



**APEX
HEALTHCARE
LIMITED**

APEX HEALTHCARE LIMITED

Plot No.: 4710 - G.I.D.C., Ankleshwar-393 002, Gujarat. (India)

QUALITY CONTROL DEPARTMENT

CERTIFICATE OF ANALYSIS

WORKING STANDARD

Name of the Product: PIROXICAM IP/BP/USP							
Batch No.	: PRAH084031415	Sampling Date	: 10.11.2015	A.R. No.	: FPPRAH0841415		
Mfg. Date	: MAR. 2015	Quantity	: 1.0 g	A.R. Date	: 10.11.2015		
Exp. Date	: FEB. 2020	Drug L.C. No.	: G/25/1642 dt. 27.07.2012	Date of Analysis	: 10.11.2015		
TESTS		SPECIFICATIONS			Use before	10.11.2016	
Description	Off-white to light tan or light yellow powder, odorless.					RESULTS	
Solubility	White or slightly yellow, crystalline powder. Practically insoluble in water, in dilute acids, and in most organic solvent slightly soluble in alcohol and in aqueous alkaline solutions. / Practically insoluble in water, soluble in methylene chloride, slightly soluble in anhydrous ethanol. / Slightly soluble in water, in dilute acids and in most organic solvents.					Off-white to light tan or light yellow, odorless. White or slightly yellow, crystalline powder. Complies	USP/IP BP USP/BP/IP
Identification	A. To comply IR test. B. To comply light absorption test. C. To comply TLC test.					Complies Complies Complies	USP/BP/IP USP/IP USP/IP
Related Substances	Impurity A: Not more than 0.20% Impurity B: Not more than 0.20% Impurity D: Not more than 0.20% Impurity G: Not more than 0.20% Impurity J: Not more than 0.20% Unspecified Impurity: Not more than 0.10% Total Impurity: Not more than 0.40%					Not Detected 0.0592% Not Detected 0.0592% Not Detected 0.0774% 0.2031%	BP
Heavy Metals	Not more than 50 ppm/ Not more than 20 ppm					Complies	USP/BP/IP
Loss on Drying	Not more than 0.5% w/w					0.22% w/w	BP
Water	Not more than 0.5% w/w					0.20% w/w	USP/IP
Sulphated Ash	Not more than 0.3%					0.065% w/w	USP/IP/BP
Assay (By HPLC)	NLT 97.0% and NMT 103.0% of Piroxicam, on dried basis					98.90% w/w	USP/IP
Assay (By Titration)	NLT 98.5% and NMT 101.0% of Piroxicam, on dried basis					99.84% w/w	BP

The product Complies with respects to above tests and prescribed Standard Specification as per USP 36/ BP2013/ IP2010.

Assay on AS IS BASIS 99.62%

Analysed By: Arif
Date: 10.11.2015

Checked By: Rajendra
Date: 10.11.2015

Approved By: Arif





Name of the Product: PIROXICAM IP/BP/USP									
Batch No.	: PRAI084031415	Sampling Date	: 14.03.2015	A.R. No.	: IPPRA10841415	Date of Analysis	: 14.03.2015	Use before	: 14.03.2015
Mfg. Date	: MAR. 2015	Quantity	: 10 g.	A.R. Date	: 14.03.2015				
Exp. Date	: FEB. 2020	Drug LJC. No.	: G/25/1642 dt. 27.07.2012						
TESTS					SPECIFICATIONS				
Description		Off-white to light tan or light yellow powder, odourless.							
Solubility		White or slightly yellow, crystalline powder. Practically insoluble in water, in dilute acids, and in most organic solvent slightly soluble in alcohol and in aqueous alkaline solutions. / Practically insoluble in water, soluble in methylene chloride, slightly soluble in anhydrous ethanol. / Slightly soluble in ethanol and in aqueous alkaline solutions; very slightly soluble in water, in dilute acids and in most organic solvents.							
Identification		A. To comply IR test. B. To comply light absorption test. C. To comply TLC test.							
Related Substances		Impurity A: Not more than 0.20% Impurity B: Not more than 0.20% Impurity D: Not more than 0.20% Impurity G: Not more than 0.20% Impurity J: Not more than 0.20% Unspecified Impurity: Not more than 0.10% Total Impurity: Not more than 0.40%							
Heavy Metals		Not more than 50 ppm/ Not more than 20 ppm							
Loss on Drying		Not more than 0.5% w/w							
Water		Not more than 0.5% w/w							
Sulphated Ash		Not more than 0.3% / Not more than 0.2%							
Assay (By HPLC)		NLT 97.0% and NMT 103.0% of Piroxicam, on dried basis							
Assay (By Titration)		NLT 98.5% and NMT 101.0% of Piroxicam, on dried basis							
Particle Size (Dry Method)		90 % less than 20 micron							
The product Complies with respects to above tests and prescribed Standard Specification as per USP 36/ BP2013/ IP2010.		Complies							
RESULTS		Off-white to light tan or light yellow; odourless.							
REFERENCE		USP/BP/IP							
		White or slightly yellow, crystalline powder.							
		Complies							
		USP/BP/IP							
		Complies							
		Not Detected							
		0.0592%							
		Not Detected							
		0.0592%							
		Not Detected							
		0.0774%							
		0.2031%							
		Complies							
		0.22% w/w							
		0.20% w/w							
		0.065% w/w							
		98.90% w/w							
		99.62% w/w							
		Complies							
		USP/BP/IP							
		BP							
		USP/IP							
		USP/IP/BP							
		USP/IP							
		BP							
		INH							

Analysed By:
Date: 14/03/2015

Checked By:
Date: 14/03/2015

Approved By:
Date: 14/03/2015