

WRS
D6-8



medochemie ltd

CERTIFICATE OF ANALYSIS

Product: Diclofenac sodium (working Standard)

Standardization date: 04/2015

Batch No: Z56397

Expiry date: 04/2017

ANALYSIS PERFORMED		SPECIFICATIONS	RESULTS
Chemical and physical	Appearance	White or slightly yellowish, slightly hygroscopic, crystalline powder. (according EP current edition)	White slightly hygroscopic powder
	Solubility	Sparingly soluble in water, freely soluble in methanol, soluble in ethanol (96 %), slightly soluble in acetone. (according EP current edition)	Conforms
	Identification	(A) IR spectrum (B) Reaction of sodium (according EP current edition)	a. Conforms b. Conforms
	Appearance of solution	A. The solution is clear B. Absorbance at 440 nm: Not more than 0.05 (according EP current edition)	a. Conforms b. Conforms
	Related substances	Impurity A: Not more than 0.2 % Impurity F: Not more than 0.15 % Any unspecified impurity: Not more than 0.10 % Total impurities: Not more than 0.4 % (according EP current edition)	Under disregard limit Under disregard limit Under disregard limit Not detected
	Heavy metals	Not more than 10 ppm (according EP current edition)	Conforms
	Loss on drying	Not more than 0.5 % (according EP current edition)	0.35%
	Assay	99.0% to 101.0 % (dried substances) (according EP current edition)	100.0% As is 99.69%
Head of QC.: <i>JeV</i>		Anna Garczynska <i>[Signature]</i> Principal Chemist	