National Animal Supplement Council

Preferred Supplier Data Sheet (PSDS) for Raw Material Suppliers and Contract Manufacturers

All Raw Material Suppliers and Contract Manufacturers must provide the information requested in this form as part of the qualification procedure for acceptance as a Preferred Supplier by NASC. Any fields not applicable to your company should be completed by entering N/A.

Please return copies of the completed form(s) and requested certifications electronically to Bill Parker at b.parker@nasc.cc or mail to:

NASC
PO Box 5168
Sun City West, AZ 85376

This information will be posted in the Members Section of the NASC Web Site for companies to download for use in qualifying and accepting the supplier.

Questions: contact Bill Parker at the NASC office (760-751-3360 X105)

SECTION 1: SITE OVERVIEW			
NAME AND ADDRESS OF COMPANY OR SITE RESPONSIBLE:	Gemini Pharmaceuticals Inc., 87 Modular Ave, Commack, NY 11725		
WEB SITE:	www.geminipharm.com		
CONTACT PERSON	Mark Jost		
TELEPHONE NUMBER:	631-543-3334		
E-MAIL:	mjost@geminipharm.com		
BUSINESS DESCRIPTION / SITE DETAILS: Contract manufacturing			
FACILITY SIZE / # EMPLOYEES:	344	DATE EST:	1982
GENERAL AND PRODUCT LIABILITY INSURANCE LEVELS:	General Liability - $1 million each occurrence Product Liability - $5 million	UNION:	No
SPECIFY TYPE(S) OF INGREDIENT(S), MANUFACTURING CAPABILITIES, PRODUCTS PRODUCED/SUPPLIED BY THE SITE, SERVICES AND THEIR INTENDED APPLICATIONS:	Contract manufacturing of OTC drug products-solid dose tablets and caplets; Dietary Supplements/Nutraceuticals -solid dose capsules and tablets; bottle packaging and bulk packaging. Make 13 billion tablets and capsules per year.		
SITE ACTIVITIES CONDUCTED:	N/A		
ORGANIZATIONAL CHART:	N/A		

SECTION 2: EVIDENCE OF COMPLIANCE		
INDEPENDENT QUALITY CERTIFICATIONS:	Yes IF YES, SPECIFY: NSF	
	QUALITY MANAGEMENT SYSTEM STANDARD:	NSF/ ANSI 422-2
	APPROVAL CERTIFICATES:	Attached
	NUMBER AND NAME OF REGISTRAR WHO PROVIDED CERTIFICATE OF APPROVAL:	C0111745-GRMADS-1/2749587: NSF/ GRMA
OTHER CERTIFICATIONS OR EXTERNAL AUDIT PROGRAMS:	ISO 17025 by ANAB for In house laboratory	
WEB SITE:	www.geminpharm.com	
DATE OF LAST FDA OR STATE AGENCY CGMP INSPECTION AND OUTCOME (PROVIDE COPY OF REPORT OF OBSERVATIONS FROM LAST FDA OR STATE INSPECTION):		02/2018

SECTION 3: RAW MATERIAL SUPPLIERS & CONTRACT MANUFACTURERS ONLY	
DO YOU HAVE Q/C RELEASE REQUIREMENTS FOR ALL SHIPMENTS WHEN THEY ARRIVE: (YES / NO)	YES
DO YOU SAMPLE EVERY LOT OF RAW MATERIALS RECEIVED: (YES / NO)	YES
DO YOU RE-PACK LARGE QUANTITIES INTO SMALLER QUANTITIES AT YOUR FACILITY: (YES / NO)	NO
DO YOU SAMPLE EVERY LOT: (YES / NO)	YES
DO YOU PERFORM ANY BLENDING AT YOUR FACILITY (YES / NO)	YES
LIST ALL INGREDIENTS HELD AT YOUR FACILITY (ATTACH A LIST/DOCUMENT IF AVAILABLE: (YES / NO)	
PHARMACEUTICAL:	NO
NUTRITIONAL:	YES
BOTANICAL:	YES
MINERAL:	YES
ENZYME:	YES
HORMONE:	NO
PROBIOTIC:	NO
CHEMICAL (OTHER):	YES
METHODS CONDUCTED IN FACILITY: (YES / NO)	
DO YOU USE AN IN-HOUSE LOT NUMBERING SYSTEM?	YES
DO YOU EVER MIX MULTIPLE LOTS OF THE SAME INGREDIENT WHEN YOU BLEND?	YES
TESTING INFORMATION: ***IF YOU RELY ON BOTH IN-HOUSE AND OUTSIDE CONTRACT LABS, PLEASE FILL OUT BOTH SECTIONS***	
DOES THIS FACILITY RELY ON AN **IN-HOUSE** LAB? (YES / NO)	YES
IN-HOUSE TESTS PERFORMED: (YES / NO)	YES
POTENCY ASSAY OF RAW MATERIALS? (YES / NO)	YES
RAW MATERIAL ASSAY? (YES / NO)	YES
MICROBIAL? (YES / NO – IF YES SPECIFY)	NO
pH? (YES / NO)	YES
MOISTURE? (YES / NO)	YES
ELEMENTAL PESTICIDES? (YES / NO – IF YES SPECIFY)	NO
HEAVY METALS? (YES / NO – IF YES SPECIFY)	YES
OTHER? (YES / NO – IF YES SPECIFY)	NO
IF YOU HAVE AN IN-HOUSE LAB PLEASE SPECIFY WHICH LAB ACCREDITATION ORGANIZATION(S) YOU ARE AFFILIATED WITH:	International Standard ISO/IEC 17025:2017 accreditation for Testing Laboratory from ANSI National Accreditation Board (ANAB).

OUTSIDE CONTRACT LABS USED	
PLEASE LIST YOUR MOST FREQUENTLY USED CONTRACT LABS AND THEIR ACCREDITATION STATUS: (e.g., ISO, FDA, USDA, AOAC, USP, NSF, NPA, A2LA, ANSI, ETC.) ***PLEASE PROVIDE ACCREDITATION NUMBER***	
NAME OF LAB #1:	**ACCUON Labs Inc.**
ADDRESS / LOCATION:	275 Marcus Blvd., Suite #N, Hauppauge, NY 11788
CONTACT NAME / PHONE NUMBER:	361-656-4958
LIST ANY CERTIFICATIONS FOR THE LAB:	ISO 17025:2017
TESTING PERFORMED BY THE OUTSIDE LAB:	
POTENCY ASSAY OF RAW MATERIALS? (YES / NO)	NO
RAW MATERIAL ASSAY? (YES / NO)	NO
MICROBIAL? (YES / NO – IF YES SPECIFY)	YES Total Microbial Count – Total Yeast/Mold Count, Test for Escherichia coli, Test for Salmonella spp., Test for Staphylococcus aureus
pH? (YES / NO)	NO
MOISTURE? (YES / NO)	NO
ELEMENTAL PESTICIDES? (YES / NO – IF YES SPECIFY)	NO
HEAVY METALS? (YES / NO – IF YES SPECIFY)	NO
OTHER? (YES / NO – IF YES SPECIFY)	NO
NAME OF LAB #2:	Eurofins, Food Integrity and Inovation
ADDRESS / LOCATION:	6304 Ronald Reagan Avenue, Madison WI 53704
CONTACT NAME / PHONE NUMBER:	1.800.675.8375
LIST ANY CERTIFICATIONS FOR THE LAB:	17025:2017
TESTING PERFORMED BY THE OUTSIDE LAB:	
POTENCY ASSAY OF RAW MATERIALS? (YES / NO)	YES
RAW MATERIAL ASSAY? (YES / NO)	YES
MICROBIAL? (YES / NO – IF YES SPECIFY)	NO
pH? (YES / NO)	NO
MOISTURE? (YES / NO)	NO
ELEMENTAL PESTICIDES? (YES / NO – IF YES SPECIFY)	NO
HEAVY METALS? (YES / NO – IF YES SPECIFY)	NO
OTHER? (YES / NO – IF YES SPECIFY)	NO
NAME OF LAB #3:	N/A
ADDRESS / LOCATION:	N/A
CONTACT NAME / PHONE NUMBER:	N/A
LIST ANY CERTIFICATIONS FOR THE LAB:	N/A
TESTING PERFORMED BY THE OUTSIDE LAB:	
POTENCY ASSAY OF RAW MATERIALS? (YES / NO)	N/A
RAW MATERIAL ASSAY? (YES / NO)	N/A
MICROBIAL? (YES / NO – IF YES SPECIFY)	N/A
pH? (YES / NO)	N/A
MOISTURE? (YES / NO)	N/A
ELEMENTAL PESTICIDES? (YES / NO – IF YES SPECIFY)	N/A
HEAVY METALS? (YES / NO – IF YES SPECIFY)	N/A
OTHER? (YES / NO – IF YES SPECIFY)	N/A

SECTION 4: CGMP COMPLIANCE DETAILS

PROVIDE A BRIEF SUMMARY OF HOW THE SUPPLIER COMPLIES WITH EACH APPLICABLE ELEMENT OF THE CURRENT GMP GUIDELINES. NON-APPLICABLE ELEMENTS SHOULD BE NOTED AS SUCH.

1. **Primary Materials and Products**
   - The incoming material receiving process was reviewed. All raw materials and packaging components are received in accordance with Gemini's approved procedures to ensure that the correct material was received, sampled, tested, and released for further processing. All production materials are inspected in accordance with Gemini Pharmaceutical's sampling procedures. The inspection room and sampling equipment are properly cleaned and sanitized prior to inspection. Laboratory analytical identity testing is performed to ensure the correctness of all incoming materials, which includes both active dietary ingredients and excipients for the subject product.
   - Quality Control testing is performed on both raw materials and finished bulk products prior to the release of all Gemini manufactured/packaged products to ensure that all products meet their release requirements for identity and potency.
2. **Premises**
   - All facilities are maintained in a clean and orderly manner at all times and in compliance with current SOP's and cGMP practices.
3. **People**
   - All employees have met all requirements for education and training dependent on job position in order to effectively perform their job in compliance with current approved procedures.
4. **Procedures**
   - All procedures are reviewed on a biennial basis to ensure compliance with current industry practices.
5. **Processes**
   - An internal audit of all quality systems/processes to assure compliance with applicable pre-defined standards is conducted on an annual basis.

IS FACILITY ISO CERTIFIED? YES / NO: IF YES SPECIFY THE ISO STANDARD AND ATTACH CURRENT CERTIFICATE.	Yes - Lab is ISO 17025:2017 certified
LIST AND ATTACH ANY OTHER CERTIFICATIONS OR EXTERNAL AUDIT PROGRAMS (E.G., NSF, USP, NPA, ISO, ETC.):	NY State Board of Pharmacy, FDA, NSF-GRMA, ISO, UL

SPECIFY MOST RECENT FACILITY INSPECTIONS BY STATE, FEDERAL, OR FOREIGN AGENCY (DATE OF INSPECTION, AND RESULTS OF THE INSPECTION SPECIFY AGENCY):

DATE	INSPECTION AGENCY	RESULTS OF THE INSPECTION
08/09/2021	UL Verification Services	PASS (Rated 93 of 100) - Compliant with 21CFR Part 11
05/25/2021	GRMA (Global Retailer Manufacturer Alliance)	Compliant with Global Retailer & Manufacturer Alliance, Inc.'s Certification Program & NSF/ANSI 455-2 – 2018 GMPs for Dietary Supplements.

SECTION 5: ADDITIONAL INFORMATION

Hazard Plan (HACCP) / DATE IMPLEMENTED:	Gemini's Food Safety Plan (FSP): Hazard Analysis and Risk-Based Preventive Controls (HARPC) / Date Implemented: 10/2018
STATISTICAL PROCESS CONTROL/PROCESS ANALYTICAL CONTROL:	Procedures have been established for the statistical sampling and inspection of finished products by attributes based on ANSI/ASQ Z104-2008 standards.
CORPORATE BIOTERRORISM ACT COMPLIANCE:	Gemini Pharmaceutical, Inc. is in compliance with the Bioterrorism Act (Public Traceability). All manufacturing facilities have completed the FDA's Food Facility Registration and are re-registered as required during each biennial registration period with the FDA. All manufacturing facilities adhere to all product traceability requirements set forth by the FDA.
DESCRIBE ALL MEASURES TAKEN BY FACILITY TO ENSURE PRODUCT QUALITY AND PRODUCT CONTAMINATION PREVENTION.	• Employees are trained on all cGMP practices and the potential sources of contamination and use the hygienic practices and procedures. • Ensure that only clean and disinfected equipment, tools and utensils are brought into the processing area. • Incoming raw materials are inspected, segregated and tested prior to use. • Ensure that only clean and disinfected equipment, tools and utensils are brought into the processing area.

	• Implement proper pest control measures. • Gemini's Food Safety Plan (FSP): Hazard Analysis and Risk-Based Preventive Controls (HARPC) Date Implemented: 10/2018
MEMBERSHIP IN INDUSTRY TRADE GROUPS:	GRMA, NSF/QAI, IFANCA (Halal)

SECTION 6: CONTRACT MANUFACTURERS

HOW DO YOU GUARANTEE BANNED SUBSTANCES (STIMULANTS, NARCOTICS, STEROIDS, DIURETICS, BETA-2-AGONISTS, BETA BLOCKERS, MASKING AGENTS, OR SIMILAR SUBSTANCES) ARE NOT PRESENT IN YOUR INGREDIENTS?	All incoming raw materials are inspected and tested prior to use. All finished products are tested prior to release to the marketplace. All materials/components are purchased through qualified/approved suppliers
HOW DO YOU QUALIFY AN INGREDIENT MANUFACTURER?	Suppliers of ingredients/components are assessed by the Quality group either through an on-sight audit or through a Vendor Assessment Questionnaire. All Vendors are continuously monitored by Quality Assurance to assure compliance with preset standards. Vendors are re-evaluated biennially.

SECTION 7: AUTHENTICITY OF INFORMATION & CONTACT INFORMATION

COMPANY NAME:	GEMINI PHARMACEUTICALS, INC		
CONTACT NAME:	Kirk P. Matzer	TITLE:	QA Compliance Manager
E-MAIL ADDRESS:	kirkm@geminipharm.com		

BY SIGNING BELOW, I CERTIFY THAT THE INFORMATION GIVEN BY ME TO THE NATIONAL ANIMAL SUPPLEMENT COUNCIL (NASC), INC. IS TRUE AND COMPLETE TO THE BEST OF MY KNOWLEDGE. I UNDERSTAND THAT IF THE INFORMATION PROVIDED IS NOT THOROUGH AND COMPLETE, NASC WILL REJECT THE FORM AND RESUBMISSION OF THE FORM WILL BE REQUIRED.

Kirk P Matzer	01/04/2022
SIGNATURE	**DATE**