

POŽADAVKY NA KVALITU PEPSINU**Specifikace požadovaného pepsinu:**

Parameter	Specification	Results
Appearance: Identification: Sieve test (<i>according to current Ph. Eur. 2.9.12</i>) Bulk density: Solubility: Appearance of Solution: pH (1% Aqua): Loss on drying::	White or slightly yellow, crystalline or amorphous, hygroscopic powder * NIR or "Haemoglobin-digestive characteristic" Min. 95% passes a sieve opening of 180 µm. 0.5-0.7 kg/Litre Very slightly soluble in water; insoluble in organic solvent Slightly opalescent with a weak acidic reaction 3.0-5.0. < 5% NIR or "at 60 °C, 4 h and 670 Pa"	
Specific activity:	Pepsin >1:10000 NF	
Added excipient:	Maltodextrin Ph. Eur./USP (GMO-free)	
Microbiological quality according to current European Pharmacopoeia (5.1.4, 2.6.12 & 2.6.13)		
Total aerobic microbial count (TAMC): Total combined yeast / moulds count (TYMC) Bile-tolerant gram-negative bacteria Escherichia coli: Staphylococcus aureus: Salmonellae:	<10 ⁴ /g <10 ² /g <10 ² /g absent/g absent/g absent/10 g	
Informative parameters have been confirmed by manufacturer of starting materials or by random analysis.		
Heavy metals (according to ICH Q3D, No 7 Option 1, calculated assuming a daily intake of the product of 10 g)	Class 1: Lead < 0.5 ppm, Cadmium < 0.5 ppm, Mercury < 3 ppm, Arsenic < 1.5 ppm (AAS) Class 2A: Cobalt < 5 ppm, Nickel < 20 ppm, Vanadium < 10 ppm (ICP-MS)	
Residual solvents according to current Ph. Eur. (2.4.24 & 5.4)	No solvents from group 1 & 2 and from group 3 Acetone not more than 5000 ppm.	
BSE/TSE (current Ph. Eur.; Chapter 5.2.8)	Pepsin complies with the Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products. Pepsin <u>is not manufactured</u> from a raw material with TSE/BSE-Risk and <u>doesn't contain</u> compounds manufactured from a raw material with TSE/BSE-Risk.	
GMO-free (according to 2003/1830/EU and 2003/1829/EU.)	Pepsin <u>has not been manufactured</u> from a raw material of genetically modified origin and <u>does not contain</u> compounds manufactured from other GMO products and their Derivatives.	

*, with none affecting transparency of the liquid. Without none artificially odor.

Specifikace testované analýzy k ověření kvality pepsinu:

Pepsin (1:10 000 NF, a.u.v.; odpovídá 2000 Ph.Eur.j./g) pro diagnostiku trichinelózy trávicí metodou s použitím magnetické míchačky 10.403. bude otestován dle postupu laboratoře:

A) podle metodického návodu SVSČR 2000 ze dne 28. 12. 2000;

B) podle ÚVEU ze dne 10. srpna 2015 podle Nařízení Komise ES č. 2015/1375) vyšetření svaloviny zvířat na přítomnost larev *Trichinella* spp.