

PRODUCTO: DEXAMETASONA SODIO FOSFATO

ITEMS	SPECIFICATIONS (EP5.0)	SPECIFICATIONS (USP32)
APPEARANCE	A white or almost white powder	White or slightly yellow crystalline powder
IDENTIFICATION	B y C	A y B
SOLUTION S.	1.0g/ 20ml water	
APPEARANCE OF SOLUTION	Clear and not more intensely coloured than reference solution B ₇	
PH	7.5~9.5	7.5~10.5
OPTICAL ROTATION	+75° ~ +83°	+74° ~ +82°
RELATED SUBSTANCES ➤ Total impurities ➤ Any impurity	≤1.0% ≤0.5%	≤2.0% ≤1.0%
INORGANIC PHOSPHATES	≤1.0%	≤1.0%
LIMIT OF FREE DEXAMETHASONE		≤1.0%
ETHANOL	≤3.0%	≤8.0%
ETHANOL AND WATER	≤13.0%	≤16.0%
ASSAY	97.0%~103.0%	97.0%~102.0%
RESIDUAL SOLVENT a) Acetone b) Methanol	≤5000ppm ≤3000ppm	≤5000ppm ≤3000ppm