

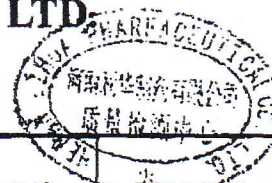
FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:

13G03-B09

Director Técnico

HENAN LIHUA PHARMACEUTICAL CO., LTD.

CERTIFICATE OF ANALYSIS



PRODUCT	PREDNISOLONE	DATE OF SAMPLING	FEB.2.2013
BATCH NUMBER	K04C20130203M	DATE OF RELEASE	FEB.4.2013
BATCH SIZE	64.10Kg	MANUFACTURING DATE: JAN.9.2013 RETEST DATE: DEC.2017	
CRITERIA: PH. EUR. PLUS ADDITIONAL REQUIREMENTS AS PER R1-CEP 2005-248-Rev 00			
NAME OF THE TEST	SPECIFICATION	RESULTS	
CHARACTERS	WHITE OR ALMOST WHITE CRYSTALLINE POWDER	QUALIFIED	
IDENTIFICATION	A:B	MEETS TEST	
SPECIFIC OPTICAL ROTATION	+113° ~ +119°	+117°	
RELATED SUBSTANCES	IMPURITY A(HYDROCORTISONE)≤1.0% IMPURITY B(PREDNISONE)≤0.30% IMPURITY C(PREDNISOLONE ACETATE)≤0.30% IMPURITY F(11-EPI-PREDNISOLONE)≤0.50% IMPURITY J(11-DEOXPREDNISOLONE)≤0.30% UNSPECIFIED IMPURITY≤0.10% TOTAL≤1.5%	IMPURITY A: 0.25% IMPURITY B: 0.08% IMPURITY C: <0.05% IMPURITY F: 0.41% IMPURITY J: <0.05% UNSPECIFIED IMPURITY: RRT(1.26)0.07% TOTAL: 0.81%	
LOSS ON DRYING	≤1.0%	0.2%	
ASSAY	96.5~102.0%	98.9%	
RESIDUAL SOLVENTS	METHANOL≤700PPM ACETONE≤200PPM	475PPM 52PPM	
PARTICLE DISTRIBUTION (In-house criteria)	80%≤15μm 98%≤30μm	90.1% 99.0%	
CONCLUSION: CONFORMS TO PH. EUR. PLUS ADDITIONAL REQUIREMENTS AS PER R1-CEP 2005-248-Rev 00			
STORAGE: STORE IN AN AIRTIGHT CONTAINER, PROTECTED FROM LIGHT			

CHECKER 刘爱利 2013.2.4

QC DIRECTOR 王A 2013.2.4

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