

CARNAUBA WAX Pellets

*/STARTER CORE PELLETS,
HYDROPHOBIC CORE/*

What is Carnauba wax?

Carnauba Wax is obtained from the leaves of Carnauba palm, formally named *Copernicaprunicifera*, which grows only in the northeastern regions of Brazil.

The color and quality of the wax are governed by the age of leaves and care used in processing.

The leaves are harvested, dried, boiled in water and the wax that floats to the top is skimmed and filtered.



Carnaúba Trees

What is composition of Carnauba wax?

Predominantly esters such as fatty acids(80-85%), fatty alcohols(10-15%), acids(3-6%), hydrocarbons(1-3%). Specific for carnauba wax is the content of esterified fatty diols (about 20%), hydroxylated fatty acids(about 6%), and cinnamic acid(about 10%)

What is Carnauba wax used for?

Carnauba wax is used for a wide array of products mostly falling into the categories of: **cosmetics, food products and polishes, pharmaceutical industry for tablet coatings and binding**

Some of the products are: Candies/sweets, fruit coating, medicine/capsules, cosmetics, toner, skin care, hair care

■ The safety of Carnauba wax

- √ **Generally Recognized As Safe (GRAS)**, according to FDA regulation at 21 CFR 184.1978
- √ **CODEX Alimentarius Commission/** Guidelines for the Production, Processing, etc.
- √ **European Economic Community (EEC) Council Regulation, EC No. 834/2007 and 889/2008/**Carnauba wax is allowed as releasing agent
- √ **USP-NF, Ph. Eur/** Carnauba wax is registered as pharmaceutical.

What are the advantages of using Carnauba Wax Pellets ?

- √ Sometimes called the “Queen of Wax”
 - : has much harder melting point(80-88°C) than other wax, and it has stability for high temperature.
- √ It is also not readily soluble.
- √ It can make something waterproof and wear resistant
- √ It can be used to create an enduring colored polish.
- √ **Carnauba wax pellets as hydrophobic core for controlled release pellet formulations**

In some formulations a hydrophobic core is needed to achieve the desired dissolution profile. Carnauba wax pellets do not require an additional water impermeable layer between the core and drug-containing layer to achieve a sigmoidal or zero-order release profile.

■ SPECIFICATION for Carnauba wax pellets (USP/NF, Ph. Eur.)

ITEM	METHOD	STANDARD
APPEARANCE	PH. EUR.	Light yellow pellet
SOLUBILITY	PH. EUR.	Insoluble in water, partially soluble in boiling alcohol, soluble in chloroform and ether - Mesh size: NLT85% described on the label
PARTICAL SIZE DISTRIBUTION	SIEVE ANALYSIS	#18/20 (850-1000 μ m) #25/35 (500-700 μ m) #35/60 (250-500 μ m) #60/80 (150-250 μ m)
MELTING RANGE	PH. EUR.	80-88 $^{\circ}$ C
RELATIVE DENSITY	PH. EUR.	About 0.97
IDENTIFICATION	PH. EUR.	Pass TLC Test
APPEARANCE OF SOLUTION	PH. EUR.	Clear and not more intensely colored than 0.05g/L solution of potassium dichromate
SULPHATED ASH	PH. EUR.	NMT 0.25%
TOTAL ASH	PH. EUR.	NMT 0.25%
ACID VALUE	PH. EUR.	2-7
ESTER VALUE	PH. EUR.	71-88
SAPONIFICATION VALUE	PH. EUR.	78-95
UNSAAPONIFIABLE MATTER	PH. EUR.	50-55%
HEAVY METALS(AS PB)	AAS	NMT 20mg/kg
ARSENIC	AAS	NMT 3mg/kg
LEAD	AAS	NMT 5mg/kg
MERCURY	AAS	NMT 1mg/kg
ORAGNIC VOLATILE IMPURITIES	PH. EUR.	MEET THE REQUIREMENT