this email.

snoitadilav noitcefnisid and cleaning

SS-MICROBIAL INGRESS

R&D Subcutaneous Implant and Injection PK study in Rabbits

SS - EL - COMFORT FLOW

CHEMICAL CHARACTERIZATION OF THE west stopper

CLEANING VALIDATION -1 - NIRVANA

CLEANING VALIDATION 2 - NIRVANA

Trypsin Activity

SS- EL

Point of Use Processing-Soil Dwell Time and Enzymatic Cleaning

SS - GIGACEPT FF WISP YOUTH

cleaning validation with simulated skin or vaginal soil

Cleaning validation of Ballooned Sensors

Particle Count of ISO 8536 - 10 control evaluation similar to the procedure used in 15-03945-N1

PART I – METHOD SUITABILITY TEST

EVALUATION OF METHOD SUITABILITY FOR ANALYSIS OF ISOPAR-H SOLUTION

DETERMINATION OF THE LEACHABLE AMOUNT OF CHEMICAL COMPOUNDS, PRESENT IN AND ON THE SPONSOR’S DEVICE IN SUPPORT OF ISO 10993-18

EVALUATION OF METHOD SUITABILITY FOR ANALYSIS OF ISOPAR-H SOLUTION

DETERMINATION OF THE LEACHABLE AMOUNT OF CHEMICAL COMPOUNDS, PRESENT IN AND ON THE SPONSOR’S DEVICE IN SUPPORT OF ISO 10993-18

ss kligman with Analgesics

Stability Metals

Stability VOC

Stability NVOC

Stability SVOC

Stability Metals

Stability NVOC

Stability SVOC

Stability VPC

SS- GIGACEPT 20 CYCLES

Cross Verification for Mouse Brain Liver Skin

Rabbit Plasma Full Validation

GMP Protocol for ISO 8536 Particle Count similar to the Non-GLP study with 10 controls in 15-03945-N1

Complement Activation - Complete - Both Direct and Indirect

Microbial ingress testing of Dentsply barrier with Swab recovery method similar to P15-1806-00B

Device Efficacy Study in Rabbits

USP 788 Particulate Count by Light Obscuration

Effect of Blood Filter Cartridge on Blood

Effect of Blood Filter Cartridge on Blood

TERUMO TECHNOLOGY TRANSFER

ss Baxter Guinea Pig Maximization Test 2016

52 week implant bioabsorability study

ISO - 14 DAY ABRIDGED IN MICE - IP

Determination of Extractables

SS- ANTIMICROBIAL - 60 DAYS

Revised P15-1960-00B Cleaning Validation of Reusable Temperature Probes for 401

Revision of P15-1968-00B Reusable Medical Device Intermediate Level Disinfection Validation - 401

PK Study by Subcutaneous Injection in Dogs

ISO - MEM ELUTION 1 HOUR EXPOSURE

SS- EL - COHERA

ss- sanofi

ISO Agar Diffusion 1 Hour Exposure

Manual Pre-Cleaning; Microbial Aerosolization

Manual Pre-Cleaning; Cleaning Techniques

Manual Pre-Cleaning; Rinse, Critical Water

Manual Pre-Cleaning; Drying Conditions

7 Day Ocular Tox in Rabbits

7 Day Ocular Toxicity in Rabbits

Pilot Intracameral Implant Study in Beagles

Ocular Intracameral PK Study in Beagles

ISO Systemic Toxicity,30-day Systemic Toxicity in Rats via repeated parenteral administration of 2 extracts (SC and CSO) , GLP

Determination of Extractables

ss - philips anioxide

Corpak Extractable Study

SS-GIGACEPT PERFORMANCE TESTING

Affect of Blood Filter cartridge on Plasma

Intracameral Ocular Toxicity Study in Beagles

MEM Elution without option for filter sterilization

NRU without the option for filter sterilization

Chemical Characteization of CardiaAQ 2S Delivery System

Exhaustive Extraction in Purified Water for Ni

13 WEEK REPEAT DOSE INTRAVENOUS TOXICITY AND TOXICOKINETIC STUDY OF PEMETREXED DIPOTASSIUM IN WISTAR RATS WITH A ONE MONTH RECOVERY PERIOD

A Repeat Oral and Intravenous Dosing Pharmacokinetic Study and Comparative Bioavailability Assay

A Repeat Oral and Intravenous Dosing Pharmacokinetic Study and Comparative Bioavailability Assay

A 14DAY REPEAT DOSE INTRANASAL INSTILLATION TOXICITY STUDY IN SPRAGUE-DAWLEY RATS WITH A 14 DAY RECOVERY PERIOD

A 14DAY REPEAT DOSE INTRANASAL INSTILLATION TOXICITY STUDY IN SPRAGUE-DAWLEY RATS WITH A 14 DAY RECOVERY PERIOD

Non-GLP stability for rabbit plasma validation

5-Day Repeat Dose Toxicity Study in Sprague Dawley Rats with a 7-Day Recovery

SS - ICP ANALYSIS