LabDiet®

LabDiet® Certified Diets:

Understanding Their History and Purpose in GLP Studies

Certified Product Lineup

RODENT DIETS	Product Name	Protein %	Fat %	Fiber %	Product Size	Product Notations
5CR4	Certified CR 14% Protein Rodent Diet	14	5.0	5.0	10 x 16 x 25 mm	Modeled after the Charles River breeding diet with 14% protein for GLP studies
5CC4	Certified CR 14% Protein Rodent Diet C (China)	14	5.0	5.0	10 x 16 x 25 mm	Modeled after 5CR4 with slight ingredient modification required for approval to import into China
5002	Certified Rodent Diet	20	4.5	5.5	10 x 16 x 25 mm	Benchmark for all rodent GLP rodent studies - historical data available upon request
5C02	Certified Rodent Diet C (China)	20	4.5	5.5	10 x 16 x 25 mm	Modeled after 5002 with slight ingredient modification required for approval to import into China
5LG3	AP Certified Rodent Diet 18%	18	3.5	6.0	10 x 16 x 25 mm	An 18% protein option, slightly lower than 5002
5K75	AP Certified PicoLab® Rodent 20%	20	4.5	6.0	10 x 16 x 25 mm	Companion product of PicoLab® Rodent 5053, Certified for GLP studies
GUINEA PIG						
5026	Certified Guinea Pig Diet	18	4.0	16	4 x 10 mm	Benchmark guinea pig diet for GLP studies - historical data available upon request
50E6	Certified PicoLab® Guinea Pig Diet	18	4.0	16	4 x 10 mm	Same formula as LabDiet® 5026 Irradiated
RABBIT DIETS						
5322	Certified Rabbit Diet	16	2.5	18	4 x 10 mm	Benchmark rabbit diet for GLP studies - historical data available upon request
5325	Certified High Fiber Rabbit Diet	14	1.5	25	4 x 10 mm	Higher fiber diet ideal for maintenance
CANINE						
5007	Certified Lab Canine Diet	25	9.0	4.0	16 x 8 mm	Benchmark canine diet for GLP studies - historical data available upon request
5C07	Certified Lab Canine Diet C (China)	25	9.0	4.0	16 x 8 mm	Modeled after 5007 with slight ingredient modification required for approval to import into China
5L66	AP Certified High Density Canine Diet	27	16	4.0	10 x 8 mm	Highly digestible diet with more energy and protein. Low stool volumes and firmer stools.
PRIMATE						
5048	Certified Primate Diet	25	5.0	6.5	16 x 22 x45 mm	Benchmark non-human primate diet for GLP studies - historical data available upon request
5S48	Certified Primate Diet Small	25	5.0	6.5	6 x 6 x 25 mm	Same formula as 5048 but in a smaller biscuit - this allows for foraging with smaller size
5C48	Certified Primate Diet C (China)	25	5.0	6.5	16 x 22 x 45 mm	Modeled after 5048 with slight ingredient modification required for approval to import into China
5K91	Certified High Fiber Primate	20	5.0	10	50 x 25 x 31 mm	Developed in 1998 for customers needing a high fiber Certified Primate Diet
MINI PIG						
5K99	Cert. Mini-Pig Grower/Maintenance Diet	16	3.0	9.0	4 x 10 mm	Ideal balance of nutrients for growth and maintenance during GLP trials
5C99	Cert. Mini-Pig Grower/Maintenance Diet C (China)	16	3.0	9.0	4 x 10 mm	Modeled after 5K99 with slight ingredient modification required for approval to import into China

Good Laboratory Practices and the Role of Certified LabDiet® Products

Good Laboratory Practice, or GLP, refers to a quality system of management controls for research laboratories and organizations. GLP ensures the uniformity, consistency, reliability, reproducibility, quality and integrity of chemical and pharmaceutical non-clinical efficacy and safety testing.

GLP helps assure regulatory authorities that the data submitted are a true reflection of the results obtained during the study and can therefore be relied on when making risk/safety assessments. GLP is a quality system concerned with the organizational processing and conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported.

GLP Regulations Involve:

- Organization and Personnel
- Quality Assurance Program
- Facilities
- Equipment, Reagents and Materials
- Test Systems
- Test and Reference Items
- Standard Operating Procedures
- Performance of the Study
- Reporting of the Results
- Storage of Records and Reports

GLP and Certified Diets:

Almost 40 years ago, the scientific community took action to control environmental factors that contribute to variation in the responses of laboratory animals to scientific manipulation. The ability to replicate research is fundamental for good science. One key to replicating research is to control all variables except those being studied. Health status and environmental factors can influence research outcomes and should be controlled to the extent possible. Laboratory animal diet is recognized as an important environmental factor that could result in potential variables in research.

Several different diet categories or groupings can be used to represent a full line of laboratory animal diets, but we focus here on the need for the product group known as a "certified diet." GLP regulations require the investigator to analyze the diet for contaminants that may be expected to influence studies in pharmaceutical and agrochemical toxicology and drug safety testing.

CFR 21 58.90 (g) states feed and water used for animals shall be analyzed periodically to ensure that contaminants known to be capable of interfering with the study and reasonably expected to be present in such feed and water are not present above those levels specified in the protocol. Documentation of such analyses shall be maintained as raw data.

The analysis is typically carried out by the diet manufacturer through an independent laboratory, and the analyzed diet is described as a "certified diet." A certificate of analysis, which is linked to that specific batch, is sent with the diet and provides a guarantee that select contaminants defined by the research community do not exceed established limits. In addition, some customers may request the analysis of nutrients such as moisture, crude protein, fiber and fat, etc.

Although the EPA and FDA suggest researchers consider contaminants that might affect a specific study, in practice, organizations, diet manufacturers, and investigators in several countries have agreed to a periodic review of analytics monitored in certified diets for appropriateness of content and stipulated maximum acceptable levels. Without such evaluation, diets could be tested for pesticides that were a significant risk in the 1970s but are no longer used. Alternatively, contaminants of more current significance may be disregarded.

Sample Collection Procedures

Product samples used for laboratory testing on Certified Diets are manually collected from a robust cross-reference of every Certified Diet production lot. These samples are composited to generate one homogeneous sample. One half of the sample will be retained at the LabDiet® manufacturing plant as a retention sample and the other half of the composite sample will be sent to an approved outside laboratory for the contaminant and assaying.

Certified LabDiet® Products Contaminant Maximum Levels

Certified LabDiet® products may contain non-nutrients that have physiologic or pathogenic effects. Acceptable maximum upper limits for contaminants have been established for diets for good laboratory practice (GLP) purposes (EPA, 1979; Pal et al., 1984). These contaminants include heavy metals, PCB's, and certain pesticides. The chart to the right is the list of contaminants and their respective guideline values for maximum amounts for certified products.

In addition to the chart-mentioned contaminants, LabDiet® Certified products are also assayed for protein, fat, fiber, ash, calcium, phosphorous, and vitamin C (primate and guinea pig diets only). These are added analyses that are not required as part of the GLP requirements.

Heavy Metals	Maximum Concentration
Arsenic	1.00 ppm
Cadmium	0.50 ppm
Lead	1.50 ppm
Mercury	0.20 ppm
Selenium	0.50 ppm
Aflatoxin	**5.00ppb**

Chlorinated Hydrocarbons	
Aldrin	0.03 ppm
BHC (Alpha)	0.05 ppm
BHC (Beta)	0.05 ppm
BHC (Delta)	0.05 ppm
Chlordane	0.05 ppm
DDT Related substances	0.15 ppm
Dieldrin	0.03 ppm
Endrin	0.03 ppm
HCB	0.05 ppm
Heptachlor	0.03 ppm
Heptachlor Epoxide	0.03 ppm
Lindane	0.05 ppm
Methoxychlor	0.50 ppm
Mirex	0.02 ppm
PCB	0.15 ppm

Organophosphates	
Diazinon	0.50 ppm
Disulfaton	0.50 ppm
Ethion	0.50 ppm
Malathion	0.50 ppm
Methyl Parathion	0.50 ppm
Parathion (Ethyl)	0.50 ppm
Thimet	0.50 ppm
Thiodan[1]	0.50 ppm
Trithion	0.50 ppm

[1]Expresses the total of endosulfan II and endosulfan sulfate