

CUTINA[®] HR PH**Further Product Name**

Ph. Eur.: "Castor Oil hydrogenated"

BP: "Castor Oil hydrogenated"

NF: "Hydrogenated castor oil"

JP: "Hydrogenated oil"

General Characterization

CUTINA[®] HR PH is a white to slightly yellowish, fine, free-flowing powder. The product is used as retardation component and pressing agent for the preparation of tablets for pharmaceutical application.

Chemical description

Hardened castor oil

Characteristic Values

The specifications stated below finally and conclusively describe the properties of the product.

Quality control data

Data which is used for quality release and is specified for each batch.

Melting point	83 - 88°C	Ph. Eur. 2.2.14
Acid value	max 4.0	Ph. Eur. 2.5.1
Hydroxyl value	145 - 165	Ph. Eur. 2.5.3 method A
Iodine value	max 5.0	Ph. Eur. 2.5.4
Alkaline impurities	max 0.20 mL	Ph. Eur. 1497
Composition of fatty acids		
Palmitic acid	max 2.0 %	Ph. Eur. 2.4.22 method A
Stearic acid	7.0 - 14.0 %	Ph. Eur. 2.4.22 method A
Arachidic acid	max 1.0 %	Ph. Eur. 2.4.22 method A
12-Oxostearic acid	max 5.0 %	Ph. Eur. 2.4.22 method A
12-Hydroxystearic acid	78.0 - 91.0 %	Ph. Eur. 2.4.22 method A
Other fatty acids	max 3.0 %	Ph. Eur. 2.4.22 method A
Nickel	max 1 ppm	Ph. Eur. 2.4.31
Melting range	85.0 - 88.0°C	USP/NF <741> class II
Heavy metals	max 0.001 %	USP/NF <231> method II
Free fatty acids	max 11.0 mL	USP/NF <401>
Hydroxyl value	154 - 162	USP/NF <401>
Iodine value	max 5.0	USP/NF <401>
Saponification value	176 - 182	USP/NF <401>
Acid value	max 2.0	JP
Moisture	conforms	JP
Color visual	conforms	JP
Alkalinity	conforms	JP
Chloride	conforms	JP
Heavy metals	conforms	JP
Residue on ignition	max 0.10 %	JP
Nickel	conforms	JP
Pesticide residues	conforms	Ph. Eur. 2.8.13 table 1
Microbiological status	conforms	Ph. Eur. 5.1.4 category 2 & 3a
Aflatoxines	conforms	Federal Health Gazette Ban V 2000
Heavy metals	conforms	Federal Health Gazette 1985

Methods of identification

As described in the current Monograph of the Ph. Eur., USP/NF and/or JP.

Methods of analysis

All test and assay methods are as described in the current Monograph of the Ph. Eur., USP/NF and/or JP.

Storage, Packaging and Shelflife

Storage Conditions

In the original sealed containers CUTINA® HR PH can be stored for at least two years, protected from moisture at below 30°C.

Rev. 1.0

Labeling Information & Registrations

INCI name(s)

Hydrogenated Castor Oil

Officially listed in / Quality conforms to

Ph. Eur.	Conforms to the analytical specification of "Castor Oil hydrogenated"
BP	Conforms to the current analytical specification in the monograph "Castor Oil hydrogenated" (copy of the Ph. Eur. Monograph)
USP/NF	Conforms to the current analytical specification in the monograph Hydrogenated castor oil.
JP	Conforms to the current analytical specification in the monograph "Hydrogenated oil"
JCIC	Hydrogenated Castor Oil (Ingredient Code 102969)
US DMF no. (Typ IV)	#16502
CAS No.	8001-78-3
EINECS No.	232-292-2
Residual solvents	Conforms to current ICH Guideline (CPMP/ICH/283/95) & Residual solvents <467>
Minimising animal spongiform encephalopathy agents	Conforms to requirements Ph. Eur. 5.2.8

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Rev. 1.0