



山东新华制药股份有限公司
SHANDONG XINHUA PHARMACEUTICAL CO., LTD.
No.1 Lutai Road, High-tech District, Zibo, Shandong, P.R.China

Feb.19,2022

Specification

Product name : caffeine

Standard: BP/EP/USP

Shelf life: 4 years

Storage condition: PRESERVE IN WELL-CLOSED CONTAINERS

Items	Specification	Test method
Appearance	White crystalline powder	EP
Identification: IR HPLC	Complies	USP
Melting point (°C)	234-239	EP
Appearance of solution	Clear and colorless	EP
Acidity	Conform	EP
Chromatographic purity: Single impurity (%) Total impurities (%)	≤0.10 ≤0.1	USP
Sulphate (ppm)	≤500	EP
Heavy metals (on Pb basis, %)	≤0.001	USP
Loss on drying (%)	≤0.5	EP
Residue on ignition (%)	≤0.1	USP
Sulphate Ash (%)	≤0.1	EP
Assay (%) (on dried basis)	98.5-101.5	EP
Residual solvents (Chloroform, ppm)	≤60	USP
HPLC assay (%) (on dried basis)	98.5-101.0% usp	USP



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Suzhou-Chem, Inc.

396 Washington Street, Suite 318

Wellesley, MA 02481

781-433-8618

info@suzhouchem.com