



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:	Proteimax Bio Technology Israel, LTD Duvdevan 4, Pardes Hana-Karkur, Israel 3708973		
WEB SITE:			
CONTACT PERSON	Arnon Krongrad, MD		
TELEPHONE NUMBER:	305 790 2363		
E-MAIL:	arnon@proteimax.com		
BUSINESS DESCRIPTION / SITE DETAILS:			
FACILITY SIZE / # EMPLOYEES:	3 employees	DATE EST:	2020
GENERAL AND PRODUCT LIABILITY INSURANCE LEVELS:		UNION:	
SPECIFY TYPE(S) OF INGREDIENT(S), MANUFACTURING CAPABILITIES, PRODUCTS PRODUCED/SUPPLIED BY THE SITE, SERVICES AND THEIR INTENDED APPLICATIONS:	Proteimax is providing a functional ingredient for use in dosage form animal health products. The ingredient is synthesized to Proteimax specifications by Ambiopharm in Beech Island, South Carolina. The ingredient is intended to alter dog, cat, and horse metabolic states: body fat content, blood glucose, and so on.		
SITE ACTIVITIES CONDUCTED:	Proteimax sets parameters for safe synthesis that are followed by its vendors. Proteimax rigorously assesses its peptides for such characteristics as biological activity, safety, stability, contamination, and so on.		
ORGANIZATIONAL CHART:			

SECTION 2: EVIDENCE OF COMPLIANCE	
INDEPENDENT QUALITY CERTIFICATIONS:	Proteimax peptide vendors are independently audited by third parties, such as the FDA. In addition, Proteimax has adopted a standard operating procedure (SOP) for qualifying its peptide vendors. This SOP procedure is based upon years of experience in peptide development. Among its requirements is submission of lots for independent external quality review. Among our external reviewers is the Gigy Lab at Harvard (see below), the top peptide lab in the world, which works with us to determine peptide quality. This is in addition to quality testing conducted and provided to us by Ambiopharm and in our lab.
QUALITY MANAGEMENT SYSTEM STANDARD:	Internal SOP
APPROVAL CERTIFICATES:	FDA
NUMBER AND NAME OF REGISTRAR WHO PROVIDED CERTIFICATE OF APPROVAL:	John Diehl, FDA (audit of Ambiopharm)



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OTHER CERTIFICATIONS OR EXTERNAL AUDIT PROGRAMS:	See above.
WEB SITE:	
DATE OF LAST FDA OR STATE AGENCY CGMP INSPECTION AND OUTCOME (PROVIDE COPY OF REPORT OF OBSERVATIONS FROM LAST FDA OR STATE INSPECTION):	FDA, January 18, 2018 [the pandemic put a pause on audits; we expect a new audit in three months]



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SECTION 3: RAW MATERIAL SUPPLIERS & CONTRACT MANUFACTURERS ONLY	
DO YOU HAVE Q/C RELEASE REQUIREMENTS FOR ALL SHIPMENTS WHEN THEY ARRIVE: (YES / NO)	Before shipping. Part of SOP.
DO YOU SAMPLE EVERY LOT OF RAW MATERIALS RECEIVED: (YES / NO)	Before shipping. Part of SOP.
DO YOU RE-PACK LARGE QUANTITIES INTO SMALLER QUANTITIES AT YOUR FACILITY: (YES / NO)	No
DO YOU SAMPLE EVERY LOT: (YES / NO)	Yes. Part of SOP>
DO YOU PERFORM ANY BLENDING AT YOUR FACILITY (YES / NO)	No
LIST ALL INGREDIENTS HELD AT YOUR FACILITY (ATTACH A LIST/DOCUMENT IF AVAILABLE: (YES / NO)	
PHARMACEUTICAL:	No
NUTRITIONAL:	No
BOTANICAL:	No
MINERAL:	No
ENZYME:	No
HORMONE:	No
PROBIOTIC:	No
PEPTIDE (OTHER): YES	Yes
METHODS CONDUCTED IN FACILITY: (YES / NO)	
DO YOU USE AN IN-HOUSE LOT NUMBERING SYSTEM?	No
DO YOU EVER MIX MULTIPLE LOTS OF THE SAME INGREDIENT WHEN YOU BLEND?	No
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. Plus Ambiopharm.
IN-HOUSE TESTS PERFORMED: (YES / NO)	Yes, for purity and bioactivity
POTENCY ASSAY OF RAW MATERIALS? (YES / NO)	Yes, for bioactivity
RAW MATERIAL ASSAY? (YES / NO)	No
MICROBIAL? (YES / NO – IF YES SPECIFY)	Yes. Bioburden and bacterial endotoxins at Ambiopharm
pH? (YES / NO)	Yes, in house
MOISTURE? (YES / NO)	Yes at Ambiopharm, Proteimax
ELEMENTAL PESTICIDES? (YES / NO – IF YES SPECIFY)	Not relevant for peptide synthesis; no source of contamination.
HEAVY METALS? (YES / NO – IF YES SPECIFY)	Yes at Ambiopharm
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:	Yes, accredited by Brazil's ANVISA



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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:	Gigy Lab
ADDRESS / LOCATION:	240 Longwood Ave. Department of Cell Biology Harvard Medical School MA, Boston 02115
CONTACT NAME / PHONE NUMBER:	Steve Gigy, PhD
LIST ANY CERTIFICATIONS FOR THE LAB:	
TESTING PERFORMED BY THE OUTSIDE LAB:	
POTENCY ASSAY OF RAW MATERIALS? (YES / NO)	No
RAW MATERIAL ASSAY? (YES / NO)	Yes (mass spectrometry analysis of purity)
MICROBIAL? (YES / NO – IF YES SPECIFY)	No
pH? (YES / NO)	No
MOISTURE? (YES / NO)	No
ELEMENTAL PESTICIDES? (YES / NO – IF YES SPECIFY)	Not relevant for peptide synthesis; no source of contamination.
HEAVY METALS? (YES / NO – IF YES SPECIFY)	No
OTHER? (YES / NO – IF YES SPECIFY)	No
NAME OF LAB #2:	
ADDRESS / LOCATION:	=====
CONTACT NAME / PHONE NUMBER:	=====
LIST ANY CERTIFICATIONS FOR THE LAB:	=====
TESTING PERFORMED BY THE OUTSIDE LAB:	
POTENCY ASSAY OF RAW MATERIALS? (YES / NO)	=====
RAW MATERIAL ASSAY? (YES / NO)	=====
MICROBIAL? (YES / NO – IF YES SPECIFY)	=====
pH? (YES / NO)	=====
MOISTURE? (YES / NO)	=====
ELEMENTAL PESTICIDES? (YES / NO – IF YES SPECIFY)	=====
HEAVY METALS? (YES / NO – IF YES SPECIFY)	=====
OTHER? (YES / NO – IF YES SPECIFY)	=====
NAME OF LAB #3:	
ADDRESS / LOCATION:	=====
CONTACT NAME / PHONE NUMBER:	=====
LIST ANY CERTIFICATIONS FOR THE LAB:	=====
TESTING PERFORMED BY THE OUTSIDE LAB:	
POTENCY ASSAY OF RAW MATERIALS? (YES / NO)	=====
RAW MATERIAL ASSAY? (YES / NO)	=====
MICROBIAL? (YES / NO – IF YES SPECIFY)	=====
pH? (YES / NO)	=====
MOISTURE? (YES / NO)	=====
ELEMENTAL PESTICIDES? (YES / NO – IF YES SPECIFY)	=====
HEAVY METALS? (YES / NO – IF YES SPECIFY)	=====



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OTHER? (YES / NO - IF YES SPECIFY)	=====
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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.

Table with 2 columns: Question (e.g., IS FACILITY ISO CERTIFIED?), Answer (e.g., Ambiopharm uses the Q7 Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients).

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

Table with 3 columns: DATE, INSPECTION AGENCY, RESULTS OF THE INSPECTION. Row 1: 2018, FDA, passed.

SECTION 5: ADDITIONAL INFORMATION

Table with 2 columns: Question (e.g., Hazard Plan (HACCP) / DATE IMPLEMENTED:), Answer (e.g., Proteimax uses a redundant quality control procedure...).

SECTION 6: CONTRACT MANUFACTURERS

Table with 2 columns: Question (e.g., HOW DO YOU GUARANTEE BANNED SUBSTANCES...), Answer (e.g., We assess purity and contamination for each lot with mass spectrometry...).

SECTION 7: AUTHENTICITY OF INFORMATION & CONTACT INFORMATION

Table with 4 columns: Field (e.g., COMPANY NAME), Value (e.g., Proteimax Bio Technology Israel, LTD), Field (e.g., TITLE), Value (e.g., Chief Strategy Officer).

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.

Table with 2 columns: SIGNATURE (with handwritten signature), DATE (February 24, 2023).