

## Folic acid

Meets USP-NF, EP, BP, JP and IP testing specifications

**Product Code: TC123M**

### Product Description :

Molecular weight : 441.40

Molecular formula:  $C_{19}H_{19}N_7O_6$

CAS No.: 59-30-3

### Quality Control

#### Appearance (USP)

Yellow, yellow-brownish, or yellowish-orange crystalline powder

#### Appearance (EP, BP)

Yellowish or orange, crystalline powder

#### Appearance (JP)

Yellow to orange-yellow crystalline powder

#### Appearance (IP)

A yellow or yellowish-orange, crystalline powder

#### Solubility (USP)

It readily dissolves in dilute solutions of alkali hydroxides and carbonates. Soluble in hot 3N hydrochloric acid, in hot 2N sulfuric acid, in hydrochloric acid, and in sulfuric acid, yielding very pale yellow solution, Very slightly soluble in water. Insoluble in alcohol, in acetone, in chloroform, and in ether

#### Solubility (EP, BP)

Practically insoluble in water and in most organic solvents. It dissolves in dilute acids and in alkaline solutions.

#### Solubility (JP)

It is practically insoluble in water, in methanol, in ethanol (95%), in pyridine and in diethyl ether. It dissolves in hydrochloric acid, in sulfuric acid, in dilute sodium hydroxide TS and in a solution of sodium carbonate decahydrate (1 in 100), and these solutions are yellow in colour.

#### Solubility (IP)

Soluble in dilute acids and in alkaline solutions; very slightly soluble in boiling water, practically insoluble in cold water and in most organic solvents

#### Identification A : UV (USP)

2.80 - 3.00 (A<sub>256</sub>/A<sub>365</sub>)

#### Identification A : specific rotation (EP, BP)

+18.00° to +22.00° (c = 1% w/v solution in 0.1M sodium hydroxide at 20 ± 0.5°C, anhydrous substance)

#### Identification A, UV : (IP)

0.001% w/v solution in 0.1M NaOH when examined in the range of 230 - 380 nm it shows three absorption maxima at

about 256nm, 283nm, 365nm and absorances are 0.59, 0.575, 0.206 respectively

#### Identification 1 : UV (JP)

Both spectra exhibit similar intensities of absorption at the same wavelengths

#### Identification B: FTIR (EP, BP)

Matches with the standard pattern

#### Identification B : TLC (IP)

The principal spot in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with the reference solution

#### Identification 2 (JP)

A blue fluorescence is produced (Under ultraviolet light at 365 nm)

#### Identification C : TLC (EP, BP)

The principal spot in the chromatogram obtained with the test solution is similar in position, fluorescence and size to the principal spot in the chromatogram obtained with the reference solution

#### Identification D : Water (USP)

5.00 - 8.50%

#### Colour and clarity of solution (JP)

1% solution in dilute NaOH is clear and yellow in colour

#### Related substances, HPLC 1: System suitability :

##### Resolution (EP, BP)

>= 2.00 (between the peaks due to folic acid and folic acid impurity E)

##### Related substances, HPLC 2: Impurity A (EP, BP)

<= 0.50%

##### Related substances, HPLC 3: Impurity D (EP, BP)

<= 0.40%

##### Related substances, HPLC 4: Impurity C,E,G : for each impurity (EP, BP)

<= 0.3%

##### Related substances, HPLC 5: Impurity H,I : for each impurity (EP, BP)

<= 0.15%

**Related substances, HPLC 6: unspecified impurity (EP, BP)**

<= 0.10%

**Related substances, HPLC 7: Total impurities (EP, BP)**

<= 1.20%

**Related compound, HPLC : (USP)**

<= 2.00%

**Specific rotation (EP, BP)**

+18.00° to +22.00° (c = 1% w/v solution in 0.1M sodium hydroxide at 20 ± 0.5°C, anhydrous substance)

**Specific rotation (IP)**

+18.00° to +22.00° (c = 1% w/v solution in 0.1M sodium hydroxide at 25°C)

**Free amines : UV (JP)**

<= 1.0%

**Related substances 1: System suitability, HPLC : Resolution (IP)**

>= 4.00 (between the peaks due to folic acid and folic acid impurity D)

**Related substances 2: Impurity A, HPLC (IP)**

<= 0.50%

**Related substances 3: Impurity D, HPLC (IP)**

<= 0.60%

**Related substances 4: Any other impurity , HPLC (IP)**

<= 0.50%

**Related substances 5: Total of other impurities, HPLC (IP)**

<= 1.00%

**Residue on ignition (USP)**

<= 0.3%

**Residue on ignition (JP)**

<= 0.5%

**Sulphated ash (EP, BP)**

<= 0.2%

**Sulphated ash (IP)**

<= 0.50%

**Water (K.F.) (USP, JP)**

<= 8.5%

**Water (K.F.) (EP, BP, IP)**

5.0 - 8.5%

**Assay, system suitability, HPLC : Resolution (USP)**

>= 3.60 (between the peaks methylparaben and folic acid

**Assay, system suitability, HPLC : Relative standard deviation (USP)**

<= 2.00% , for the ratios of the folic acid peak area to the internal standard peak area

**Assay (HPLC, anhydrous basis) (USP)**

97.00 - 102.00%

**Assay (HPLC, anhydrous basis) (EP, BP)**

96.00 - 102.00%

**Assay (UV, anhydrous basis) (JP)**

98.00 - 102.00%

**Assay (HPLC, anhydrous basis) : (IP)**

95.00 - 102.00%

**Storage and Shelf Life:**

Store at 2 - 8°C, away from bright light.

Shelf life is 36 months.

Use before expiry date given on the product label.

**Disclaimer :**

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