

**CERTIFICATE of ANALYSIS****HYDROCORTISONE USP37, MICRONIZED****BATCH N.:** B0721/1 14020**MAN. DATE:** Sep/14**RE-TEST DATE:** Sep/19**DESCRIPTION:** White or almost white, crystalline powder. Practically insoluble in water; sparingly soluble in alcohol; very slightly soluble in ether.

TEST	SPECIFICATIONS	RESULTS
1. Appearance	White or almost white crystalline powder	Complies
2. Identification	IR UV	Concordant
3. Specific optical rotation	According to reference standard Absorptivity difference $\leq 2.5\%$ (242 nm) $+ 150^\circ$ to $+ 156^\circ$ (c=1, Dioxan, 25 °C)	1.8 % $+ 151^\circ$
4. Loss on drying	$\leq 1.0\%$	0.0 %
5. Residue on ignition	$\leq 0.5\%$	$< 0.5\%$
6. Chromatographic purity HPLC	Individual $\leq 0.5\%$ Total $\leq 2.0\%$	0.41 % 0.85 %
7. Residual solvents	Meet the requirements	Complies
8. Assay HPLC (dried basis)	97.0 - 102.0 %	98.7 %
9. Particle size	90 % $\leq 25\ \mu\text{m}$	17 μm

10/03/15
Quality Assurance Department