
	Product specifications	UPDATE # 5
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Supplier:	
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Manufacturing plant	
Address:	Fryčovice 297

Name:	Consolidae radix, MESH Comfrey root, finely ground
Country of origin:	CZ
Description (characteristics of the product):	The drug consists of fine powder of the brown-black root, xylem it is whitish
Composition:	Dried root of the genus <i>Symphytum officinale</i> L.
Net weight of the entire package:	15 kg
Type of packaging, packaging material:	Three-layer paper bag with cross bottom
Optimal storage conditions:	store in a dry place up to 25 °C max. air humidity 70%
Minimum shelf life:	36 months
Collection time:	September - October

Sensory requirements:	
Color:	black-brown above, whitish xylem
Taste and smell:	weak characteristic odor, slightly sweet and astringent

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Microbiological requirements: according to ŸL 2009, add. 2010 (for preparations that are poured with hot water)			
Monitored indicator External laboratory at random	Maximum required value	Frequency of monitoring	
			Internal laboratory
TAMC (Total Aerobic Bacterial Count)	max.107 CFU/g(ml)		
TYMC (Total Yeast and Mold Count)	max.105 CFU/g(ml)	at random	
Salmonella sp.	Neg. in 25 g	at random	
E.coli	max. 103 CFU/g(ml)	at random	


Physical and chemical quality requirements (German pharmacopoeia 1992)			
Monitored indicator:	Desired value	Frequency of monitoring	
		External laboratory	Internal laboratory
Swelling Index:	min. 8.0%	at random	
Ash:	max. 10.0%	at random	
Losses on drying	max. 12.0%	at random	
Ash insoluble in HCl:	max. 4.0%	at random	
Foreign impurities:	max. 2.0%	at random	

Ÿ the products meet the requirements of Act No. 110/1997 Coll. on food and tobacco products, as amended; Commission Regulation (EC) No. 1881/2006, consolidated version, setting maximum limits for certain contaminating substances in foodstuffs; Regulation (EC) No. 1334/2008 Coll., on flavorings and some food ingredients with aromatic properties for use in or on food; Decree No. 225/2008 Coll., which establishes requirements for dietary supplements and food fortification with food supplements.

Ÿ The products meet the requirements of Commission Regulation (EU) 2015/1933 amending Regulation 1881/2006 regarding the maximum limits of polycyclic aromatic hydrocarbons in cocoa fiber, banana chips, dietary supplements, dried herbs and dried spices; Regulation of the European Parliament and of the Council (EC) C.396/2005 on maximum limits for pesticide residues in food and feed of plant and animal origin and on their surface and amending Council Directive 91/414/EEC

GMO Statement
Neither the raw material nor its components contain genetically modified organisms.

Ionizing radiation treatment statement:
We declare that the above raw material is not treated with ionizing radiation.

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Information about the presence of allergens			
Allergenic ingredients:	Contains the product allergenic component	Allergenic ingredient	Possibility of cross contamination
Cereals containing gluten and their products (*) with the exception of glucose syrup and dextrose from wheat, wheat-based maltodextrins, glucose syrup made from barley starch and distillates made from cereals	No		No
Crustaceans and their products	No		No
Eggs and egg products	No		No
Fish and fish products	No		No
Groundnut kernels (peanuts) and products thereof	No		No
Soybeans (soy) and products thereof	No		No
Milk and milk products (including lactose)	No		No
Dried nuts and their products (**)	No		No
Celery and its products with the exception of leaf oil a celery seed and celery oleoresin	No		No
Mustard and products thereof except mustard oil and essential oil and mustard seed oleoresin	No		No
Sesame seeds and their products	No		No
Sulfur dioxide and sulphites in concentrations higher than 10mg/l, expressed as SO ₂	No		No
Lupine and its products	No		No
Molluscs and their products	No		No

* cereals containing gluten - wheat, rye, barley, spelled wheat, oats, kamut or their hybrids varieties

** dry nuts - almonds, hazelnuts, walnuts, cashews, pecans, brazil nuts, pistachios, macadamia nuts and Queensland nuts

*** an allergenic component that could inadvertently get into the product from another manufactured product due to cross contamination

SPECIFICATION APPROVAL:

We declare that the information given in the technical specification of the product is true (corresponds to reality) and that the product meets the requirements of applicable legislation.