PHARMATRANS SANAQ AG

PHARMACEUTICALS

SPECIFICATIONS

IBUPROFEN DC-100

Ibuprofen granulated

(Ph. EUR)

Appearance	White or nearly white particles		visual
Solublity	Practically insoluble in water, freely soluble in acetone, in methanol and in methylene chloride; it dissolves in dilute solutions of alkali hydroxides and carbonates		informative
Physical Parameters			
Particle size distribution	≥ 75 % 200 –500 µm		
Bulk Density	0.5 –0.7 g/ml (for information only)		Ph. EUR
Identification			
A Melting point	75 –78 °C		Ph. EUR
C Infrared Absorption	IR-spectrum equivalent reference standard		Ph. EUR
Chemical Parameters			
Appearance of solution	Clear and colorless		Ph. EUR
Optical rotation	- 0.05 to + 0.05 °		Ph. EUR
Related Substances	Specidied impurities *)	J, A, N ≤ 0.15 %	Ph. EUR
	Other detectable impurities	B, D, E, K, L, M ≤ 0.05 %	
	Unspecified impurities	≤ 0.05 % for all unidentified peaks	
	Total impurities	≤ 0.2 %(Peaks < 0.03 % are disregarded)	
Elemental Impurities	Fe ≤ 1300 ppm, Cr ≤ 25 ppm		Ph. EUR
Loss on drying	≤ 0.5 %		Ph. EUR
Sulphated ash	≤ 0.1%		Ph. EUR
Assay	98.5to 101.0%		Ph. EUR
Microbiological Parameters			
TAMC	< 1000 CFU/g		Ph. EUR
TYMC	< 100 CFU/g		Ph. EUR
E. coli	absence in 1 g sample		Ph. EUR

*) The starting materialIbuprofen Ph. Eur. for Ibuprofen DC100 doesnot contain the impurityF.

Organic solvents in accordance to Ph.Eur.,5.4 and USP <467> (CPMP/ICH/283/95) are not used neither by manufacturing of Ibuprofen DC100nor by cleaning of equipment.The starting material of Ibuprofen DC100 is exclusively ofsyntheticorigin. A contamination with animal material by manufacturing, storage or shipment in the original closedcontainerswill not occur. Therefore, Ibuprofen DC100 is free from BovineSpongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE). Ibuprofen DC100 complieswith the requirements of EMA/410/01 rev.3.

Ibuprofen DC-100 is a proprietary registered mark belong to third parties and not to Pharmatrans

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