Technical Report

Significance of *amylase* in CanXida Restore (Formula RST)

"*In CanXida Restore (Formula RST),* ***amylase*** *aids carbohydrate digestion, synergizes with probiotics to support gut flora, disrupts biofilms, modulates intestinal barrier function, thus promoting digestive comfort and overall health".*

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Executive Summary

Amylase, a pivotal enzyme in carbohydrate digestion. Originating from the pancreas and salivary glands, amylase contributes to the breakdown of complex carbohydrates into simpler sugars. Amylase's functional properties extend beyond digestion, influencing nutrient absorption, glycemic control, prebiotic function, and antimicrobial activity. When combined with probiotics, amylase demonstrates synergistic effects, offering health benefits such as supporting gut microbiota health, enhancing digestive efficiency, regulating biofilm formation, exhibiting anti-inflammatory effects, preventing dysbiosis, and potentially influencing mental well-being.

The biosafety profile of amylase is contingent on its source and production method. Microbial-derived amylases are generally considered safe, but thorough allergenicity studies are essential. Amylase's stability under diverse environmental conditions is vital for assessing its safety in practical applications. Microbial targets of amylase include *Staphylococcus aureus*, *Escherichia coli*, *Pseudomonas aeruginosa*, *Candida albicans*, and *Streptococcus mutans*, suggesting potential antimicrobial applications.

Inclusion of amylase in the CanXida Restore formula highlights its role in enhancing digestive health. The formula, coupled with probiotics, may relieve symptoms associated with inflammation and gut dysbiosis, offering potential benefits in promoting optimal digestion, maintaining gut microbiota balance, and supporting overall well-being*.

1. Introduction

Amylase is an enzyme responsible for the breakdown of carbohydrates during digestion. It is primarily produced in the pancreas and salivary glands, with trace amounts present in other areas of the body (Akinfemiwa et al., 2023).

Enzymes, a type of cellular protein, facilitate essential chemical reactions in the body. They naturally aid in muscle building, toxin removal, and the digestion of food during the digestive process.

Amylase, an enzyme that was among the first to be investigated, was initially documented in the early 1800s. The term "***diastaste***" was originally used, but it was subsequently changed to "amylase" in the early 20th century as part of scientific research (Tiwari et al., 2015).

Testing blood amylase levels helps diagnose conditions like acute pancreatitis, peptic ulcer, ileus, strangulation or mumps.

2. Types of *amylase enzyme*:

There are three primary classes of amylase enzymes, namely alpha-, beta-, and gamma amylases. These enzymes have specific targets within the carbohydrate molecule, allowing for precise breakdown and utilization (Lahiri et al., 2021).

These enzymes can also be classified into exo-amylases and endo-amylases based on their different modes of action (Lahiri, Nag, Banerjee, et al., 2021 a).

- ***Exo-amylases*** specifically act on non-reducing ends of substrates, leading to the breakdown of these substrates into shorter end products.
- In contrast, ***endo-amylases*** exhibit a random effect on internal glycosidic linkages found within starch molecules, resulting in the production of oligosaccharides with varying lengths.

3. Functional properties of Amylase

Amylase is an enzyme that has a vital function in the digestive system. It possesses multiple functional properties:

3.1. Carbohydrate Digestion:

Amylase breaks down complex carbohydrates, specifically starches, into simpler sugars. The process of carbohydrate digestion initiates in the mouth where salivary amylase breaks the internal α-1,4 bonds of polysaccharides. This process is then carried on by pancreatic α-amylase in the small intestine, resulting in the production of oligo-, tri-, and disaccharides (Peyrot des Gachons & Breslin, 2016; Tunnicliffe et al., 2015).

3.2. Nutrient Absorption:

The collaborative action of amylase and brush border enzymes facilitates the breakdown of carbohydrates in the small intestine, enhancing the absorption of simple sugars and serving as a crucial source of energy for the body (Akinfemiwa et al., 2023; Peyrot des Gachons & Breslin, 2016).

3.3. Glycemic Control:

Amylase helps regulate blood sugar levels by converting complex carbohydrates into sugars, which are then absorbed slowly into the bloodstream. This can contribute to better glycemic control (Tundis et al., 2010; Tunnicliffe et al., 2015).

3.4. Prebiotic Function:

The breakdown products of carbohydrates, like short-chain oligosaccharides, can serve as prebiotics (Zeng et al., 2023). These substances nourish beneficial gut bacteria, promoting a healthy gut microbiota.

3.5. Reduced Digestive Discomfort:

Research indicates that the addition of pancreatic enzyme supplements to the treatment of functional dyspepsia is advantageous and leads to a considerable reduction in symptoms such as excessive gas, abdominal distention, burping, feeling of fullness, and discomfort after eating (Soni et al., 2020).

3.6. Promotes Antimicrobial activity

Digestive enzymes support the stomach's anti-microbial activity by breaking down food, creating an environment that hinders harmful microorganisms (Soni et al., 2020).

The blood serum amylase level is tested for various diagnostic purposes. A higher concentration of amylase (hyperamylasemia) can be indicative of acute pancreatitis, strangulation, peptic ulcer, ileus or mump.

4. Synergistic effects with probiotics:

Combining amylase with probiotics can offer several health benefits (Monica et al., 2023):

However, ***Amylase*** is an enzyme that plays a crucial role in the digestion of carbohydrates, breaking down complex sugars into simpler forms such as maltose and glucose. ***Probiotics***, on the other hand, are live beneficial bacteria that confer various health benefits, particularly in promoting a balanced gut microbiota.

4.1. Gut Microbiota Health:

Amylase can support gut microbiota health by aiding in the breakdown of carbohydrates, creating an environment favorable for the growth of beneficial bacteria promoted by probiotics.

Table 1 outlines the diverse health advantages of amylase-supplemented drugs.

4.2. Digestive Efficiency:

Amylase plays a key role in the digestion of carbohydrates, breaking them down into simpler sugars. This enzymatic activity, combined with probiotics, can enhance digestive efficiency and nutrient absorption in the small intestine*.

4.3. Biofilm Regulation:

Amylase's ability to disrupt biofilm formation is crucial in maintaining a healthy intestinal environment. By preventing the formation of thick polymicrobial biofilms, the combination of amylase and probiotics supports a balanced gut ecosystem *.

4.4. Anti-Inflammatory Effects:

Amylase, alongside probiotics, may exhibit anti-inflammatory effects, potentially reducing inflammation in the gastrointestinal tract. This anti-inflammatory action can contribute to overall gut health*.

4.5. Prevention of Dysbiosis:

Amylase, by aiding in the digestion of carbohydrates, supports the growth of beneficial bacteria promoted by probiotics. This collaboration helps maintain microbial balance, preventing dysbiosis and associated adverse conditions*.

Table 1: *Clinical trials that have used amylase for either treatment or prevention are detailed here. Source: clinicaltrials.gov*

Clinical trial ID	Health Condition	Status
NCT02475369	Celiac disease	*Terminated*
NCT05157867	• Irritable bowel syndrome • Non-coeliac wheat sensitivity	*Not yet recruiting*
NCT04873466	• Constipation • Methane Production • Quality of Life	*Completed*
NCT03667963	Carbohydrate intolerance	*Completed*
NCT04542473	Malnutrition	*Active, not recruiting*
NCT05211440	• Digestive health • Gastrointestinal health	*Completed*
NCT05392166	Diabetic children	*Recruiting*
NCT05520411	• Bloating • Stomach Distended	*Completed*
NCT03443180	Type1diabetes	*Completed*
NCT03467737	Malnutrition, child	*Completed*
NCT02127021	Pancreaticoduodenectomy	*Completed*
NCT02733848	Hypoglycemia	*Terminated*
NCT04420676	Covid	*Active, not recruiting*

4.6. Improved Intestinal Barrier:

Amylase's role in disrupting biofilms can contribute to the maintenance of the intestinal barrier. By preventing the formation of thick polymicrobial biofilms, the combination of amylase and probiotics protects the integrity of the gut lining*.

4.7. Gastrointestinal Symptom Relief:

The probiotic & amylase blend holds promise in alleviating mild to moderate gastrointestinal symptoms. This combined formulation is envisioned to address common discomfort linked to the gastrointestinal tract, providing relief for individuals experiencing such issues*.

4.8. Potential for Mental Well-Being:

Through the gut-brain axis, amylase and probiotics may positively influence mental well-being*.

It's important to note that while these findings are promising, individual responses to probiotics can vary. Also, Different strains have unique attributes, and combining specific strains at effective doses is necessary to optimize health benefits for the host. Consulting with healthcare professionals before introducing new supplements, especially for individuals with chronic health issues, is advisable.

5. Biosafety Profile of *amylase*

The key aspect of the biosafety profile of amylase lies in its origin. Amylase can be derived from different sources, including bacteria, fungi, and plants. The production method and source organism are critical factors influencing the safety of amylase. Microbial-derived amylases, particularly those produced by well-characterized and non-pathogenic strains, are generally considered safe. However, potential allergens or toxins associated with certain microbial strains must be thoroughly evaluated (Ladics & Sewalt, 2018).

Another important consideration is the purification process of amylase. Purification methods, such as chromatography and filtration, are employed to isolate amylase from the production medium. It is crucial to ensure that these processes effectively remove any contaminants, which could pose safety concerns if present in the final product (de Souza & e Magalhães, 2010).

The next aspect involves assessing the potential for allergenicity. Amylase proteins can induce allergic reactions in sensitive individuals (Morren et al., 1993). Therefore, it is necessary to conduct thorough allergenicity studies to identify potential allergenic components within the amylase and evaluate their impact on human health.

Alpha amylase is considered safe to be used in Food applications according to FDA (Sewalt et al., 2018). However, it is not currently approved for any drug applications. More research is needed to determine the safety and efficacy of amylase for therapeutic use.

Furthermore, the assessment of amylase's stability and activity under various environmental conditions is vital for determining its safety in practical applications. This includes studying the enzyme's behavior in different pH ranges, temperature conditions, and the presence of other chemicals commonly encountered in industrial processes*.

Overall, amylase is a safe and well-tolerated enzyme when used in food and industrial applications (Soni et al., 2020). However, there are some potential biosafety concerns associated with its use as a drug. More research is needed to determine the safety and efficacy of amylase for therapeutic use.

6. Microbial Targets of Amylase

While it is not traditionally recognized as an antimicrobial agent, some studies suggest that amylase may have an impact on microbial biofilms, which are structured communities of microorganisms. Here is the list of some microbial targets of amylase enzyme (Lahiri, Nag, Banerjee, et al., 2021b; Lahiri, Nag, Sarkar, et al., 2021 c):

- ***Staphylococcus aureus:*** *Staphylococcus aureus*, a bacterium often linked to skin infections, has the ability to form biofilms, which can pose difficulties in treatment.
- ***Escherichia coli (E. coli):*** This intestinal bacterium causes gastrointestinal illnesses. In some situations, *E. coli* biofilms might be harmful.
- ***Pseudomonas aeruginosa:*** This opportunistic bacterium forms strong biofilms and infects immunocompromised and cystic fibrosis patients.
- ***Candida albicans:*** A yeast species, Candida albicans, can form biofilms on

mucosal surfaces and medical devices, contributing to fungal infections.

- ***Streptococcus mutans:*** *Streptococcus mutans*, which causes dental caries, develops biofilms on teeth that cause plaque.

7. Significance of *amylase* in CanXida Restore Formula

The inclusion of amylase in the CanXida Restore formula can significantly contribute to digestive health and overall well-being. Amylase plays a crucial role in breaking down carbohydrates, which can enhance digestion in the small intestine, leading to improved nutrient absorption. This enzymatic activity, combined with probiotics in the formula, may synergistically modulates digestive efficiency and support the development of a balanced gut microbiota*.

The breakdown products of carbohydrates, such as short-chain oligosaccharides, may act as prebiotics in the CanXida Restore formula, nurturing beneficial gut bacteria. This dual action of amylase and probiotics can contribute to maintaining a balanced gut microbiota, crucial for digestive health and immune function*.

Individuals using the CanXida Restore formula may experience relief from symptoms associated with carbohydrate intolerance or gut dysbiosis, such as bloating, gas, and abdominal discomfort. The formula, with its combination of amylase and probiotics, can potentially promote optimal digestion, fostering a healthier gut environment*.

This anti-inflammatory action may further contribute to overall gut health and well-being. Additionally, amylase's potential to disrupt harmful biofilms in the formula can help maintain the integrity of the intestinal barrier, guarding against the entry of harmful pathogens and toxins. Furthermore, the antimicrobial activity of enzyme amylase in a CanXida restore formula may also disrupt Candida albicans biofilms, aiding in the prevention and management of infections, hence it can work parallel with the main role CanXida restore formula*.

While the CanXida Restore formula can offer various digestive and gut health benefits, individual responses to supplements can vary. The multifaceted functional properties of amylase in the CanXida Restore formula

underscore its potential in promoting digestive health and overall well-being*.

** 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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