

**Ludiflash®**

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Test parameter	Requirement	Method
<b>Characters</b>		
Appearance	White to slightly yellowish powder	Visual
<b>Identification</b>		
Identity (IR) <sup>1)</sup>	Must comply	PM 0511 <sup>1)</sup>
<b>Tests</b>		
Water (Karl-Fischer)	Max. 4.0 g/ 100 g	PM 1076
Residual solvents <sup>2)</sup> (class 3: total Acetate, HPLC)	Max. 5000 ppm	PM 1093
<b>Assay</b>		
Polyvinyl Acetate (calc. from saponification value)	3.5 - 6.0 g/ 100g	PM 1087
Povidone (K 30, photometric)	0.25 – 0.60 g/100g	PM 1075
Crospovidone (K CL-SF, gravimetric)	4.0 - 6.0 g/100g	PM 1090
D-Mannitol (HPLC)	84.0 - 92.0 g/100g	PM 1089
Heavy metals	Max.10 mg/kg	Ph. Eur. 2.4.8 (Method C)
<b>Other tests</b>		
Microbiological enumeration test		Ph. Eur. 2.6.12
Total aerobic microbial count (TAMC)	Max. 10 <sup>2</sup> CFU/g	
Total combined yeasts and moulds count (TYMC)	Max. 10 CFU/g	

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Test for specified microorganisms		Ph. Eur. 2.6.13
Escherichia coli	Absent/g	
Pseudomonas aeruginosa	Absent/g	
Staphylococcus aureus	Absent/g	
Bile-tolerant gram-negative bacteria	Max. 10 CFU/g	
Salmonella	Absent/10 g	

<sup>1)</sup> May also be determined by other means / methods (General Notices Ph. Eur./USP)

<sup>2)</sup> No other organic solvents are likely to be present. The requirements of ICH Q3C, Ph. Eur. 5.4 and USP <467> are met.

Ludiflash® meets the requirements of this specification.

The aforementioned data shall constitute the agreed contractual quality of the product at the time of passing of risk. The data are controlled at regular intervals as part of our quality assurance program. SELLER MAKES NO WARRANTY OF ANY KIND, EITHER EXPRESS OR IMPLIED, BY FACT OR LAW, INCLUDING WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE.

The statements under the heading "Characters" are not to be interpreted in a strict sense and are not requirements.