

Qualitative Evaluation for the Establishment of Chinese Medicine Reference Standard – Berberine Chloride

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ABSTRACT

The raw material of berberine chloride was examined prior to the preparation of the “Berberine Chloride Reference Standard”. The physico-chemical properties of the candidate material were evaluated by a collaborative study from seven laboratories. Analytical data obtained were summarized as follows: the UV maximum absorption wavelength and the corresponding specific absorbance were 227.8, 263.0, 344.6, 421.2 nm and 821.8, 796.7, 724.5, 154.8, respectively. IR Spectra showed IR absorption at 2846, 1634, 1567 and 1506 cm^{-1} . HPLC analysis revealed 3-8 impurities where individual amount was $\leq 0.41\%$ and the total amount from any single laboratory was $\leq 0.52\%$.

Base on the above results, the candidate material met the requirement of authorization as the Berberine Chloride Reference Standard.

Key words: berberine chloride, Chinese medicine reference standard, collaborative study

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