

**INTENDED USE:** A NSAID to reduce fever & relieve mild to moderate pain from conditions such as muscle aches, toothaches, common cold, & headaches

**PACKAGING:** Customized based on customer request

\*According to USP 38 (20-60 mesh) | \*DMF Active | \*More grades available

ITEM	SPECIFICATION
[CHARACTER]	Appearance: White crystals, commonly tabular or needle-like, or white crystalline powder
[IDENTIFICATION]	A. A ferric acid reaction test: Complies B. IR Spectrum: Complies
[TEST]	Loss on drying: $\leq 0.5\%$ Readily Carbonizable substances $\leq$ Matching Fluid Q Residue on ignition: $\leq 0.05\%$ Substances Insoluble in Sodium Carbonate TS: Clear Chloride (%): $\leq 0.014\%$ Sulfate (%): $\leq 0.04\%$ Heavy Metals (%): $\leq 0.001\%$ Limit of free Salicylic Acid: $\leq 0.1\%$
[ASSAY]	Contains 99.5 %-100.5 %, calculated on dried basis
[PARTICLE SIZE]	$\geq 84.0\%$ on 60 mesh

**Contact the Fine Chemicals Department**201.242.5104 | [finechem@mitsubishiingredients.com](mailto:finechem@mitsubishiingredients.com)**Customer Service**800.628.3092 | [info@mifiusa.com](mailto:info@mifiusa.com)

**Disclaimer:** The Food & Drug Administration has not evaluated any of the statements enclosed. These products are not intended to diagnose, treat, cure or prevent any disease. Also, this product list is for use only by the intended customer and contains information that may be privileged or confidential. Any use of this product list without the Fine Chemicals Department's express written consent is prohibited.

# HYDROCORTISONE

# OTC PRODUCTS

**INTENDED USE:** Topical, Ophthalmic, & Oral to treat inflammation of the skin

**PACKAGING:** Customized based on customer request

\*According to USP 38 | \*DMF Active | \*Particle size distribution based on customer requirements

ITEM	SPECIFICATION
[CHARACTER]	Appearance: White to almost white crystalline powder
[IDENTIFICATION]	A. IR. The IR spectrum of the sample should conform to that of the reference standard B. Ultraviolet absorption: $\Delta E/E \leq 2.5\%$
[TEST]	Specific Optical rotation: $+150^\circ \sim +156^\circ$ Loss on drying: $\leq 1.0\%$   Residue on ignition: $\leq 0.5\%$ Related substances: Individual impurity $\leq 0.5\%$   Total impurities $\leq 2.0\%$ Residual solvents: Methanol $\leq 3000\text{ppm}$   Cyclohexane $\leq 3880\text{ppm}$
[ASSAY]	Contains 97.0% -102.0% of C <sub>21</sub> H <sub>30</sub> O <sub>5</sub> , calculated on dried basis

# IBUPROFEN

**INTENDED USE:** A NSAID to reduce fever & treat pain or inflammation caused by many conditions such as headache, toothache, back pain, arthritis, menstrual cramps, or minor injury

**PACKAGING:** Customized based on customer request

\*According to USP 39/BP2016 | \*DMF Active

ITEM	SPECIFICATION
[CHARACTER]	Appearance: White or almost white crystalline powder, or colorless crystals having a slight characteristic color
[IDENTIFICATION]	A. Melting Point: 75-78° C B. Infrared Absorption (IR): Conforms to reference spectrum
[TEST]	Ibuprofen related compound C: $\leq 1\%$ Appearance of Solution: Clear and colorless Angle of Optical Rotation: $-0.05^\circ \sim +0.05^\circ$ Heavy Metals: $\leq 0.001\%$ Related substance [Ignore ( $< 0.03$ )]: Impurity A $\leq 0.15\%$ Impurity J: $\leq 0.15\%$   Impurity N: $\leq 0.15\%$   Impurity F: $\leq 0.1\%$ Another Largest single impurity: $\leq 0.05\%$ Total Impurities: $\leq 0.2\%$   Loss on Drying: $\leq 0.5\%$ Residual solvents: Ethanol $\leq 5000\text{ppm}$   Dichloromethane $\leq 600\text{ppm}$ Sulphated Ash: $\leq 0.1\%$
[ASSAY]	Contains 97.0%-103.0%, calculated on dried basis