

Pyridoxine Hydrochloride

Specification and Tests

1. **Appearance:** white or almost white powder
2. **Solution 5% in water:** clear and colourless
A solution 5% in water complies with the test described in the monograph of Ph.Eur.
3. **pH of this solution:** 2.4 - 3.0
Dissolve 1 g in 20 ml of distilled water and measure the pH value potentiometrically.
4. **Identity:** corresponds
Infrared absorption spectrum:
The absorption maxima in the spectrum obtained with the substance (in KBr discs) correspond in position and relative intensity to those in the spectrum obtained with pyridoxine hydrochloride standard.
Reaction of chlorides:
see position 10.
5. **Loss on drying:** max. 0.5 %
Dry about 1 g (accurately weighed) at 105°C for 4 hours.
6. **Sulphated ash:** max. 0.1 %
Proceed according to the test described in the monograph of Ph. Eur.

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7. Heavy metals: **max. 20 ppm**
Proceed according to the test described in the monograph of Ph. Eur.
8. Lead: **max. 2 ppm**
Proceed according to the test described in the monograph of FCC.
9. Related substances: **passes test**
Proceed according to the liquid chromatographic method described in the monograph of Ph.Eur.
10. Chloride content: **16.9 - 17.6 % (on dry material)**
Proceed according to the test described in the monograph of USP.
11. Organic Volatile Impurities: **meets USP requirements**
Proceed according to the test described in the monograph of USP.
12. Assay: **99.0 - 100.5 % (on dry material)**
Proceed according to the "Assay" described in the monograph of Ph.Eur.

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