

SPECIFICATION / Ibuprofen DC100

(Ibuprofen Ph.Eur., granulated)

	Specification	Test method
Description		
Appearance	White or nearly white particles	visual
Solubility	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	Ph. Eur.
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	Specified impurities *)	J, A, N ≤ 0.15 %
	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	98.5 to 101.0 %	Ph. Eur.
Microbiological Quality		
TAMC	≤ 10 ³ CFU/g	Ph. Eur.
TYMC	≤ 10 ² CFU/g	Ph. Eur.
E.coli	absence in 1 g sample	Ph. Eur.

*) The starting material Ibuprofen Ph. Eur. for Ibuprofen DC100 does not contain the impurity F.

Organic solvents in accordance to Ph. Eur., 5.4 and USP <467> (CPMP/ICH/283/95) are not used neither by manufacturing of Ibuprofen DC100 nor by cleaning of equipment.

The starting material of Ibuprofen DC100 is exclusively of synthetic origin. A contamination with animal material by manufacturing, storage or shipment in the original closed containers will not occur. Therefore, Ibuprofen DC100 is free from Bovine Spongiform Encephalopathy (BSE) and Transmissible Spongiform Encephalopathy (TSE). Ibuprofen DC100 complies with the requirements of EMA/410/01 rev.3.