

CERTIFICATE OF ANALYSIS

Lot: 0080213

DICLOFENAC SODIUM Ph.Eur. (COS Grade)

Batch No.: RDGS-I/1212/0156A		Mfg. Date : Dec. 2012		Receipt Date : 23/12/2012	
Batch Size : 700.82 Kgs.		Exp. Date : Nov. 2017		Report No. : ARDS/12/311	
TEST		OBSERVATION		SPECIFICATION	
Appearance	Almost white crystalline powder, slightly hygroscopic	A white or slightly yellowish slightly hygroscopic, crystalline powder.		Sparingly soluble in water, freely soluble in methanol, soluble in ethanol 96%, slightly soluble in acetone.	
Solubility	Complies	It melts at about 280°C, with decomposition.		The infrared absorption spectrum of the sample must be concordant with that of Diclofenac sodium reference/working standard spectrum.	
(D) Reaction of sodium(b)	Conformed	Conformed		The solution is clear. Not more than 0.05	
Appearance of solution Ab.5% In MeOH/440nm/1cm	Complies 0.028	Unspecified Imp. Not more than 0.10 % Impurity-A Not more than 0.2 % Total impurities Not more than 0.5 %		Less than 10 ppm Not more than 10 ppm	
Heavy metals	Less than 10 ppm	Not more than 0.5 % (w/w)		Not more than 10 ppm	
Loss on drying (At 105°C for 3 hrs)	0.26 % (w/w)	Not less than 99.0 % and Not more than 101.0 % (w/w)		Not more than 1000 ppm Not more than 100 ppm	
Assay (Calculated on dried basis)	99.7 % (w/w)	Below Detection Limit		Below Detection Limit	
Additional In-House test	Below Detection Limit	Below Detection Limit		Below Detection Limit	
EDTA Content	Below Detection Limit	Below Detection Limit		Below Detection Limit	
Residual solvents	Below Detection Limit	Below Detection Limit		Below Detection Limit	
2-Propanol	Below Detection Limit	Below Detection Limit		Below Detection Limit	
Toluene	Below Detection Limit	Below Detection Limit		Below Detection Limit	
The Sample Complies as per Ph.Eur. & Additional In-House test.					
Prepared by : <i>[Signature]</i> Date : 01/02/13		Checked by : <i>[Signature]</i> Date : 01/02/13		Approved by : <i>[Signature]</i> Date : 01/02/13	
Incharge QC		Incharge QA		Date :	