

adiDAO[®]

DIAMINE OXIDASE (DAO) enzyme Protein extract from pig kidneys



DAO enzyme is a paradigm shift. A new therapeutic approach for many chronic pathologies associated with DAO deficiency and Histamine intolerance.

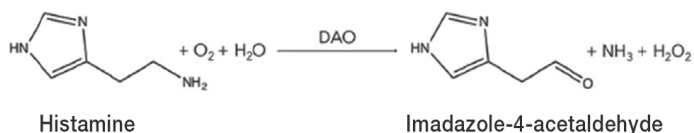
DAO deficiency is a metabolic disorder that affects 16% of global population and is involved as cause of a large variety of symptoms.

Our product offers clinically tested outstanding efficacy to tackle different symptoms associated with DAO deficiency.

As a result of the improvement in the enzyme's processes of extraction and purification a more active DAO with higher degrading capacity is obtained.

Introduction

DAO is a flavoprotein/enzyme that catalyses the aerobic oxidation of amines, mainly histamine, to the corresponding aldehyde and ammonia. Diamine Oxidase is synthesized mainly in the cells of the intestinal mucus.



The main barrier against histamine in the intestine is the DAO enzyme. This enzyme inhibits the transepithelial permeability of exogenous histamine, which prevents its passage into the systemic circulation.

Enzymatic Activity

The DAO enzyme contained in the Active Ingredient presents an enzymatic activity of **more than 298 mU/g DAO (>14.500 kHDU/g DAO)**.

The unit of measure mU means the DAO activity able to degrade 1 nmol of histamine per minute. Contrary to Histamine Degrading Units (HDU), mU is the unit of the International System of Units.

The equivalence between mU and HDU is the following:

$$\text{mU} = \frac{\text{HDU}}{48.501,82}$$

In finished products the DAO activity is **around 0,61 mU/dose (30.000 HDU/dose)**, and it may vary depending on the finished pharmaceutical form.

Composition

The active dietary ingredient of protein extract from pig kidneys is the DAO enzyme, an homodimer consisting of 2 equal subunits with a molecular weight of 87 kDa each. Each subunit contains a pyridoxal phosphate molecule and a copper atom.

- **Systematic name:** Diamine Oxidase (DAO)
- **CAS-N°:** 9001-53-0
- **EC Number:** 1.4.3.22
- **Molecular weight:** 170 kDa
- **Locus:** 7q36.1 (AOC1 gene)

Possible Applications

- Migraine and other types of headaches.
- Attention-Deficit/Hyperactivity Disorder (ADHD).
- Digestive disorders.
- Atopic dermatitis.
- Fibromyalgia and generalized muscular pain.
- Others.

Regulatory Categories

Dietary Ingredient:

- Novel Food according to EU Regulation 2018/1023.
- GRAS (Generally Recognized as Safe) according to US-FDA regulation 21 CFR 170.30 (a) and 21 CFR 170.30 (b).

Possible finished product categories:

- European Union: Food for Special Medical Purposes (FSMP) or Food Supplement.
- United States: Food Supplement or Medical Foods.

Possible Finished Forms

- Tablets with gastro-resistant coating.
- Capsules containing mini-tablets with gastro-resistant coating.
- Powder in gastro-resistant capsules.
- Microcapsules with gastro-resistant coating for functional foods.
- Topical compositions.
- Mini capsules with gastro-resistant coating.
- Food matrices and/or functional foods.

ACTIVE DIETARY INGREDIENT TECHNICAL CHARACTERISTICS

Parameters		Specifications
Physical analysis	Organoleptic characteristics	Pig kidney protein extract with natural content of Diamine Oxidase (DAO). Colour: brownish.
Physiochemical analysis	Density	0,3 - 0,4 g/cm ³
	Granulometry	< 1 mm
	Physical state	20°C: Solid powder. 100°C: Solid powder
	pH	6,4 - 6,8
	Solubility	In water (20°C): Partially soluble In main organic solvents: Does not dissolve
Chemical analysis	Enzymatic activity	>298 mU/g DAO >14.500 KHDU/g DAO
Microbiological analysis	<i>Brachyspira spp</i>	Negative (Real time PCR)
	<i>Listeria monocytogenes</i>	Negative (Real time PCR)
	Staphylococcus aureus	<100 CFU/g
	Influenza A	Negative (Real time PCR)
	<i>Escherichia coli</i>	<10 CFU/g
	TAMC	<10 ⁵ CFU/g
	TYMC	<10 ⁵ CFU/g
	Salmonella spp	Absence in 10g
	Bile salt resistant Enterobacteriaceae	<10 ⁴ CFU/g
Allergens		Free allergen product conforms to the Regulation (EU) no. 1169/2011. Lactose, histamine and gluten free.
Shelf life		24 months from manufacturing date.
Storage		Refrigerated (2-8°C). Avoiding temperatures over 40°C while handling and transportation.

LOGISTICAL INFORMATION

Thermal box (36 cm diameter x 43 cm height drum) containing 4 kg of Active Dietary Ingredient in 4 food-contact polyethylene bags of 1 kg each. An alternative delivery package can be assessed according to specific requirements.

Recommended Transportation: air shipment with refrigerated temperature (2-8°C). Avoiding temperatures over 40°C while handling and transportation.

DR Healthcare is a leading biomedical company in research, development, innovation and manufacturing of nutraceutical products aimed at the dietary management of DAO deficiency and its associated pathologies.

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