

Savan Group

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TYPICAL ANALYSIS / SPECIFICATION

PRODUCT : FENOTEROL HYDROBROMIDE Ph. Eur.
SHELF LIFE : THREE YEARS SUBJECT TO CORRECT STORAGE

Test	Result	Specifications
Description	Corresponds	Corresponding
Solubility	Corresponds	Corresponding
Identification IR Test of bromide	Corresponds Positive	Corresponding Positive
Acidity	4.5	4.2 to 5.2
Appearance of solution Clarity Colour	Clear Corresponds	Clear Not more intensely coloured than reference solution Y7
Phenone (absorbance at 330nm)	0.02 (0.01%)	NMT 0.42 (0.2%)
Dioastereoisomers	1.9%	NMT 4.0%
Iron	Less than 5 ppm	NMT 5 ppm
Heavy metals	Less than 10 ppm	NMT 10 ppm
Loss on drying	0.1%	NMT 0.5%
Sulphated ash	Less than 0.1%	NMT 0.1%
Assay	99.5%	99.0% to 101.0%

ADDITIONAL TESTS

Residual solvents (HS-GLC)

Methylene chloride	463 ppm	NMT 600 ppm
Acetone	Less than 18 ppm	NMT 1000 ppm
Methanol	742 ppm	NMT 1000 ppm