

Ludipress®

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TEST PARAMETER	REQUIREMENTS	METHOD
Characters		
Appearance	White, free-flowing powder	visual
Tests		
Lactose monohydrate (polarimetric)	Min. 91.1 g/100 g Max. 94.9 g/100 g	PM 0370
povidone (Kollidon® 30, soluble) (photometric)	Min. 3.0 g/100 g Max. 4.0 g/100 g	PM 0103
crospovidone (Kollidon® CL, insoluble) (gravimetric)	Min. 3.0 g/100 g Max. 4.0 g/100 g	PM 0113
Heavy metals	Max. 10 mg/kg	PM 160
Water (Karl-Fischer titration)	Max. 6.0 g/100 g	PM 0138

Ludipress® meets the requirements of this specification.

The Lactose monohydrate used for the production of the different Ludipress grades corresponds to the current monograph "Lactose monohydrate" in Ph.Eur., USP/NF and to the current monograph "Lactose" in JP.

The Kollidon 30 used for the production of the different Ludipress grades fulfills the requirements of the Ph.Eur., USP and JP monographs "Povidone".

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The Kollidon CL used for the production of the different Ludipress grades corresponds to the requirements of the USP/NF and JPE monographs "Crospovidone" and it meets also the specifications of the Ph.Eur. monograph "Crospovidone".

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. Neither these data nor the properties of product specimens shall imply any legally binding guarantee of certain properties or of fitness for a specific purpose. No liability of ours can be derived therefrom. The statements under the heading "Characters" are not to be interpreted in a strict sense and are not requirements.

not for regulatory purposes