

Savan Group

PO Box 2061 Steyning Sussex BN5 0AQ UK

Tel: +44 1903 815702

Fax: +44 1903 815759



TYPICAL ANALYSIS / SPECIFICATION

PRODUCT : DEXAMETHASONE SODIUM PHOSPHATE
SHELF LIFE : THREE YEARS SUBJECT TO CORRECT STORAGE

Test	Specification	Result
Description	White or almost white crystalline powder	Conforms
Identification	A) Complies by TLC B) Positive reaction	Conforms Conforms
pH	7.5 – 10.5	8.2
Specific rotation	+74° to +82°	+79.0°
Phosphate ions	<1.0%	Conforms
Chromatographic purity	Principal impurity <1.0% Total impurities <2.0%	0.27% 0.65%
Limit of free dexamethasone	< 1.0%	0.06%
Ethanol	<5000ppm	349ppm
Ethanol and water	<16.0%	5.1%
Assay	97.0 – 102.0%	100%

Conclusion – It conforms to USP28