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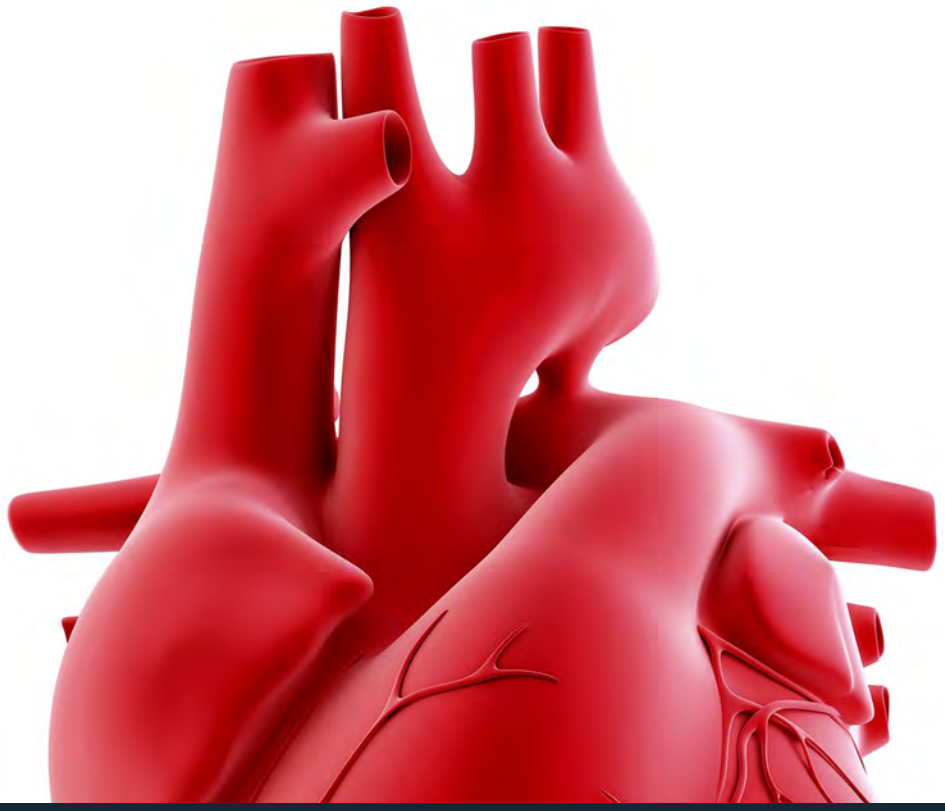


ANKASCIN® 568-R

Safe, Effective, and Approved Red Yeast Rice Extract

THIS WHITE PAPER WILL OUTLINE THE ENORMOUS MARKET POTENTIAL OF THE HEART HEALTH MARKET, AS WELL AS THE IMPORTANCE OF ANKASCIN® 568-R IN MEETING THE DEMANDS OF THIS MARKET.

WHITE PAPER

SunWay Biotech Co., LTD.

CONTENTS

OVERVIEW

Red yeast rice is prized for its ability to lower cholesterol and maintain healthy blood glucose and blood pressure levels. But, currently, most red yeast rice supplements are barred from the US and other markets because of their monacolin K content, which is considered in the US to be a drug and not a supplement.

ANKASCIN® 568-R answers the call for a safe and effective red yeast rice supplement ingredient, since it includes the active compounds beneficial for heart health and no monacolin K. Backed by myriad clinical trials, the ingredient is FDA approved as a new dietary ingredient and holds 28 patents worldwide. And, with heart disease on the rise worldwide, the market potential for such an ingredient holds enormous potential.

INTRODUCTION

Global Market is Primed for Heart Health Supplements

According to the World Health Organization (WHO),[1] cardiovascular diseases (CVDs) are the leading cause of death globally. WHO says that about 17.5 million people worldwide died from CVDs in 2012 alone, representing 31 percent of all global deaths. Stateside, the Center for Disease Control and Prevention (CDC) reports that CVDs cause one-quarter of American deaths, amounting to 601,000 lives yearly, without discriminating for gender: heart disease is the leading cause of death for both men and women.[2]

"CVD is a growing problem," says John Pans, president of SunWay. **"But the risk factors for CVD — including high cholesterol, hypertension, and diabetes — are also on the rise.** This is thanks in part to lifestyle habits like smoking, drinking alcohol, and being sedentary. But it's also a result of unhealthy diets and the stresses of modern life. This indicates demand for supplements to address these before they progress."

WHO reports that one-third of heart disease incidents can be attributed to **high cholesterol**, and this risk factor in particular has been linked to 2.6 million deaths globally.[3,4] Further, the prevalence of high cholesterol is about 40 percent of the world's population, with the highest numbers in Europe (54 percent of people) and America (about 50 percent of people).

As far as **hypertension**, WHO reports that more than 1 in 5 adults worldwide have it, and complications account for over 9 million deaths yearly.[5,6] **Diabetes** is also on the rise, WHO reports, with incidence jumping from 108 million individuals in 1980 to 422 million in 2014. Further, WHO says that an estimated 1.5 million deaths were directly caused by diabetes in 2012.[7,8]

Diabetes is also a major cause of stroke, and the CDC reports that more than 795,000 Americans have a stroke every year and stroke claims over 130,000 American lives yearly, representing one out of every 20 deaths.[9]

The good news? CVD and its risk factors can all be prevented or reduced by addressing behavioral factors like tobacco use, diet, and exercise, and by taking supplements. And consumers are beginning to understand this.

While one study found that it would be cost-effective to treat as many as 67 percent of all adults in the US over age 40 with cholesterol-lowering statins,[10] data shows that consumers may actually respond more positively to dietary supplement use.

The global nutraceutical market is healthy, and expected to reach a value of $285 billion by 2021, up from $198.7 billion in 2016 — that's an annual compound growth rate of 7.5 percent, says Research and Markets.

When it comes to heart health, consumers are very concerned — and they're looking to the supplement industry for answers. Top of mind are high blood pressure, with 28 percent of consumers very concerned with preventing the condition, high cholesterol, (26 percent very concerned) and heart disease (25 percent very concerned), says NMI's Health & Wellness Trends Database. Their concern is leading them to the supplement aisle, with Council for Responsible Nutrition reporting that 21 percent of American supplement users cite heart health as their top reason for using supplements.

Thanks to this interest, Euromonitor International reports that retail sales of functional foods with a cardiovascular health positioning accounted for $7 billion in sales in 2013, growing at a 2 percent CAGR from 2008. Dietary supplements are in even higher demand though, bringing in a bit less in sales — $3.7 billion — but showing a much higher rate of growth at an 8 percent CAGR between 2008 and 2013. The market researcher says that supplements positioned for heart health accounted for 14 percent of total supplement sales in North America, and 9 percent in western Europe alone, bringing in combined regional sales of $2.4 billion in 2013. In the US, NutraIngredients-USA reports that **wholesale sales of US heart health ingredients topped $563 million in 2008 and were predicted to grow at a CAGR of 20 percent.**

By 2020, Nutrition Business Journal predicts that these ingredients have the potential to reach a market value of more than $3 billion, since about 14 percent of supplements launched globally currently have a heart health positioning (a figure that has grown 71 percent between 2011 and 2015). And, going forward, **Market Research Future predicts that the heart health products market will grow at a CAGR of 6.5 percent between 2016 and 2022, reaching a value of $15.2 billion for ingredients alone by 2018.**

Red Yeast Rice is Poised for Success

Red yeast rice is prized for its ability to lower cholesterol, improve blood circulation, and improve digestion.[11] Theses benefits are a result of compounds in red yeast rice called monacolins, and one in particular called monacolin K.

However, the US Food and Drug Administration (FDA) classifies red yeast rice products containing more than trace amounts of monacolin K as unapproved new drugs — not dietary supplements.[12] In Europe, the European Food Safety Authority (EFSA) allows for health claims stating a cause and effect relationship between monacolin K and maintenance of normal blood LDL cholesterol concentrations.

That said, consumers are still demanding this ingredient. The National Institutes of Health reports that in 2008 and 2009, US sales of red yeast rice dietary supplements reached approximately $20 million per year. By 2015, says Nutrition Business Journal, that number jumped to $49 million. "It's clear that consumers are looking for red yeast rice ingredients," says Pans. **"ANKASCIN® 568-R is the only safe and effective red yeast rice ingredient on the market with no monacolin K."**

> "MULTIPLE RED YEAST RICE SUPLLEMENTS CONTAIN A VARIED RANGE OF STATINS."
>
> ConsumerLab. com

ANKASCIN® 568-R

What is ANKASCIN® 568-R?

ANKASCIN® 568-R, is an extract of fermented products of *Monascus purpureus* NTU 568 (Figure 1). Our technique including this particular strain was transferred from the laboratory of Professor Tzu-Ming Pan at National Taiwan University. This strain has been supported by more than 120 SCI publications. Our R&D team has dedicated years in doing clinical trials verifying their effects on blood lipid (cholesterol), blood glucose, and blood pressure regulation.

The beneficial effects come from two high levels of active compounds monascin (MS) and ankaflavin (AK) in our ANKASCIN® 568-R. They are the yellow pigment metabolites naturally produced from our patented solid fermentation technique.

Although monacolin K is the most commonly used effective compound to regulate metabolic syndrome in history, it carries with it some side effects. However, MS and AK have no side effects and even boast better outcomes than monacolin K.

ANKASCIN® 568-R

"ANKASCIN® 568-R, which contains active compounds monascin and ankaflavin, can regulate blood lipid, blood glucose, and blood pressure levels, and boost memory and cognitive health."

What are MS and AK?

Monascin (MS)

Monascus purpureus NTU 568 secondary metabolite product — Monascin — has been shown to prevent or ameliorate hypercholesterolemia, hyperlipidemia, and obesity. Recently, MS has been shown to improve hyperglycemia, regulate diabetes, attenuate oxidative stress, inhibit insulin resistance, and suppress inflammatory cytokine production.[13] Additionally, MS is a peroxisome proliferator-activated receptor-gamma (PPARγ) agonist, which up-regulates insulin sensitivity. In recent studies, researchers have found that it is effective in inhibiting hyperglycemia in AGE- or MG-treated animals.[13,14]

Ankaflavin (AK)

Ankaflavin has been identified as a naturally occurring secondary metabolite from red yeast rice. It counteracts the symptoms of metabolic syndrome by inhibiting hypercholesterolemia and nonalcoholic fatty liver disease, protects against cardiovascular disease and atherosclerosis, and boasts anti-obesity, anti-cancer, and anti-inflammatory effects in the airway.[15] AK also positively regulates several transcription factors associated with the prevention of metabolic syndrome and other diseases, including PPARγ, PPARα, and Nrf2. Taken together, these results suggest that AK is associated with a beneficial effects profile when used by patients suffering from metabolic syndrome.[15]

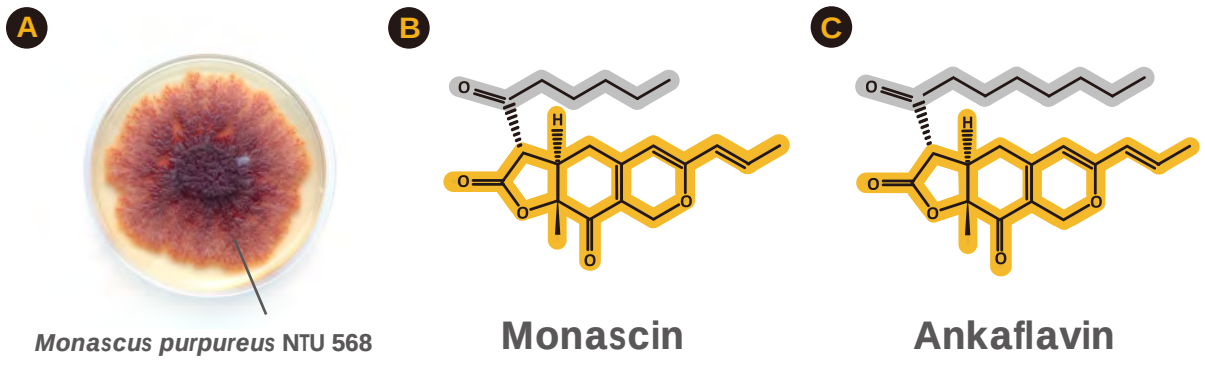


Figure 1: *Monascus purpureus* NTU 568 and chemical structure of monascin and ankaflavin

CLINICAL EVIDENCE

The two new active compounds in ANKASCIN® 568-R, monascin and ankaflavin, have been evaluated in a number of clinical trials. Here, we take a detailed look at three of these, focused on the areas of blood lipids, blood glucose, and blood pressure.

1

Title: **A Randomized, Double-Blind Clinical Study of the Effects of ANKASCIN 568 Plus on Blood Lipids Regulation**

Authors: Tzu-Ming Pan and Chin-Kun Wang

Journal: Journal of Food and Drug analysis (2017) I-8 (online)[16]

Design: Randomized and double-blind

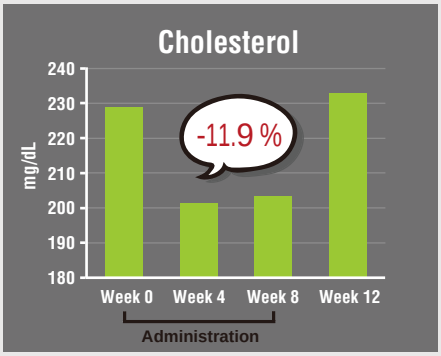
Population: 40 subjects (Inclusion criteria: LDL-C in the range of 130-190 mg/dL and serum cholesterol greater than 180 mg/dL; 30 females; 10 males)

Dose: 110 mg ANKASCIN® 568-R/day

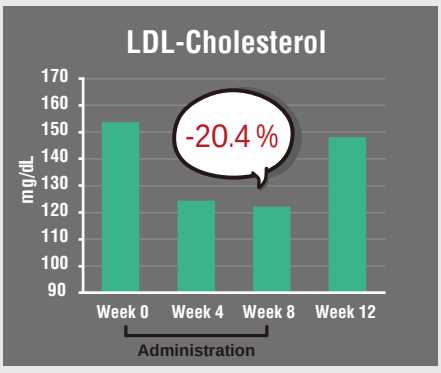
Duration: 8 weeks

Evaluation: week 0 (baseline), week 4, week 8, week 12

Results:



- After just 4 weeks of administration, serum cholesterol was significantly reduced by 11.9%.
- Similar improvements were recorded after 8 weeks of use.
- After another 4 weeks' washout (without administration), serum cholesterol reverted to baseline levels.



- After just 4 weeks of administration, LDL-C was significantly reduced by 19%.
- Better improvements (20.4%) were recorded after 8 weeks of use.
- After another 4 weeks' washout, LDL-C reverted to baseline levels.

Figure 2

Key Conclusion

ANKASCIN® 568-R significantly reduced subjects' serum cholesterol and LDL-C to nearly desirable levels in as little as 4 weeks and were maintained in 8 weeks.

2

Title: **A Randomized, Double-Blind Clinical Study to Determine the Effect of ANKASCIN 568 Plus on Blood Glucose Regulation**

Authors: Tzu-Ming Pan and Chin-Kun Wang

Journal: Journal of Food and Drug Analysis 25 (2017) 409-416[17]

Design: Randomized and double-blind

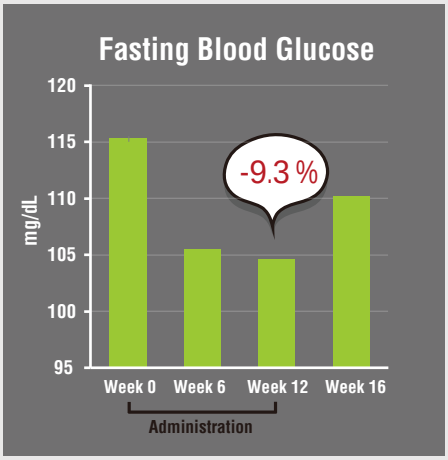
Population: 39 subjects (Inclusion criteria: fasting glucose levels in the range of 100-125 mg/dL and glycated hemoglobin (HbA1c) at 5.7-6.4%; 21 females; 18 males)

Dose: 220 mg ANKASCIN® 568-R/day

Duration: 12 weeks

Evaluation: week 0, week 6, week 12, week 16

Results:



- After just 6 weeks of administration, FBG was significantly reduced.
- Better improvements (9.3%) were recorded after 12 weeks of use.
- Even after another 4 weeks' washout (without administration), FBG levels were lower than the starting levels.

Figure 3

Key Conclusion **ANKASCIN® 568-R significantly reduced fasting blood glucose to sub-health level after 12 weeks of administration.**

3

Title: **A Randomized, Double-Blind Clinical Study on Blood Pressure Reduction and Blood Lipid Profile Amelioration on Treatment with ANKASCIN 568**

Authors: Tzu-Ming Pan and Sheng-Huang Hsiao

Journal: Chinese Journal of Physiology 60(3), 2017 (accepted)

Design: Randomized and double-blind

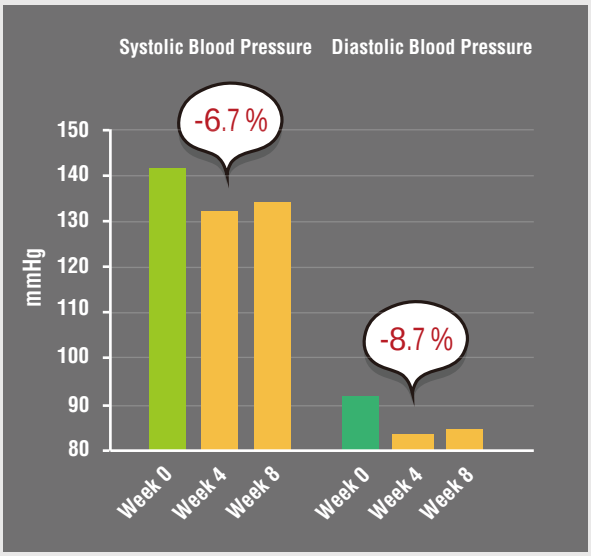
Population: 21 subjects (Inclusion criteria: age 20-65 years, clinical diagnosis of essential hypertension, SBP or DBP range of 130–179 mmHg or 85–109 mmHg, respectively; 11 females; 10 males)

Dose: 220 mg ANKASCIN® 568-R/day

Duration: 8 weeks

Evaluation: week 0, week 4, week 8

Results:



- After 4 weeks of administration, systolic blood pressure fell from high to pre-hypertension levels, decreasing by a total of 6.7%. Similar results were maintained after 8 weeks of use.
- Diastolic blood pressure also significantly decreased by a total of 8.7% after just 4 weeks of administration. Similar results were maintained after 8 weeks of use.

Figure 4

Key Conclusion

ANKASCIN® 568-R significantly reduced systolic and diastolic blood pressure from hypertension to pre-hypertension levels in just 4 weeks of administration, and effects were maintained in the long term.

MEMORY AND COGNITIVE HEALTH

Dementia is a general term used to describe a decline in mental ability severe enough to interfere with daily life. **There are an estimated 46.8 million people worldwide living with dementia, as of 2015. This number is estimated to double every 20 years, reaching about 74.7 million in 2030 and 131.5 million in 2050.**[18] The most common type of dementia is Alzheimer's disease (AD), a progressive disease characterized by memory loss, language breakdown, and eventually, death. Brains of patients with AD shrink and, usually, present abnormal structures characterized by senile plaques and neurofibrillary tangles.[19]

The main pathological factor for AD is thought to be the progressive accumulation of amyloid beta (Aβ) peptides in the brain, generated by the cleavage of the amyloid precursor protein (APP) by a combination of β-secretases and γ-secretases.[20] Aβ buildup has been considered as a potential biomarker for future clinical diagnosis.[21] Hyperphosphorylation of tau, a microtubule-associated protein which aggregates to form tangles, also damages the brains of patients with AD.

SunWay research demonstrates the protective effect of *Monascus purpureus* NTU 568 fermented products (ANKASCIN® 568 plus) on aluminum-induced memory and learning deficit, as well as AD-like pathologic changes such as Aβ, p-tau, and APP.

Aluminum-induced AD rats may not only increase A β's aggregation[22,23] but also cause tau hyperphosphorylation. The hyperhopsphorylation of tau shall lead to neurofibrillary tangles formation in brain. In Figure 5A-5C showed that levels of $A\beta_{1-42}$, $A\beta_{1-40}$ and pTau were elevated by 95% in aluminum-induced AD rats groups in contrast to these levels had signification reduction in ANKASCIN® 568 plus treated groups.

APP is cleaved by several secretases to produce Aβ. In this study, expression of APP in the brain was analyzed by immunohistochemical staining. Hippocampal neurons may upregulate APP in response to aluminum-induced damage.[24] Figure 5D shows that APP was overexpressed in the hippocampus of aluminum-induced rats. ANKASCIN® 568 plus prevented aluminum-triggered APP overexpression, which would have, in turn, increased Aβ production. This may be one of the ways in which ANKASCIN® 568 plus reduces deposition of Aβ in brains of aluminium-induced rats.[25]

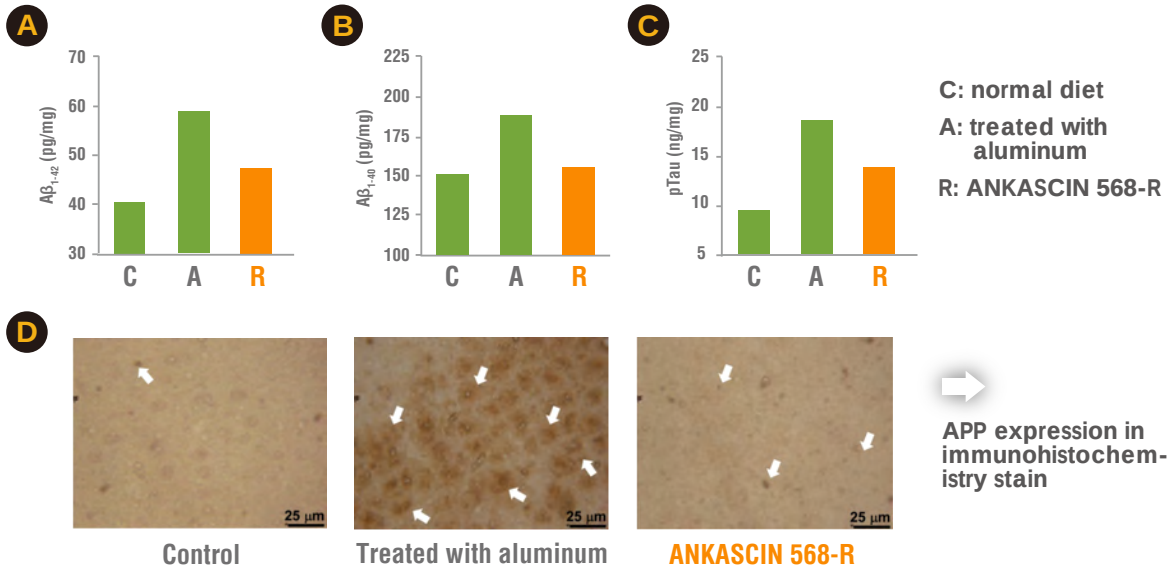


Figure 5: Key risk factors ($A\beta_{1-42}$, $A\beta_{1-40}$, pTau) and Amyloid Precusor Protein (APP) were detected

SAFETY AND FDA APPROVAL

The Power of Red

Red yeast rice has been used for treating hyperlipidemia because the secondary metabolite from the *Monascus* species, monacolin K, is a 3-hydroxy-3-methylglutaryl-coenzyme A (HMG-CoA) reductase inhibitor in the cholesterol biosynthesis pathway. As such, it has been proven to be one of the functional compounds of red yeast rice with hypolipidemic ability.

However, monacolin K is chemically identical to the active ingredient in the cholesterol-lowering drug lovastatin, which is a member of the statin drug class and is used as a hypolipidemic agent to lower circulating levels of cholesterol in patients with hypercholesterolemia, thereby aiding in the prevention of cardiovascular disease. Notwithstanding its therapeutic effects, the use of statins might lead to side effects like rhabdomyolysis.

> **"Since monacolin K levels in many commercial red yeast rice supplements are unknown to consumers, they risk overdose and subsequent muscle weakness or pain, or even rhabdomyolysis."**

Often, consumers have no idea how much monacolin K (statin) is included in traditional red yeast rice dietary supplements; as a result, some people who take both statin drugs and supplements to help manage hyperlipidemia might experience side effects and drug interactions due to overdose, including muscle weakness or pain, or even rhabdomyolysis. Statin-induced rhabdomyolysis is a rare albeit potentially fatal complication of HMG-CoA reductase inhibition with an estimated incidence rate of about 0.44 per 10,000 persons per year of therapy. Because of this condition, the US Food and Drug Administration (FDA) has determined that red yeast rice products that contain more than trace amounts of monacolin K are unapproved new drugs and cannot be sold legally as dietary supplements. In recent years, Europe and other countries are also starting focus on drugs in food supplements, and are restricting or banning monacolin K in such products.

No Monacolin K

Because of worldwide legal limitations and the potential for side effects, SunWay's main goal is to minimize side effects while maximizing the benefit of its ingredient. After improving laboratory fermentation methods over the course of several years, "We can now proudly say that we have found a red yeast rice extract that does not contain monacolin K, but still boasts beneficial effects in regulating blood lipids." says Pans. "And it is the first red yeast rice extract free of monacolin K in the world."

Through in-house research (Figure. 6), scientists analyzed different commercial RYR products and found that the daily serving in each did in fact contain monacolin K. The effects of SunWay Biotech's ANKASCIN® 568-R, however, were not contributed by monacolin K, indicating that this ingredient had equivalent benefits without the side effects of monacolin K.

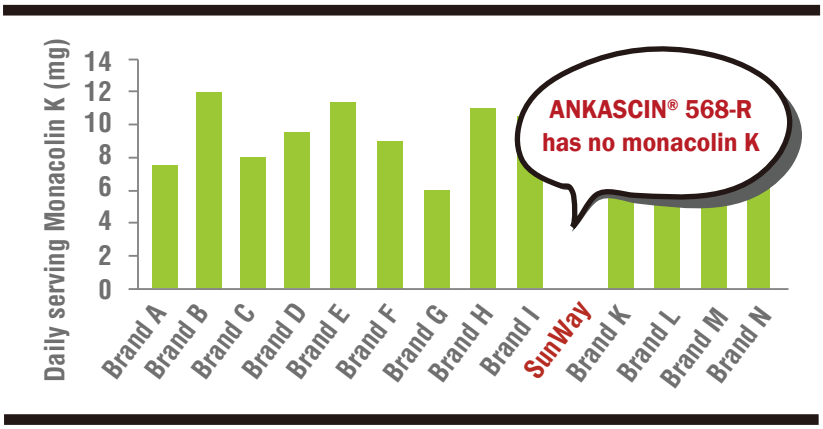


Figure 6: Comparison of monacolin K levels in commercial red yeast rice products

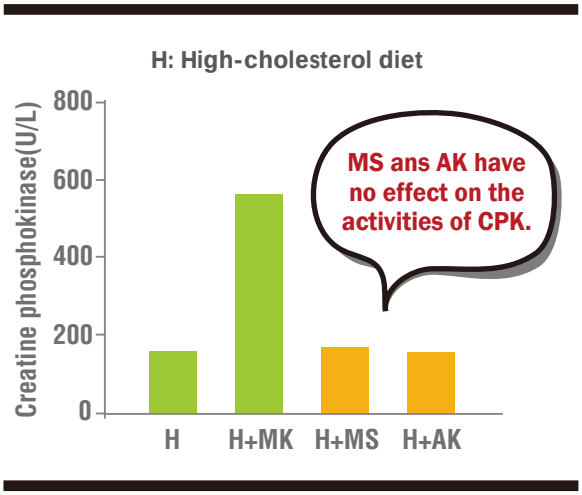


Figure 7: Serum CPK levels were detected

Further, monacolin K has been found to significantly increase the activity of creatine phosphokinase (CPK), leading to myopathy, rhabdomyolysis, and kidney toxicity when CPK is excessive in serum. Regarding this issue, our scientific research (Figure. 7) shows that the major compounds of ANKASCIN® 568-R – MS and AK — have no effect on the activities of CPK.[26]

Drug Interactions

Some people who take statin drugs together with red yeast rice dietary supplements that include monacolin K may experience side effects due to overdose, including muscle weakness or pain, or rhabdomyolysis. Research from SunWay has found no increased risk of rhabdomyolysis with *Monascus purpureus* NTU 568 fermented products (NTU 568) alone, and has confirmed better results on total cholesterol and triglycerides than a regimen of statin drugs alone (exp. lovastatin).[27]

In addition to the beneficial effects of SunWay's ingredient on blood sugar and blood pressure, studies show that there are no side effects when combined with blood sugar or blood pressure drugs.[28,29] Moreover, reports from SunWay show that NTU 568 boasts superior effects on oral glucose tolerance, blood glucose regulation in combination with pioglitazone[28], and antihypertensive effects in combination with amlodipine.[29]

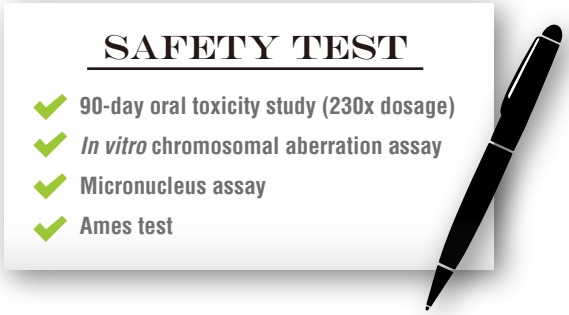
Safety Assessments

Safe for liver and kidney function

The majority of commercial red yeast products can cause liver and kidney toxicity. Thus, it was important to reach the food safety risks. To do so, SunWay scientists assayed AST and ALT levels in the liver, and BUN, creatinine, and uric acid levels in the kidney. NTU 568 administration caused no significant difference in the AST and ALT levels.[28-30] Further, no toxic side effects were observed when NTU 568 was administered in tandem with a blood lipids drug (lovastatin), blood glucose drug (pioglitazone), or blood pressure drug (amlodipine). Overall, during our clinical study, no significant difference was found in liver and kidney functions between the treatment group (ANKASCIN® 568-R) and control group.[28]

Safety assessments

SunWay has achieved four safety tests including:



US FDA and Patent Approved

In 2015, ANKASCIN® 568-R was honorably reviewed and accepted by the US FDA as a **NEW DIETARY INGREDIENT** (NDI), which made it the only eligible red yeast rice ingredient on the US market that can legally apply claims and clearly specify the contents of active compounds. It has been used in a formula receiving an NPN (80071270) and, this year, a food supplement containing ANKASCIN® 568-R was approved by Italian authorities.

ANKASCIN® 568-R is also certified with myriad patents from the US, EU, Canada, Japan, Australia, China, Korea, Singapore, Taiwan, and others. Therefore, it is suitable for a variety of dietary supplements and fortified foods worldwide.

DISCUSSION

It is undeniable that consumers are concerned about staying healthy as they age, particularly when it comes to heart and cognitive health. Incidence of hypertension, diabetes, and high cholesterol are on the rise worldwide. And, because these are all risk factors for cardiovascular disease, consumers are looking for a way to manage or mitigate these symptoms with natural dietary supplements either in tandem with or without the use of pharmaceuticals.

ANKASCIN® 568-R has been shown to reduce serum cholesterol, fasting blood glucose levels, and systolic and diastolic blood pressure levels, often bringing levels down from high to prehypertension levels. It manages to do this all **without the inclusion of monacolin K,** a component of red yeast rice that's barred from use in dietary supplements in the US and brings with it a host of risks for individuals already using statin drugs to control their cholesterol. In fact, unlike the majority of red yeast rice products available, ANKASCIN® 568-R is safe to use in tandem with pharmaceutical drugs used for blood lipids, blood glucose, or blood pressure.

"ANKASCIN® 568-R provides supplement and functional food formulators with the best of both worlds: all the benefits of red yeast rice and none of the dangers associated with monacolin K," says Pans. It is approved by the US FDA as a new dietary ingredient, and is the only eligible red yeast rice ingredient on the US market capable of legally applying structure/function claims and clearly specifying the active compound content."

The Council for Responsible Nutrition found that about one in five American supplement users cite heart health as their top reason for shopping the supplement aisle. Formulators would be wise to consider using a heart health ingredient that's both time-tested and verified by modern science like ANKASCIN® 568-R.

"IT IS CRITICAL THAT YOU CHOOSE AND USE RED YEAST RICE INGREDIENTS CAREFULLY."

THERE ARE LOTS OF HEART HEALTH INGREDIENTS...

WHY US ?

TOP 7 REASONS

1. Your product deserves the best ingredients. ANKASCIN® 568-R has **clinically proven benefits** for blood lipid, blood sugar, and blood pressure levels.

2. Safety first! ANKASCIN® 568-R has been reviewed and accepted as **New Dietary Ingredient** by the US Food and Drug Administration.

3. Most commercial red yeast rice supplements contain statins (monacolin K), which can cause side effects and even overdose. Choosing ANKASCIN® 568-R eliminates this risk, since it contains **no monacolin K**.

4. ANKASCIN® 568-R is backed by more than 10 years of clinical research resulting in **120 scientific publications**.

5. Having a patent is essential. ANKASCIN® 568-R is **patented** to ensure that your investment will make a powerful impact on the market.

6. Consumers — especially millennials — are looking for **non-GMO** supplements. Ingredients like ANKASCIN® 568-R that are non-GMO can help you get there.

7. Allergen testing is one of the most prevalent quality assurance elements within the dietary supplement industry. ANKASCIN® 568-R is **allergen-free**, building trust between your product and your consumers.

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* These statements have not been evaluated by Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease.

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