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C.F. e PARTITA IVA 00098610330
CAP. SOC. EURO 2.000.000 I.V.
R.I.PC 032-1483
R.D.PC 44507
MECC EXPORT PC002237

azienda chimica e farmaceutica

SPECIFICA TECNICA

Prodotto **IDROSSIPROPILMETILCELLULOSA PHARMA**

NOME INCI	HYDROXYPROPYL METHYLCELLULOSE
NOME INCI USA	Hydroxypropyl Methylcellulose
CAS	9004-65-3
EINECS / ELINCS	Polymer

SPECIFICA	METODO	Lim. Inf. - Lim. Sup.	u.m.
Identificazione IR	EP	conforme alla specifica	
Perdita all'essiccamento		0,00 - 5,00	%
Viscosità 2% soluzione, secco		2.700,0 - 5.040,0	mPa.s
Ceneri solforiche		0,00 - 1,50	%
pH		5,00 - 8,00	
Contenuto metossile		28,00 - 30,00	%
Contenuto di hydroxypropoxyl		7,0 - 12,0	%
Revisione Capitolato		1	
Data Approvazione		07/09/2016	

Gli eventuali metodi d'analisi non riportati sono metodi interni del produttore ottenibili su specifica richiesta

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cGMP Statement: Product manufactured to comply with USP-NF <1078> and The Joint IPEC-PQG Good Manufacturing Practices Guide for Pharmaceutical Excipients, 2006 as published under the auspices of the International Pharmaceutical Excipient Council (IPEC, 2006).
Food grades are manufactured to comply with 21 CFR, Sec. 110 [Current Good Manufacturing Practice in manufacturing, packing or holding human food].

European Commission Directive 2008/84/EC on Food Additives E Numbers: E464 Hydroxypropyl Methyl Cellulose

Joint FAO/WHO Expert Committee on Food Additives (JECFA) Numbers: INS 464 Hydroxypropyl Methyl Cellulose

Harmonized Tariff Codes (HTC): Hydroxypropyl Methyl Cellulose: 3912.39.0000

Origin Information: Hydroxypropyl Methyl Cellulose is a synthetic polymer derived from plant origin. It is derived from cellulose, the most abundant polymer in nature.
It is manufactured using highly purified cellulose pulp, which is made from softwood trees (such as pine). This cellulose is treated with synthetic chemicals to obtain the properties of the desired polymer.
This polymer is inert and highly purified with virtually no odor or color.
Description of Manufacture: Methylcellulose is a cellulose ether, produced by reacting alkali cellulose with methylchloride and/or propylene oxide (PO) under rigidly controlled conditions.
The structure of the cellulose molecule can be visualized as a polymer chain composed of repeating cellobiose units. These, in turn, are composed of two anhydroglucose units (â-glucopyranose residues).
Each anhydroglucose unit contains three hydroxyl groups. By substituting methoxyl and hydroxypropyl groups (straight chain) for some of the hydrogens of these hydroxyls, methylhydroxypropylcellulose (MHPC or HPMC) is obtained.
When only methoxyl groups are substituted, methylcellulose (MC) is obtained. By substituting methoxyl and hydroxyethyl groups (straight chain) for some of the hydrogens of these hydroxyls, methylhydroxyethylcellulose (MHEC) is obtained.
The hydroxyl groups substituted per anhydroglucose unit is known as the degree of substitution, or D.S. If all three hydroxyls are replaced, the maximum theoretical D.S. of 3.0 (impossible in practice) would result.
Substitution can also occur when ethylene oxide and propylene oxide reacting at previously substituted hydroxyls, can polymerize to form a side chain (branching). The average number of moles of substituents that become attached to each anhydroglucose unit in cellulose, in the two ways described, are called moles of substituent combined, or M.S. (Molecular Substitution).
Solubility in water is achieved as the degree of substitution is increased. By selecting appropriate reaction conditions and moles of substituent, complete and quick solubility in water is obtained. For the low viscous types we use hydrogen peroxide or acid to shorten the polymer chain in a specific reactor.

Residual Solvents: A residual solvents statement of compliance is contained in the Certificate of Analysis.

BSE/TSE Information: These are plant-based products, and neither uses nor has any reason to suspect that these products come into contact with or contain bovine, caprine or ovine-derived materials or chemicals in either the components or the process used for manufacture, nor do they come in contact with animal products during storage or shipment. As such, there is no concern about these products containing BSE (Bovine Spongiform Encephalopathy)/TSE (Transmissible Spongiform Encephalopathies) specified risk material as defined in the European Commission Decision 97/534/EC or EMEA/410/01.

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Allergens/Hypersensitivities: Manufacturer does not intentionally add any of the substances included below. Doel maintains dedicated manufacturing facilities for these products and neither uses, nor has any reason to suspect that these products (or any component of these products) come into contact with, the substances below. Also, manufacture, storage and distribution are performed in a highly controlled manner to avoid contact with any foreign substances including those listed below.
These products do not require labeling with reference to EU Directives 2003/15/EC (cosmetic directive) or 2003/89/EC (food directive).
These products meet the requirements of the U.S. Food and Drug Administration Food Allergen Labeling and Consumer Protection Act of 2004.

The list below is comprised from the EU Council Directive 2003/89/EC, 2006/142/EC and 2007/68/EC the US FDA Food Allergen Labeling and Consumer Protection Act of 2004, and other commonly requested allergens.
Antioxidants
Artificial color/flavor
Artificial sweeteners
Benzoic acid and products thereof
Bee pollen
Beef and beef derivatives
Butylated hydroxyanisole (BHA)
Carrots
Casein
Cereals containing gluten and products thereof
Chocolate/Chocolate Derivatives
Cinnamon
Cocoa and products thereof
Coconut
Coriander
Corn and products thereof
Crustaceans and products thereof (including shrimp)
Dyes or Azo colors including tartrazine
Eggs and products thereof
Environmental Hormones (including alkylphenol or derivatives)
FD&C Colors or dyes
Fish and products thereof
Fruits
Gluten
Grains (wheat, rye, oats, barley, spelt, malt or any derivative thereof)
Hydrolyzed Animal or Plant Protein
Iodine
Latex
Legumes (including soybeans and products thereof)
Lupine and products thereof
Milk and products thereof (including lactose)
Mollusks and products thereof (including snails, clams, octopus, squid, etc.)

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Monosodium Glutamate/Glutamates
Mustard and products thereof
Natural color/flavors
Nuts and products thereof
Peanuts and products thereof
Pork & pork derivatives
Preservatives (including benzoic acid salts and esters, sorbic acid salts and esters, sulfites)
Rice
Seeds and/or oils and products derived from (canola, poppy, safflower, sesame, sunflower, etc.)
Sodium (elemental)
Starch
Sugar (sucrose, maltose, dextrose, glucose, etc.)
Sulfur dioxide and sulfites @ concentrations >10 ppm as SO_2
Tertiary Butylhydroquinoe (TBHQ)
Tocopherols
Tree Nuts or Other Nuts and/or oils and products derived from (walnuts, cashews, almonds, pistachios, etc.)
Vanilline
Vegetables (including celery & Umbelliferae family)
Yeast (Autolyzed)/Yeast extract

EU Cosmetic Directive EC 2009, 76/768/EEC and Amendments and IFRA Fragrance Ingredients: These products do not contain the following chemicals listed in the Cosmetics Directive or the current IFRA Fragrance Ingredients list in either the raw materials, the manufacturing process or the finished product. These products do not come in contact with any of the listed chemicals during packaging or storage prior to delivery to the customer. None of these products require labeling with reference to these Directives. We do not test for these chemicals.
For a complete list of IFRA fragrance ingredients please refer to:
http://www.ifraorg.org/Home/Code,+Standards+Compliance/IFRA+Standards/page.aspx/56.
Alpha-Isomethyl Ionone
Amyl Cinnamal
Amylcinnamyl Alcohol
Anise alcohol
Benzyl Alcohol
BenzylBenzoate
Benzyl Cinnamate
Benzyl Salicylate
Butylphenyl Methylpropional
Cashmeran
Cinnamal
Cinnamyl Alcohol
Citral
Citronellol
Coumarin
Diethylphthalate
Dibutylphthalate
Dimethylphthalate
Diethylhexylphthalate
Other Phthalates
Eugenol

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Prodotto **IDROSSIPROPILMETILCELLULOSA PHARMA**

Evernia Prunastri (Oakmoss) Extract
Evernia Furfuracea (Treemoss) Extract
Farnesol
Furfural
Gamma Butyrlactone
Geraniol
Geranyl Nitrile
Glycol Ethers
Glyoxal
Hexyl Cinnamal
Hydroxycitronellal
Hydroxyisohexyl 3-Cyclohexene Carboxaldehyde
Isoeugenol
Limonene
Linalool
Methyl 2-Octynoate
Nitromusks
Polycyclic Musks
Natural Musk
Macrocyclic Musks
Camphor
Estragol
Eucalyptus Oil
Menthol
Methyleugenol
Methyl Octine Carbonate
Phenylacetaldehyde
Rose Crystals
Safrol
Tagetes Extracts & Oils
Thyme Oil
Total Aldehydes
Peru Balm & Derivatives
BHA
BHT
NTA
EDTA
Napthalene

Other Chemicals: manufacturer does not use nor has any reason to suspect that these products contain the following chemicals either in the raw materials, the manufacturing process or finished product.
Further, these products do not come in contact with these chemicals during packaging or storage prior to delivery to the customer.
3-MCPD (ref. European Council Directive 446/2001/EC)
Absorbable organic halogens (AOX)
Acetonitrile
Acrylamide
Aflatoxins

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Alkyl phenol ethoxylates
Amines or their derivatives, including nitrosamines
Asbestos
Benz[a]pyrene
Benzoates or Benzoin
Boron or borates
Castor Oil
Colophony
Coniferyl Alcohol
Cyanuric acid
Diacetyl
Diethylene Glycol
Di(2-ethylhexyl) phthalate (DEHP, CAS# 117-81-7)
Dimethylfumarate
Dioxins
Formaldehyde (ref. EU ComDec 2001/59/EC)
Glycerin
Lanolin
Palm Oil
Propionic acid
Preservatives
Salicylic acid
Silanes
Talc
Tributyltin
Vegetable oil
Bisphenol A diglycidyl ether (BADGE) (ref. European Council Directive 2001/61/EC)
Bisphenol F diglycidyl ether (BFDGE) (ref. European Council Directive 2001/61/EC)
NOvolac glycidyl ether (NOGE) (ref. European Council Directive 2001/61/EC)
Bromodiphenylethers (ref. EU Dangerous Substances Directive 76/769/EEC, Directive 2003/11/EC and EU Water Policy Directive Decision 2455/2001))
Methansulfonic acid and derivatives thereof (such as benezenesulfonic acid esters, tosilates, di-isetonates and methansulfonyl chloride) and other sulfonic acids
Nitrofen (2,4-dichloro-1-(4-nitrophenoxy)benzene, CAS# 1826-75-5)
Thiuram Mix (tetra methyl thiuram monosulfide, tetra methyl thiuram disulfide, tetra ethyl thiuram monosulfide (=disulfiram), dipenta methylene thiuram disulfide)
GMO Information: The starting material is wood pulp. Our suppliers have informed us that the pulp is not sourced from genetically modified organisms. Further, genetically modified organisms are not used to manufacture our MC/HPMC/MHEC products. Therefore, these products are considered not genetically modified and not derived from a genetically modified organism as defined by the EC regulations 1830/2003/EC on labeling and traceability and 1829/2003/EC on genetically modified food and feed and any amending legislation.

Irradiation: Manufacturer does not irradiate these products and none of the raw materials used in the production of these products have been irradiated.

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Prodotto **IDROSSIPROPILMETILCELLULOSA PHARMA**

Metal Catalysts and Reagents: Metals in pharmaceutical substances, which include excipients, and drug products are classified in EU Directive EMEA/CHMP/SWP/4446/2000, Guideline on the Specification Limits for Residues of Metal Catalysts or Metal Reagents, effective September 1, 2008, with the exposure limits for oral exposure listed below.

Class	Metals	Exposure Limits, ppm
1A	Pt, Pd	< 10
1B	Ir, Rh, Ru, Os	< 10 total
1C	Mo, Ni, Cr, V	< 25
2	Cu, Mn	< 250
3	Zn, Fe	< 1300

Melamine : These products do not contain melamine in the raw materials or the finished product nor do they come in contact with melamine during packaging or storage prior to delivery to the customer.
Cellulose derivatives are not at risk components in FDA's August 2009 Guidance for Industry Pharmaceutical Components at Risk for Melamine Contamination.
Therefore, no melamine control program is required and we do not test for melamine or report it on our COAs.
Raw materials are qualified through our supplier qualification program and none of the raw materials are considered at risk for melamine contamination.
These products have tamper-evident packaging and controls are in place throughout our supply chain to ensure traceability and prevent adulteration.

Aflatoxin: Aflatoxin is a mycotoxin produced by some strains of the fungus Aspergillus. Associated concerns relate to nuts, groundnuts, dried fruit and cereals. Manufacturer does not conduct testing for aflatoxins but we would not anticipate any mycotoxins to be present in these products based on the origin and nature of our processing.

Nanotechnology: These products are not manufactured using nanotechnology techniques and do not contain materials produced from nanotechnology.

Recommended Re-Evaluation Date, Storage & Handling: Our recommended testing protocol for methyl cellulose to insure the product we make or inventory meets the requirements of its type, is to retest every 2 years
Also, 12 month retests are recommended after the initial 24 month period. There is no expiration date for these materials, and they may be retested and requalified at the recommended interval indefinitely.
Methylcellulose does not have a shelf life in the sense that it loses it effectiveness or fitness-for-use. It has a retesting interval which is assigned to assure that the product can still satisfy the original viscosity specifications.

Deterioration Characteristics: Hydroxypropyl Methyl Cellulose is a hydrophilic polymer, therefore some moisture pick-up and/or viscosity loss of very high viscosity materials on long storage can be expected.