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| Terhormon SpA | Product Specification PANCREATIN EP/USP | |
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| Pancreatin Specification | | HIGH LIPASE | 10x | 9x | 8 x | 7 x | 6x | 5 x | 4 x | 3 x |
|--|----------|---|-----|-----|------|------|------|------|------|------|
| Ph. Eur. U./mg | Lipase | ≥ 65 | 55 | 50 | 45 | 39 | 34 | 28 | 22.5 | 17 |
| | Amylase | 54 | 50 | 48 | 42 | 37 | 32 | 26 | 21 | 15 |
| | Protease | > 3.5 | 3.8 | 3.4 | 3.0 | 2.6 | 2.3 | 1.9 | 1.5 | 1.1 |
| USP U./mg | Lipase | ≥ 45 | 40 | 37 | 33.0 | 28.6 | 24.9 | 20.5 | 16.8 | 12.4 |
| | Amylase | 275 | 250 | 225 | 200 | 175 | 150 | 125 | 100 | 75 |
| | Protease | 225 | 250 | 225 | 200 | 175 | 150 | 125 | 100 | 75 |
| Appearance | | slightly brown, amorphous powder/granules | | | | | | | | |
| Identification | | according to current European Pharmacopoeia | | | | | | | | |
| Loss on drying | | ≤ 5,0 % | | | | | | | | |
| Fat content | | ≤ 5,0 % | | | | | | | | |
| Total aerobic microbial count (TAMC) | | ≤10 ⁴ Cfu/g | | | | | | | | |
| Total yeast/moulds count (TYMC) | | ≤10 ² Cfu/g | | | | | | | | |
| <i>Escherichia coli</i> | | absent/1g | | | | | | | | |
| <i>Salmonella</i> | | absent/10 g | | | | | | | | |
| Residual solvent | | according to CPMP/ICH/283/95. ICH Topic Q3C (R4) - Impurities: Guideline for <i>Residual Solvents</i> . | | | | | | | | |
| Particle size | | from 20 to 80 mesh | | | | | | | | |
| Customized qualities are available upon request | | | | | | | | | | |

Authorized excipients: Saccharose (3% maize starch), Lactose

BSE/TSE: Pancreatin complies with the Guidance on Minimizing the Risk of Transmitting Animal Spongiform Encephalopathy Agents via Human and Veterinary Medicinal Products (EMA/410/01-Rev.1) in line with 2001/82/EC and 2001/83/EC (Ph. Eur. 5.2.8.). Pancreatin is manufactured using pork pancreas glands without BSE/TSE.

GMO: Pancreatin has not been manufactured from a raw material of genetically modified origin. It's GMO free.

Storage conditions: Store in airtight container closure.

Expiry date: 30 months