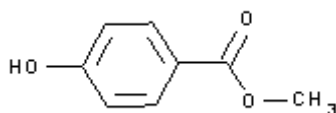


**PRODUCT CODE: 143332****Methyl 4-Hydroxybenzoate (USP-NF, BP, Ph. Eur., JP) pure, pharma grade**

 $C_8H_8O_3$ 

M.= 152,15

CAS [99-76-3]

EINECS 202-785-7

TARIC 2918 29 00 90

SYNONYMS: 4-Hydroxybenzoic Acid Methyl Ester, Methyl Paraben, Methyl p-Hydroxybenzoate**PHYSICAL DATA:** crystalline powder, White, in water at 20°C M.P.: 131 °C • B.P.: 270 °C • pH5,8 •**BIBLIOGRAPHY:** Merck Index **12**, 6.182 13, 6.129 Sax **HJL500** • Safety **2** , **1908 D** • Beilstein **10** , **158 IV** , **360** • BRN 509801 • BP.**2018** • USP -**NF 36** • Ph. Eur. **8.0** (2014) **9.0** (2017) • F.C.C **10 11** • Royal Decree **I1422** • BOE **24227980(9-10-82)****171984(20-01-1998)****243(8-10-2009)** • Regulation (EU) n° 231/2012 •**HAZARDOUS:** RTECS: DH 2450000 • LD50 oral rbt 6.000 mg/kg • LD50 ipr mus 960 mg/kg**SPECIFICATIONS:**

| | |
|---------------------------------------|-------------|
| Assay (Acidim.) | 99,0-100,5% |
| Identity : | |
| Identity according to Pharmacopoeias: | passes test |
| A 1% , 1 cm, λ258 nm | 1040-1120 |
| Melting range | 125-128°C |
| T.L.C. | passes test |

Maximum limit of impurities

| | |
|--|-------------|
| Appearance and colour of solution | passes test |
| Acidity | passes test |
| Insoluble matter in C ₂ H ₅ OH 96% | passes test |
| Residue on ignition (as SO ₄) | 0,1 % |
| Residual solvents (Ph.Eur/USP) | passes test |
| Related substances: | |
| Impurity A (4-Hidroxibenzoic Acid) | 0,5 % |
| Unspecified impurities | 0,5 % |
| Total impurities | 1,0 % |
| Elemental impurities (ICH Q3D): | |
| Class 1 | |
| Cd | 0,5 ppm |
| Pb | 0,5 ppm |
| As | 1,5 ppm |
| Hg | 5 ppm |
| Class 2A | |
| Co | 5 ppm |
| V | 10 ppm |
| Ni | 20 ppm |
| Class 2B | |
| Tl | 0,8 ppm |
| Au | 10 ppm |
| Pd | 10 ppm |
| Ir | 10 ppm |
| Os | 10 ppm |
| Rh | 10 ppm |
| Ru | 10 ppm |
| Se | 15 ppm |
| Ag | 15 ppm |
| Pt | 10 ppm |
| Class 3 | |
| Li | 55 ppm |
| Sb | 120 ppm |
| Ba | 140 ppm |
| Mo | 25 ppm |
| Cu | 250 ppm |
| Sn | 600 ppm |
| Cr | 25 ppm |