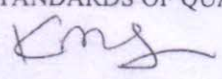


CERTIFICATE OF ANALYSIS**PRODUCT NAME : PREDNISOLONE ACETATE IP (MICRONISED & STERILE)**

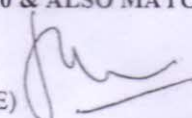
AR NO.	FP 0002	MFG.	APR - 2017	SAMPLING DATE	04 / 05 / 2017
BATCH NO.	PA/ 170401	EXP.	MAR - 2021	TESTING DATE	04 / 05 / 2017
RELEASE QTY.	31,800 GMS	SAMPLED BY	KSK	DATE OF RELEASE	04 / 05 / 2017

SR.	TESTS	RESULT	SPECIFICATION
1	DESCRIPTION	ALMOST WHITE, FINE CRYSTALLINE POWDER,	A WHITE OR ALMOST WHITE, FINE CRYSTALLINE POWDER
2	SOLUBILITY	COMPLIES	PRACTICALLY INSOLUBLE IN WATER, SLIGHTLY SOLUBLE IN ALCOHOL AND IN METHYLENE CHLORIDE.
3	IDENTIFICATION TESTS		
	A. IR SPECTRUM	COMPLIES	TO COMPLY WITH WORKING REFERENCE STANDARD
	B. THIN LAYER CHROMATOGRAPHY	COMPLIES	TO COMPLY AS PER IP 2010
	C. REACT WITH SULPHURIC ACID	COMPLIES	THE SOLUTIONS COLOR WILL BE GREENISH YELLOW IN ULTRA-VIOLET LIGHT AT 365 nm
	D. REACTION OF ACETYL	COMPLIES	TO COMPLY AS PER IP 2010
4	SPECIFIC OPTICAL ROTATION	+ 134.14°	BETWEEN +128° AND +137°
5	RELATED SUBSTANCE BY HPLC .	COMPLIES	IMPURITY A & B : NMT 1.0% w/w IMPURITY C : NMT 0.5% w/w ANY OTHER IMPURITY : NMT 0.1% w/w TOTAL IMPURITY : NMT 2.0% w/w
6	LOSS ON DRYING	0.21 %w/w	NMT 0.5 % w/w
7	ASSAY ON DRIED BASIS	99.58 %w/w	BETWEEN 97.0 AND 103.0 % w/w
ADDITIONAL TESTS			
1	COLOUR VALUE AT 420 nm (0.5% w/v SOLUTION IN METHANOL)	0.0018	LIMIT : NMT 0.05
2	% TRANSMITTANCE AT 650 nm	99.16 %w/w	LIMIT : NLT 97.0 % w/w
3	PARTICLE SIZE	COMPLIES	90% < 5 MICRONS 100% < 10 MICRONS
4	STERILITY	STERILE	MUST BE STERILE
5	MELTING RANGE	234°-236°C	IT MELTS AT ABOUT 230°C, WITH DECOMPOSITION.

CONCLUSION : THE ABOVE SAMPLE COMPLIES / DOES NOT COMPLY WITH THE PRESCRIBED STANDARDS OF QUALITY AS PER IP 2010 & ALSO MATCH WITH USP SPECIFICATIONS.ANALYSED BY: 

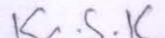
DESIGNATION : QC CHEMIST

DATE : 04 / 05 / 2017

CHECKED BY: 

(QC EXECUTIVE)

DATE : 04 / 05 / 2017

APPROVED BY: 

(QA HEAD)

DATE : 04 / 05 / 2017