PHARMATRANS SANAQ AG

PHARMACEUTICALS

SPECIFICATION

PVP-P SANAQ®
(Ph. Eur, USP-NF)

Test	Specification	Test Method
Appearance	White powder	Ph. Eur, USP-NF
Solubility, practically insoluble in	Water, alcohol	Ph. Eur, USP-NF
Identification, A B C D	Positive	Ph. Eur, USP-NF
pH (in 1% suspension)	5.0 – 8.0	Ph. Eur, USP-NF
Peroxides, as H202	≤ 400 ppm	Ph. Eur, USP-NF
Water-soluble substances	≤ 1.0 %	Ph. Eur, USP-NF
Impurity A, (1-Vinylpyrrolidin-2-one)	≤ 10 ppm	Ph. Eur, USP-NF
Heavy metals	≤ 10 ppm	Ph. Eur, USP-NF
Loss on drying	≤ 5. %	Ph. Eur, USP-NF
Sulphated ash	≤ 0.1 %	Ph. Eur, USP-NF
Assay, as Nitrogen content	11.0 – 12.8 %	Ph. Eur, USP-NF
Residual solvents	complies	Ph. Eur, USP-NF
Microbiological status	complies	Ph. Eur, USP-NF
Particle size (average)	100 micron	Ph. Eur, USP-NF

CONFORM
Ph. Eur, USP-NF

PHARMATRANS SANAQ AG

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