WECARE-PROBIOTICS

Akkermansia muciniphila Akk 11: A clinically Validated Probiotic with Scalable production for Metabolic and Cognitive health

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Auckland, New Zealand
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INTRODUCTION

FUNCTIONAL RESEARCH

OUR INVESTMENTS


Bifidobacterium animalis subsp. lactis
BLa80
GRAS
L80

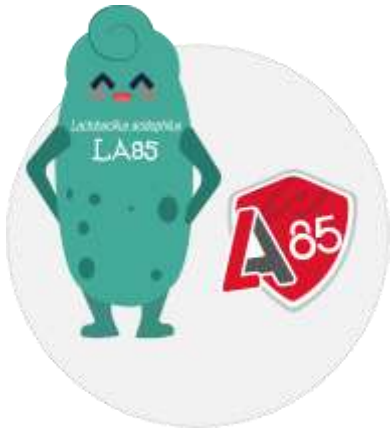

Lactobacillus rhamnosus
LRa05
GRAS
R05


Weissella cibaria
BC99
GRAS
B99


Akk11
GRAS
AKK11


BL21
L21


BBr60
B60


LA85
A85

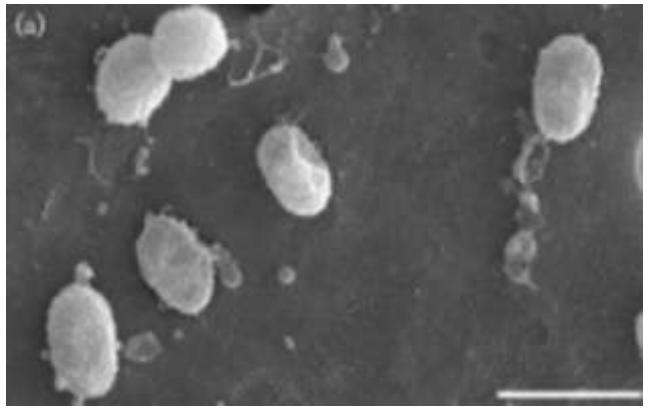

LPo5
P05


LC86
C86


PA53
A53

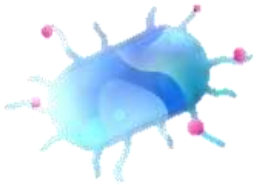
Akkermansia muciniphila

- A Gram-negative, strictly anaerobic gut commensal bacterium and mucin-degrading species.
- First discovered in 2004 by Muriel Derrien and Willem de Vos from Wageningen University in the Netherlands, and was isolated from the feces of healthy individuals.



The electron microscope image of Akkermansia muciniphila strain "Muc T" isolated by Derrien

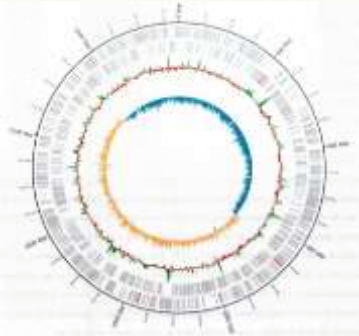
- Type Strain： ATCC BAA-835 (Muc T)
- Optimal Growth Conditions: 37℃、pH 6.5
- Characteristics：Primarily degrades mucin as its main source of carbon, energy, and nitrogen.



https://doi.org/10.1016/j.tim.2024.08.010
https://science.food.gov.uk/article/125531-safety-assessment-on-pasteurised-akkermansia-muciniphila-used-as-a-food-supplement-rp1468

SAFETY ASSESSMENT

Genomic analysis

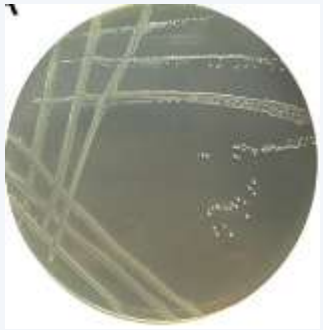


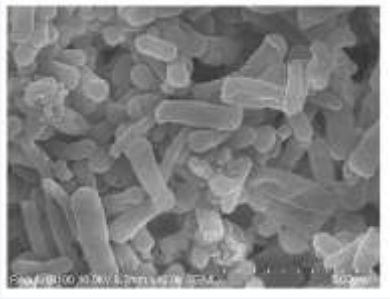
ANI analysis: 98.36%
Akkermansia muciniphila
ATCC BAA-835

- VFDB database;
- VirulenceFinder databas
- CARD database
- ResFinder database
- HMMER software
- PathogenFinder database

Deposit Number:
ATCC: PTA-127863
CCTCC: M 2024119
DSMZ: DSM 35205

Extracorporeal physiological and biochemical assays





***In-vitro* tests**

- Hemolytic
- Antibiotic susceptibility
- D-lactic acid
- Biogenic amines
- Cytotoxicity

Tolerance

① Acid (pH 2.5)
② Simulated gastric fluid
③ Simulated intestinal fluid
④ Bile salts (0.3%)
⑤ Cell adhesion: Tested on Caco-2 cells

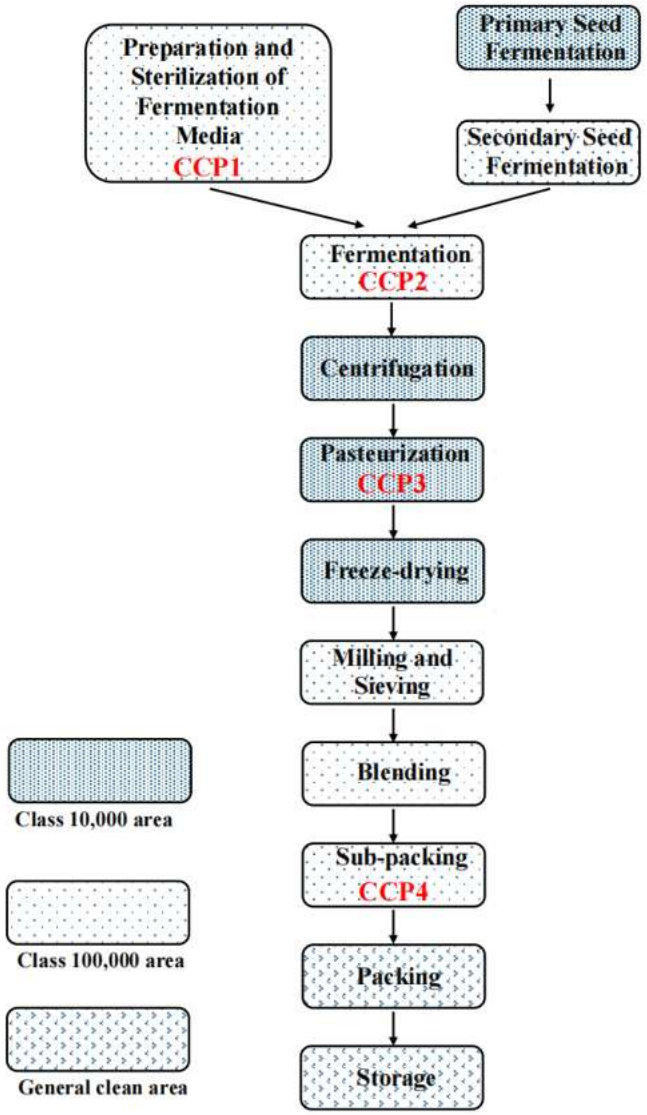
In Vivo Toxicology Test

① Bacterial Reverse Mutation Assay
② Mammalian Erythrocyte Micronucleus Test
③ 14-Day Acute Toxicity Study
④ 90-Day Subchronic Toxicity Study

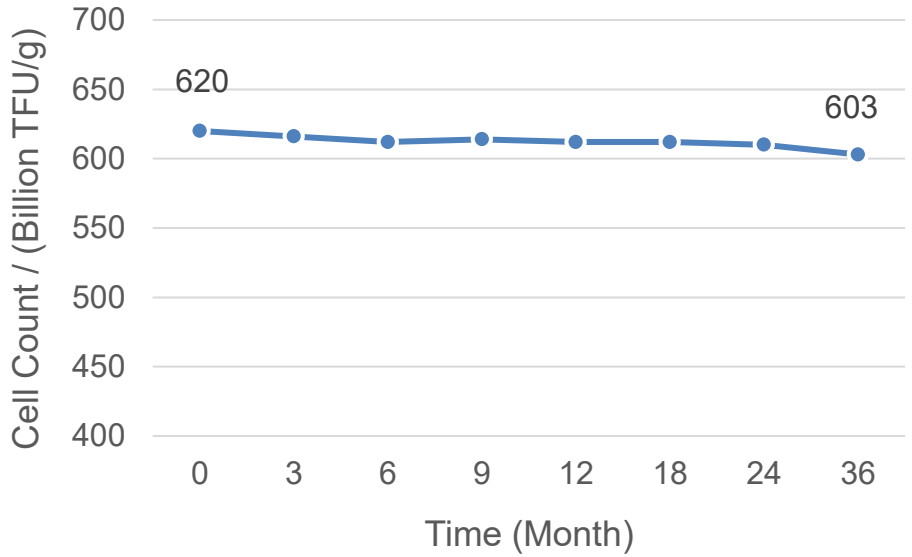
No genotoxicity or oral toxicity was observed.

PRODUCTION AND STABILITY

Process Flow Chart



Stability Test Data for Pasteurized Akk11 bacterial powder (600B)



Conclusion：

① pAkk11 powder packed in aluminum foil pouch is quite stable for up to 36 months at 25° C and 75% RH.
② At all storage conditions the moisture content remains to be below 5%.
③ pAkk11 (Pasteurized) was stored at 25° C for 36 months, and the bacterial count remained above 600B TFU/g, with less than 5% loss.

INDUSTRIALIZATION

Live Akk11 up to 600B AFU/g / pAkk11 up to 800B TFU/g

Raw bacterial powder ID purity > 99.9% (WGS sequencing)

Safety and Efficacy

Evidence on Clinical Studies and Animal Studies

Shelf Life : Live Akk11 for 24m / pAkk for 36m

Cell count remained stable under room temperature

Annual Capacity:

200 Tons raw powder

Manufactured with Quality Assurance

GMP, cGMP standards, HACCP, ISO22000 etc.

DEMONSTRATION PRODUCTS

Product Formula: Akk11, Inulin, Potato starch, Fructo-oligosaccharides (FOS)

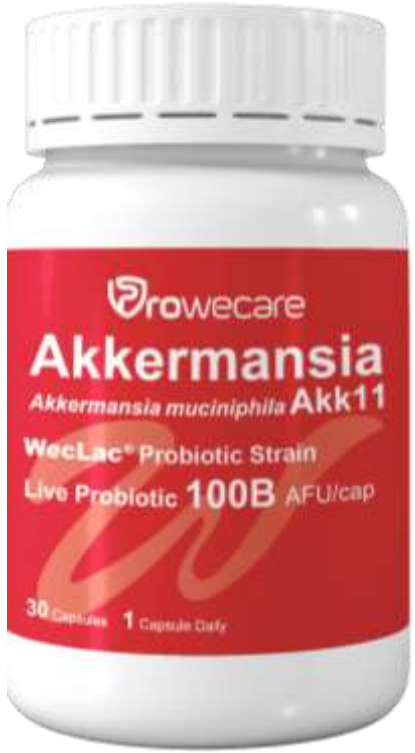
Product Benefits:

① Supports weight management

② Promotes metabolic health

③ Enhances gut health

④ Boosts immunity



INTRODUCTION

FUNCTIONAL RESEARCH

OUR INVESTMENTS

EFFICIENCY RESEARCH

No.	Function	Title	DOI
1	Obesity Management	Investigating the Role of *Akkermansia muciniphila* Akk11 in Modulating Obesity and Intestinal Dysbiosis: A Comparative Study of Live and Pasteurized Treatments	Accepted
2	Obesity Management	*Akkermansia muciniphila* Akk11 Alleviates Obesity by Enhancing GLP-1 Secretion in Animal Models	Under review
3	Blood Glucose Management	*Akkermansia muciniphila* Akk11 supplementation improves glucose metabolism in a mouse model of type 2 diabetes	Under review
4	Liver Health	Exploring the Protective Effects of *Akkermansia muciniphila* on Alcohol-Induced Liver Damage	Under review
5	Improve Parkinson's Disease	*Akkermansia muciniphila* Akk11 supplementation attenuates MPTP-induced neurodegeneration by inhibiting microglial NLRP3 inflammasome	https://doi.org/10.1007/s12602-025-10499-1

CLINICAL RESEARCH

No.	Registration number	Dosage	Period	Title	Status
1	NCT06653101	30B AFU/day	8 Weeks	Akkermansia muciniphila Akk11 Modulates Gut Microbiota and Metabolic Health: A Randomized, Double-blind, Placebo-controlled Clinical Trial	SCI Under review
2	NCT06780007	10B AFU/day	12 Weeks	Effects of Akkermansia muciniphila Akk11 on Weight Management and Regulation of the Gut–Brain–Liver Axis:A Randomized, Double-Blind, Placebo-Controlled Clinical Trial	SCI Under review
3	NCT06728098	1B AFU/day	12 Weeks	Randomized, Double-Blind, Placebo-Controlled Trial on the Effects of Akk11 on Body Fat Percentage and Body Mass Index in Adults with Obesity	In progress
4	NCT06964932	100B TFU/day	12 Weeks	Safety and Efficacy of High-Dose Pasteurized Akk11 in Improving Lipid Metabolism in Obese Individuals	In progress
5	NCT06964919	10B TFU/day	12 Weeks	Efficacy and Safety of Pasteurized Akkermansia muciniphila Akk11 in Weight and Metabolic Regulation: A Randomized, Double-Blind, Placebo-Controlled Trial	SCI Under review
6	N/A	30B TFU/day	12 Weeks	Impact of Pasteurized Akk11 on Obesity-Associated Glycemic Regulation: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial	To be initiated
7	N/A	30B TFU/day	12 Weeks	Efficacy of Pasteurized Akk11 in Glycemic Control of Diabesity: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial	To be initiated
8	N/A	30B TFU/day	12 Weeks	The Impact of Pasteurized *Akkermansia muciniphila* Akk11 on Blood Glucose Levels in Patients with Metabolic Syndrome: A Randomized, Double-Blind, Placebo-Controlled Clinical Trial	To be initiated

CLINICAL RESEARCH 1 (*Akkermansia muciniphila* Akk11)

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Trial design

Primary endpoints
- Body composition

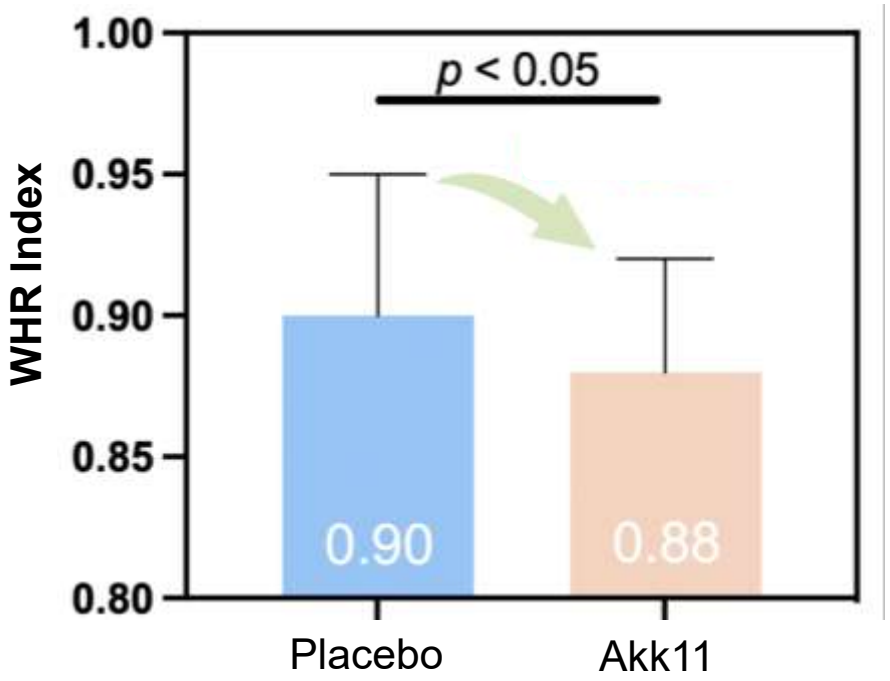
Secondary endpoints
- Questionnaire on PHQ-9, PSQI
- Metabolic biomarkers: insulin, fasting glucose, etc
- Gut microbiota: 16S rRNA on samples

Akkermansia muciniphila Akk11 Modulates Gut Microbiota and Metabolic Health: A Randomized, Double-blind, Placebo-controlled Clinical Trial

Number of Subjects Enrolled	**106**
Key Inclusion Criteria	① Healthy individuals aged 18–45 years ② BMI ≥24 kg/m² ③ body fat percentage ≥25% (male) / ≥30% (female)
Study design	Randomized, double-blind, placebo-controlled
Intervention Method	Oral Akk11 capsules for 8 consecutive weeks
Intervention Dosage	① Placebo group: Prebiotics (inulin, FOS) ② Akk11 group: Prebiotics + **30 Billion AFU/day**
Clinical Trial Registration Number	NCT06653101
Clinical Phase	Manuscript Under review

CLINICAL RESEARCH 1

Waist-to-hip ratio decreased by 0.02



Clinical Significance of Parameter Improvements

1. Every 0.01 reduction in waist-to-hip ratio (WHR) is associated with a 3-5% [1] significant decrease in cardiovascular disease risk

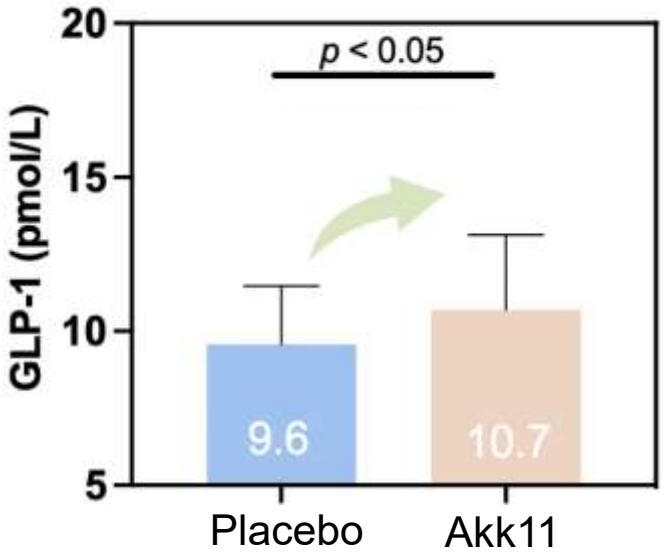
2. Typical probiotic interventions achieve WHR reductions of approximately 0.01 [2], whereas this trial demonstrated a 0.02 decrease, indicating Akk11's superior efficacy in body composition improvement

1.https://doi.org/10.1093/eurheartj/ehm026
2.https://doi.org/10.1111/obr.13667

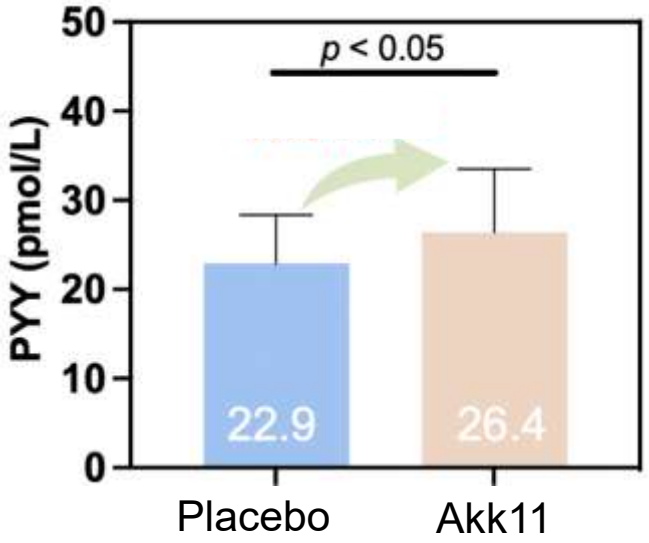
- **Akk11 effectively improves fat distribution, particularly by reducing abdominal fat accumulation**

CLINICAL RESEARCH 1

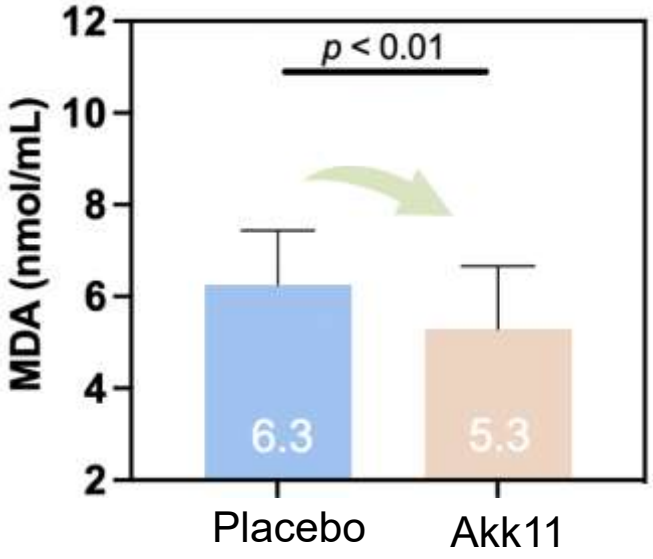
GLP-1 levels rose by 11.5%



PYY levels elevated by 15.3%



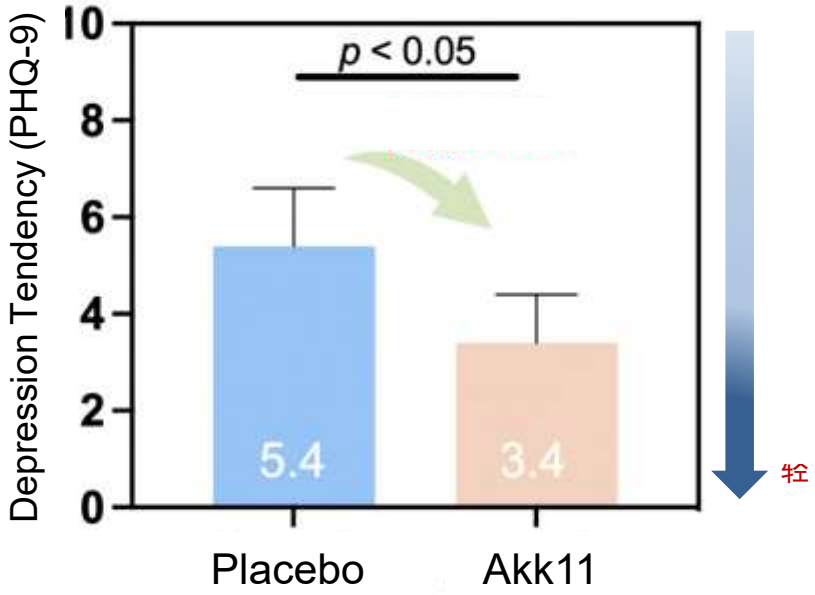
MDA levels reduced by 15.9%



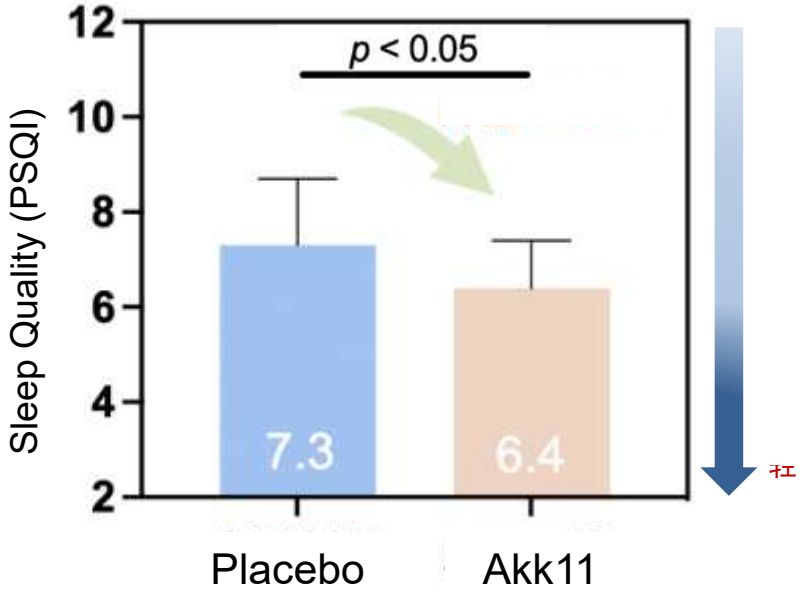
➢ **Akk11 effectively improves metabolic parameters in overweight or obese individuals**

CLINICAL RESEARCH 1

Depression Severity
reduced by 37.0%



Sleep Quality
reduced by 12.3%



➢ The scores on the depression tendency and sleep quality scales of the subjects significantly decreased with the intervention with Akk11, indicates that the Akk11 can effectively **alleviate depressive mood** and **improve sleep quality.**

CLINICAL RESEARCH 2 (*Akkermansia muciniphila* Akk11)

WECARE-PROBIOTICS

Trial design

Effects of *Akkermansia muciniphila* Akk11 on Weight Management and Regulation of the Gut–Brain–Liver Axis:A Randomized, Double-Blind, Placebo-Controlled Clinical Trial

Primary endpoints

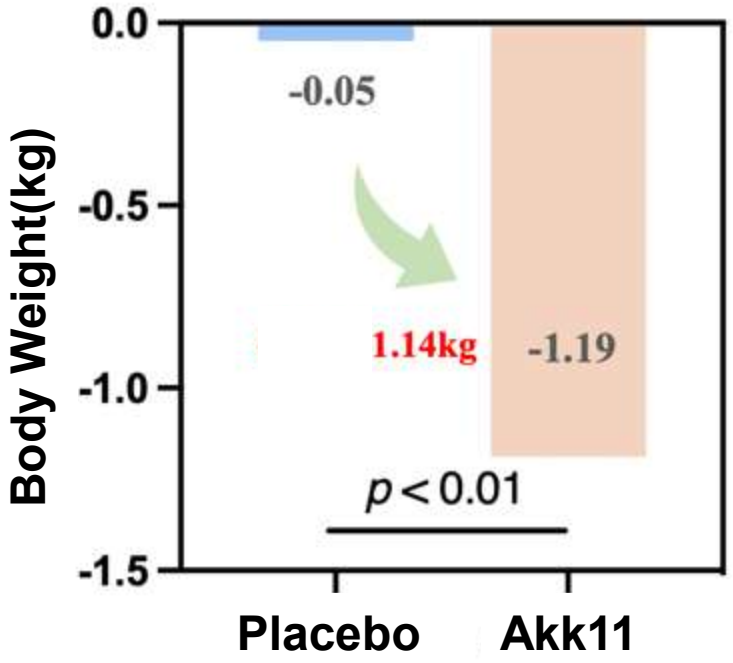
- Body weight ,Changes in BMI

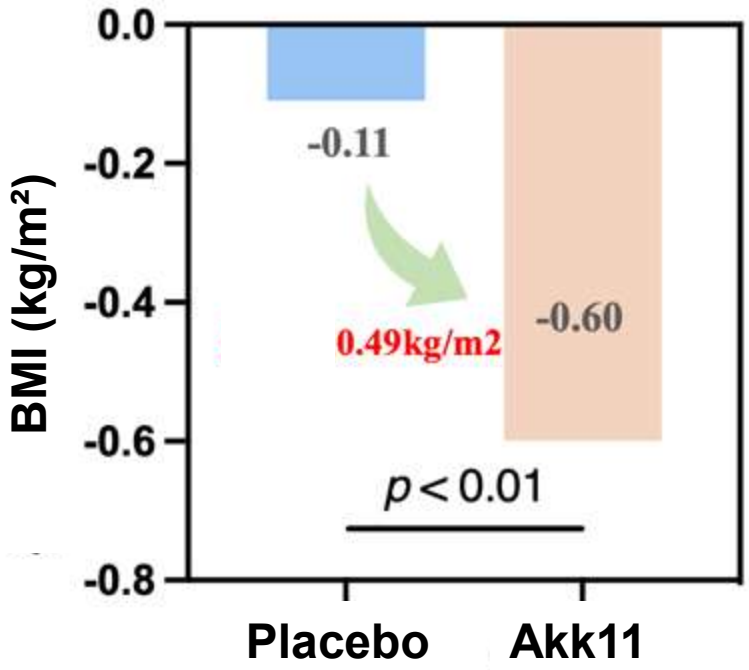
Secondary endpoints

- Body composition: visceral fat index, waist circumference, WHR, etc
- Metabolic biomarkers: insulin, fasting glucose, etc
- Brain function assessment: MRI (Exploratory endpoint)
- Systemic inflammatory markers: IL-6, TNF-α, etc
- Immune indicators: IgG, etc
- Gut microbiota: 16S rRNA analysis

Number of Subjects Enrolled	**101**
Key Inclusion Criteria	① Individuals aged 18–65 years ② 28≤ BMI ≥35 kg/m²
Study design	Randomized, double-blind, placebo-controlled
Intervention Method	Oral Akk11 capsules for 12 consecutive weeks
Intervention Dosage	① Placebo group: Prebiotics (inulin, FOS) ② Akk11 group: Prebiotics + **10 Billion AFU/day**
Clinical Trial Registration Number	NCT06780007
Clinical Phase	Manuscript Under review

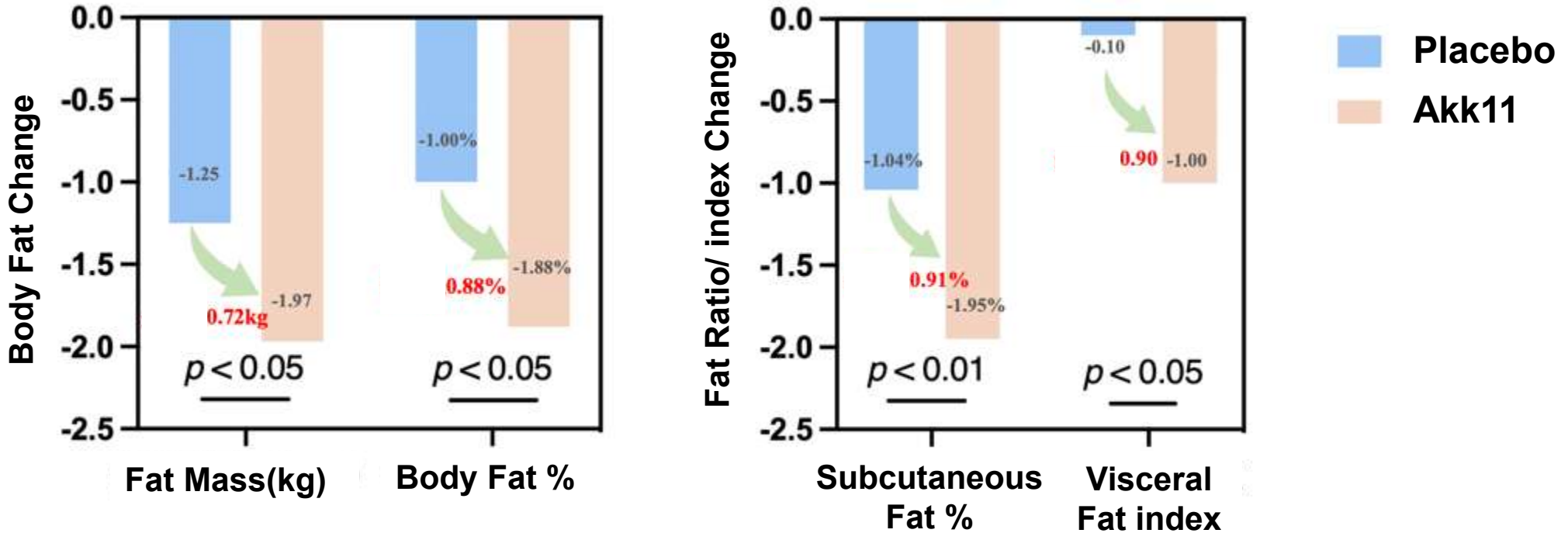
Akk11 Promotes weight reduction and regulates body-mass index





- Compared with placebo, Akk11 intervention led to significant reductions in body weight and body-mass index, demonstrating its efficacy in promoting **weight loss** and **modulating BMI**.

Akk11 Improve Body Composition



- Akk11 significantly decreased both absolute fat mass and percent body fat, while also lowering the subcutaneous fat ratio and visceral fat index. These findings indicate that Akk11 effectively reduces **overall** and **regional fat accumulation**, thereby improving body composition.

CLINICAL RESEARCH 3 (Pasteurized *Akkermansia muciniphila* Akk11)

WECARE-PROBIOTICS

Trial design

Efficacy and Safety of Pasteurized *Akkermansia muciniphila* Akk11 in Weight and Metabolic Regulation: A Randomized, Double-Blind, Placebo-Controlled Trial

Primary endpoints

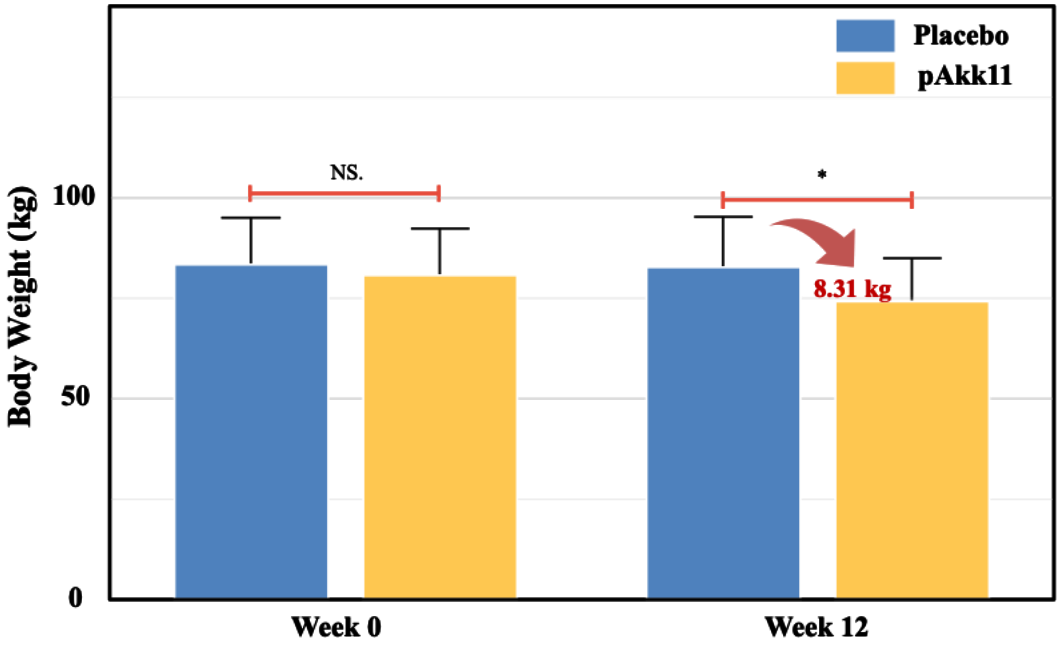
• Glycemic parameters: fasting plasma glucose (FPG), glycated hemoglobin. Metabolic hormones: PYY, GLP-1, leptin, insulin, adiponectin

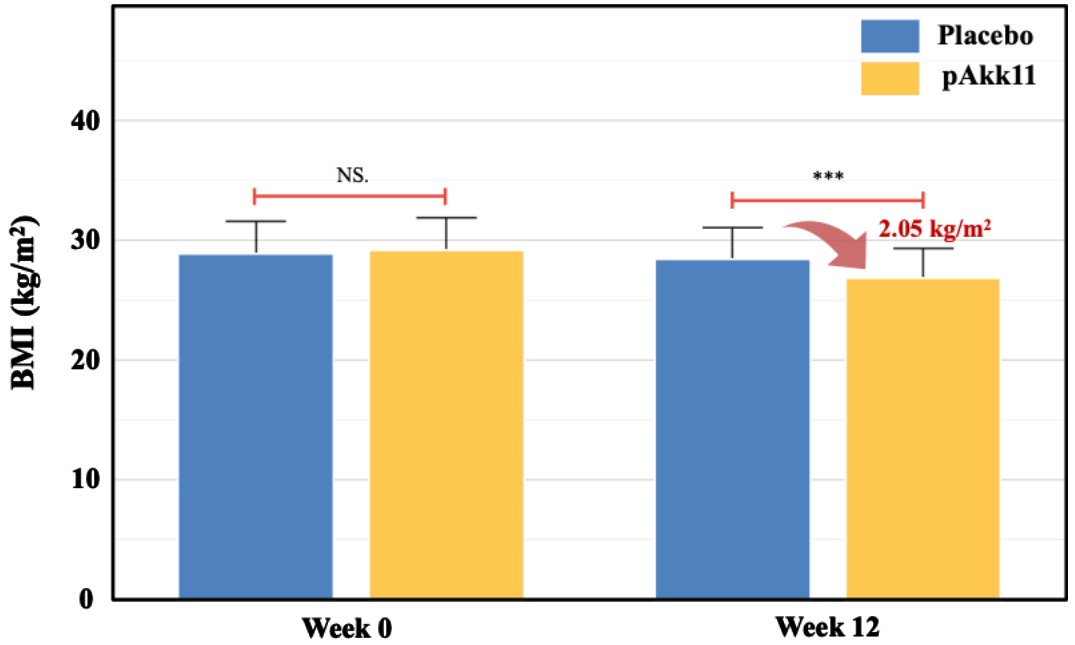
Secondary endpoints

• Body composition: body weight, BMI, etc
• Lipid profile: total cholesterol, LDL-C, HDL-C, triglycerides
• Systemic inflammatory markers: IL-6, TNF-α, etc
• Gut microbiota: 16S rRNA analysis

Number of Subjects Enrolled	**72**
Key Inclusion Criteria	① Individuals aged 18–65 years ② BMI ≥25 kg/m²
Study design	Randomized, double-blind, placebo-controlled
Intervention Method	Oral Akk11 capsules for 12 consecutive weeks
Intervention Dosage	① Placebo group: Prebiotics (inulin, FOS) ② Akk11 group: Prebiotics + **10 Billion TFU/day**
Clinical Trial Registration Number	NCT06964919
Clinical Phase	Manuscript Under review

pAkk11 Improve Body Composition

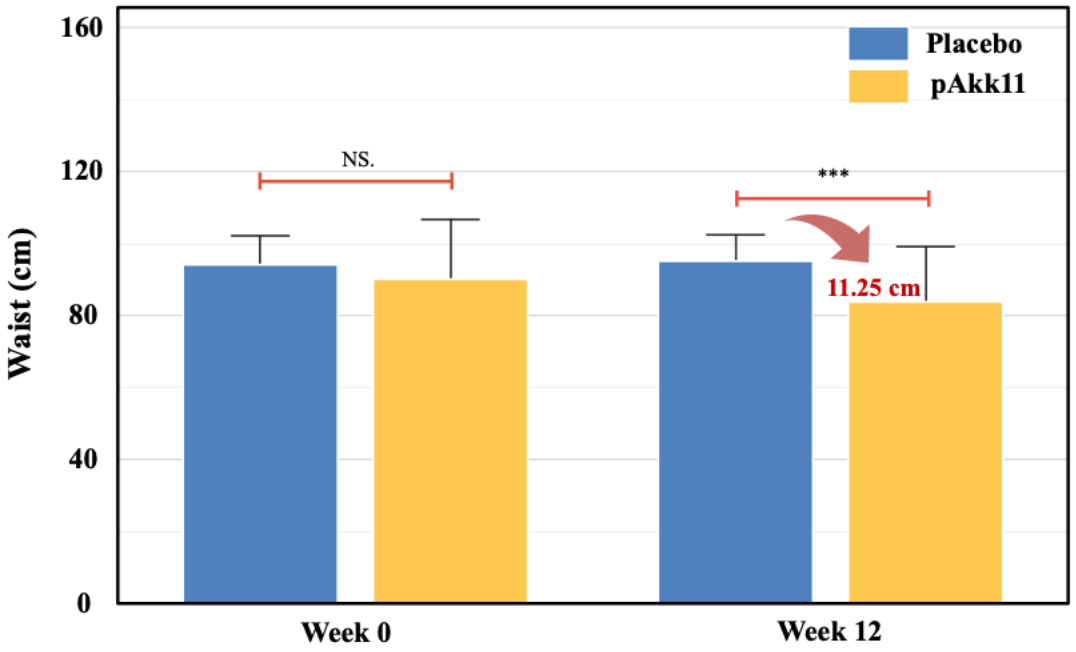


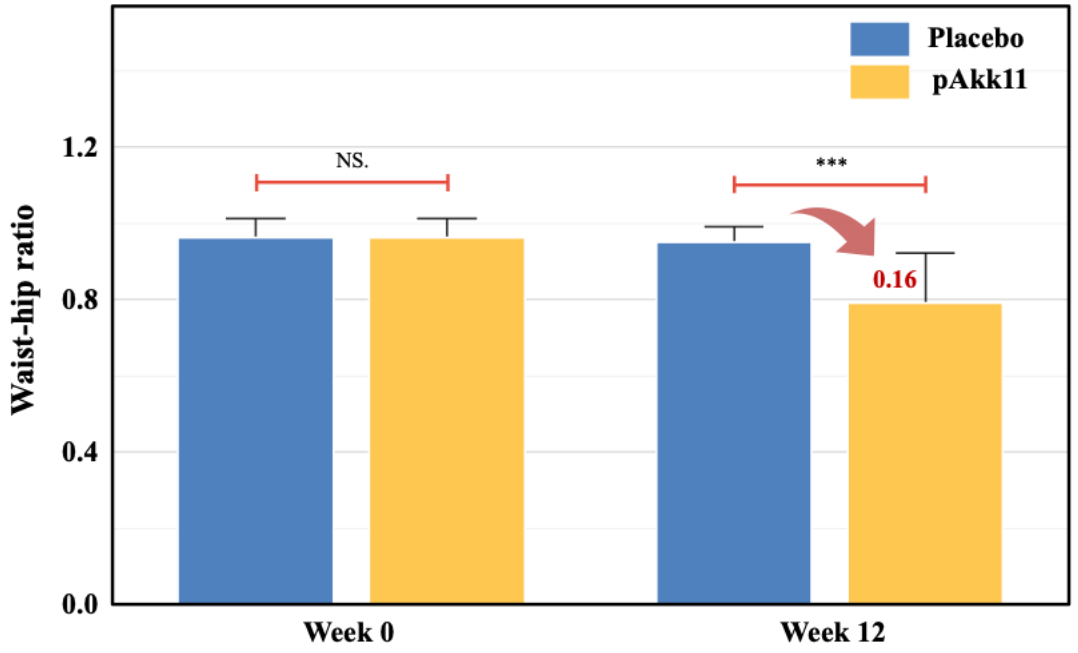


➢ Compared with the placebo group, subjects in the pAkk11 intervention group experienced a significant reduction in **body weight** (mean decrease: 8.31 kg) and BMI (mean decrease: ≈2 kg/m²).

WECARE-PROBIOTICS

pAkk11 Improve Body Composition





- **Waist circumference** declined markedly in the pAkk11 group (mean reduction: 11.25 cm), accompanied by a significant decrease in waist-to-hip ratio (mean reduction: ≈0.16).
- These changes collectively indicate a pronounced improvement in body-composition parameters.

Good Safety

- Gene, in vitro, in vivo
- Clinically proven strains generally exhibit a good safety profile

Tolerance

- Tolerance is generally good among the study population

Efficiency

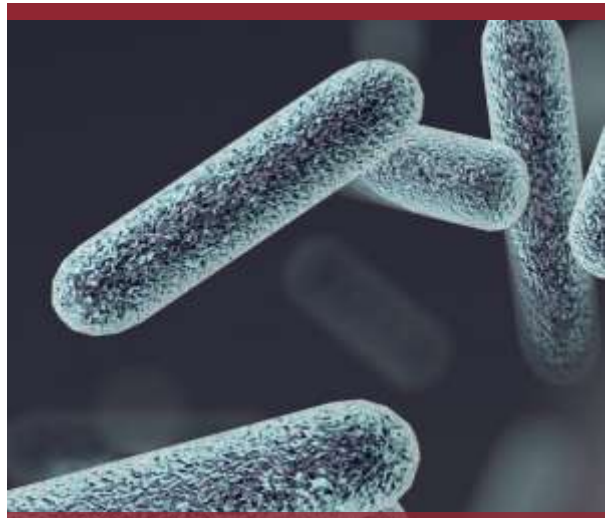
- Body composition improvement (body fat, visceral fat)
- Anthropometric improvement (BMI, WHR, body weight)
- Appetite hormones regulation (PYY, GLP-1)
- Mood health and sleep quality

INTRODUCTION | FUNCTIONAL RESEARCH | **OUR INVESTMENTS**

Products & Service

WECARE-PROBIOTICS

WECARE-BIO



- Functional Strain Development **CRO**
- Strain Processing Development **CDMO**
- Industrial Scale-up **CMO**
- Clinical Research and Global Regulatory Compliance Support

WECARE-PROBIOTICS

- Human Nutrition & Health
- Dairy and Beverages
- Personal Care Microbiome

WECARE-AGRI

- **Animal Health**
  Swine, Poultry, Ruminants, Aquaculture, Pets
- **Plant and Soil Health**
  Crop Protection, Soil Improvement

WECARE-PHARM

- Preclinical and Clinical Translation
- Pilot-scale and Industrial Scale-up
- Regulatory Compliance Support

Manufacturing Facility

Plant & Capacity

90% probiotic raw material production capacity in China

Food Grade

830MT Probiotic Powder

200MT *Weizmannia coagulans* Powder

200MT ***Akkermansia muciniphila* Powder**

13,000MT Probiotic Preparation

10,000MT Probiotic Fermentation Culture

Plant 1
Suzhou Factory #1

30MT
Probiotic Powder
3,000MT
Probiotic Preparation

Plant 2
Luohe Factory #1

200MT
Probiotic Powder
200MT
Weizmannia coagulans Powder
10,000MT
Probiotic Preparation

Plant 3
Suzhou Factory #2

600MT
Probiotic Powder
200MT
Akkermansia muciniphila Powder
10,000MT
Probiotic Fermentation Culture

Plant 4
Luohe Factory #2
(Under Construction)

1200MT
Probiotic Powder

Feed Grade

1,000MT *Bacillus coagulans* Powder

500MT *Bacillus polymyxa* Powder

Plant 1
Luohe Factory #3

1,000MT
Bacillus coagulans Powder
500MT
Bacillus polymyxa Powder

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Corporate Culture

Mission: Quality Probiotics, Quality Life

Vision: Focus on microecology for human health and environment

Value: Integrity, Win-Win

Norm: Quality, Service, Profession, Concentration

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