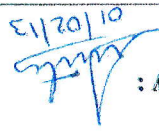
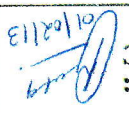
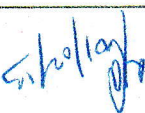


CERTIFICATE OF ANALYSIS

Lot: 0080213

DICLOFENAC SODIUM Ph.Eur. (COS Grade)

Batch No.: RDGS-I/12/2/0156A		Mfg. Date : Dec. 2012		Receipt Date : 23/12/2012		Batch Size : 700.82 Kgs.		TEST	
Appearance		Almost white crystalline powder, slightly hygroscopic		A white or slightly yellowish slightly hygroscopic, crystalline powder.		Solubility		Complies	
Identification		Conformed		The Infrared absorption spectrum of the sample must be concordant with that of Diclofenac sodium reference/working standard spectrum.		Solubility		Sparingly soluble in water, freely soluble in methanol, soluble in ethanol 96%, slightly soluble in acetone.	
(A) By IR spectrophotometer		Conformed		The Infrared absorption spectrum of the sample must be concordant with that of Diclofenac sodium reference/working standard spectrum.		Solubility		Sparingly soluble in water, freely soluble in methanol, soluble in ethanol 96%, slightly soluble in acetone.	
(D) Reaction of sodium(b)		Conformed		The solution is clear.		Solubility		Sparingly soluble in water, freely soluble in methanol, soluble in ethanol 96%, slightly soluble in acetone.	
Appearance of solution		Complies		The solution is clear.		Solubility		Sparingly soluble in water, freely soluble in methanol, soluble in ethanol 96%, slightly soluble in acetone.	
Ab.5% In MeOH/440nm/1cm		0.028		The solution is clear.		Solubility		Sparingly soluble in water, freely soluble in methanol, soluble in ethanol 96%, slightly soluble in acetone.	
Related substances		0.01 %		Unspecified Imp. Not more than 0.10 %		Solubility		Sparingly soluble in water, freely soluble in methanol, soluble in ethanol 96%, slightly soluble in acetone.	
(By HPLC)		0.01 %		Impurity-A Not more than 0.2 %		Solubility		Sparingly soluble in water, freely soluble in methanol, soluble in ethanol 96%, slightly soluble in acetone.	
Heavy metals		Less than 10 ppm		Total impurities Not more than 0.5 %		Solubility		Sparingly soluble in water, freely soluble in methanol, soluble in ethanol 96%, slightly soluble in acetone.	
Loss on drying		0.26 % (w/w)		Not more than 10 ppm		Solubility		Sparingly soluble in water, freely soluble in methanol, soluble in ethanol 96%, slightly soluble in acetone.	
(At 105°C for 3 hrs)		99.7 % (w/w)		Not less than 99.0 % and Not more than 101.0 % (w/w)		Solubility		Sparingly soluble in water, freely soluble in methanol, soluble in ethanol 96%, slightly soluble in acetone.	
Assay		99.7 % (w/w)		Not less than 99.0 % and Not more than 101.0 % (w/w)		Solubility		Sparingly soluble in water, freely soluble in methanol, soluble in ethanol 96%, slightly soluble in acetone.	
Additional In-House test		Below Detection Limit		Not more than 10 ppm		Solubility		Sparingly soluble in water, freely soluble in methanol, soluble in ethanol 96%, slightly soluble in acetone.	
EDTA Content		Below Detection Limit		Not more than 10 ppm		Solubility		Sparingly soluble in water, freely soluble in methanol, soluble in ethanol 96%, slightly soluble in acetone.	
Residual solvents		Below Detection Limit		Not more than 100 ppm		Solubility		Sparingly soluble in water, freely soluble in methanol, soluble in ethanol 96%, slightly soluble in acetone.	
2- Propanol		Below Detection Limit		Not more than 100 ppm		Solubility		Sparingly soluble in water, freely soluble in methanol, soluble in ethanol 96%, slightly soluble in acetone.	
Toluene		Below Detection Limit		Not more than 100 ppm		Solubility		Sparingly soluble in water, freely soluble in methanol, soluble in ethanol 96%, slightly soluble in acetone.	
The Sample Complies as per Ph.Eur. & Additional In-House test.		The Sample Complies as per Ph.Eur. & Additional In-House test.		The Sample Complies as per Ph.Eur. & Additional In-House test.		The Sample Complies as per Ph.Eur. & Additional In-House test.		The Sample Complies as per Ph.Eur. & Additional In-House test.	
Prepared by : 		Checked by : 		Approved by : 		Date : 01/02/13		Date : 01/02/13	
Date : 01/02/13		Incharge QC		Incharge QA		Date : 01/02/13		Date : 01/02/13	

