

CERTIFICATE OF ANALYSIS

PRODUCT NAME : SALBUTAMOL SULPHATE USP31

TESTS	RESULTS	SPECIFICATIONS
DESCRIPTION	ALMOST WHITE CRYSTALLINE POWDER	A WHITE OR ALMOST CRYSTALLINE POWDER.
SOLUBILITY	FREELY SOLUBLE IN WATER SLIGHTLY SOLUBLE IN CHLOROFORM AND ETHER	FREELY SOLUBLE IN WATER, SLIGHTLY SOLUBLE IN CHLOROFORM AND ETHER
IDENTIFICATION		
A.	COMPLIES	THE UV ABSORPTION SPECTRUM OF THE SAMPLE SHOWS AN ABSORPTION MAX. AT 276 IR (TO COMPLY WITH STD. SPECTRUM) CHROMOTOGRAM OBTAINED WITH TEST SOLUTION (B) IS SIMILAR IN POSITION COLOUR AND SIZE TO THE PRINCIPAL SPOT IN THE CHROMOTOGRAM OBTAINED WITH THE REFERENCE SOLUTION. AN ORANGE-RED COLOUR DEVELOPES IN METHYLENE CHLORIDE LAYER. IT GIVES REACTION (A) OF SULPHATES.
B.	COMPLIES	
C.	COMPLIES	
D.	COMPLIES	
E.	COMPLIES	
ACIDITY OR ALKALINITY	0.28 ML	NMT 0.4 ML OF 0.01 M HCL
CLARITY AND COLOUR OF THE SOLUTION	COMPLIES	1.0% SOLUTION IS NOT MORE INTENSELY COLOURED THAN REFERENCE SOLUTION BY 6
RELATED SUBSTANCE	COMPLIES	IN THE CHROMOTOGRAM THE SECONDARY SPOT OBTAINED WITH THE TEST SOLUTION IS NMT 0.5%
BORON CONTENT	COMPLIES	NMT 50 PPM
L.O.D.	0.26%	NMT 0.5% W/W
SULPHATED ASH	0.039%	NMT 0.1% W/W
ASSAY	99.7%	NLT 98.0% AND NMT 101.0% ON ANHYDROUS BASIS AS (C ₂₆ H ₄₄ H ₂ O ₁₀ S CALCULATED WITH REFERENCE TO THE DRIED SUBSTANCE)