International Journal of Scientific & Engineering Research, Volume 5, Issue 10, October-2014
ISSN 2229-5518

High-performance liquid chromatography method for the analysis of sodium benzoate

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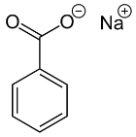
Abstract: Sodium Benzoate use as preservative in pharmaceutical and food industry. Only titrimetric methods are available in pharmacopeias for the determination of sodium benzoate assay. Chromatography & stability indicating method is not available for the determination of sodium benzoate assay. Rapid economical, reproducible and simple direct method was developed and validated for determination of sodium benzoate using high performance liquid chromatography (HPLC). Sodium Benzoate concentration estimated with isocratic elution using a mixture of buffer and methanol and water (60: 40 v/v) within 10 min, Flow rate 1.00ml, and wavelength 254nm and column C18. This method was suitable and validated for specificity, linearity, precision, accurate and ruggedness. The proposed method was successfully applied in the determinate of raw material assay for sodium benzoate.

Index Terms— Accurate & stability indicating chromatography method for Sodium Benzoate.

1. INTRODUCTION:



Sodium benzoate has the chemical formula NaC7H5O2; it is a widely used food preservative, with E number E211. It is the sodium salt of benzoic acid and exists in this form when dissolved in water. It can be produced by reacting sodium hydroxide with benzoic acid. Benzoic acid occurs naturally at low levels in cranberries, prunes, greengage plums, cinnamon, ripe cloves, and apples Sodium benzoate is a preservative. It is bacteriostatic and fungistatic under acidic conditions. It is most widely used in acidic foods such as salad dressings (vinegar), carbonated drinks (carbonic acid), jams and fruit juices (citric acid), pickles (vinegar), and condiments. It is also used as a preservative in medicines and cosmetics.[1][2] Concentration as a preservative is limited by the FDA in the U.S. to 0.1% by weight.[3] Sodium benzoate is also allowed as an animal food additive at up to 0.1%, according to AFCO's official publication.[4]

Sodium benzoate is produced by the neutralization of benzoic acid with sodium hydroxide.[5] Sodium benzoate can also be prepared by adding benzoic acid to a hot concentrated solution of sodium carbonate until effervescence ceases. The solution is then evaporated, cooled and allowed to crystallize or evaporate to dryness, and then granulated

In the United States, sodium benzoate is designated as generally recognized as safe (GRAS) by Food and Drug Administration.[6] The International Programme on Chemical Safety found no adverse effects in humans at doses of 647–825 mg/kg of body weight per day.[7][8]. No chromatography method is available for determination assay of Sodium Benzoate in raw material. At present all pharmacopeia i.e., British Pharmacopeias[9] and Indian Pharmacopoeia[10] having potentiometric titrimetric methods.

2. EXPERIMENTAL:

2.1 Reagent Chemical & Instruments:

Methanol (HPLC grade), Potassium dihydrogen orthophosphate (AR grade), Triethyl amine (AR grade), Ortho phosphoric acid (AR grade), and deionized water was used to prepare solution.

HPC system consisting pump, UV detector, auto sampler software for the detection. Column used 250 x 4mm, RP 18, 10 microns. Chromatographic condition is as follows.

2.2 Chromatographic condition:

a) Flow rate : 1.0 ml /min.
b) Detection : 254 nm.
c) Application : 20 µl
d) Run Time : 10min,

2.3 Buffer :

Dissolve 6.8 gm potassium dihydrogen ortho phosphate in 1000 ml water, add 1 ml of Triethyl amine adjust the pH to 5.5 (± 0.1) with ortho phosphoric acid. Filter it through 0.45 micron Nylon membrane filter paper, degas it with ultrasonic bath for 5 to 10 minutes

2.4 Mobile phase:

Mix Buffer and methanol in ratio (60:40 v/v) degas it with ultrasonic bath for 5 to 10 minutes.

2.5 Standard Preparation:

Weigh accurately about 20 mg Sodium Benzoate Working standard and transfer it into a 200 ml volumetric flask, add 150 ml of mobile phase. Sonicate, Make up the volume with mobile phase.
Pipette out 25 ml of this solution to 100 ml volumetric flask and make up the volume with mobile phase.

2.6 Sample Preparation:

Weigh accurately about 20 mg Sodium Benzoate and transfer it into a 200 ml volumetric flask, add 150 ml of mobile phase Sonicate. Make up the volume with mobile phase.
Pipette out 25 ml of this solution to 100 ml volumetric flask and make up the volume with mobile phase.
Procedure for injection:
Separately inject 20 µl of blank, Standard preparation in five replicate and sample preparation in duplicate into the equilibrated chromatographic system and record the chromatograms and measure the response of the major peaks due to sodium benzoate.

2.7 System suitability:

Total Number of theoretical plates not less than 2000.
Tailing factor not more than 2.0.
Relative Standard Deviation of area for five injection of standard preparation is not more than 2.0 %.

3. METHOD VALIDATION [11][12][13]:

3.1 Precision:

The precision was tested with 5 repeated injection of Sodium Benzoate standard solution. The relative standard deviation (RSD) less than 2% and triplication sample preparation RSD less than 2.00%. The reproducibility of the chromatographic separation was very good as shown by the very narrow window of the retention time.

3.2 Specificity:

Initially blank sample without Sodium Benzoate inject. No peak observed in blank solution. Sodium Benzoate Standard Inject and peck was observed at 4.1 retention time (RT). No interference of any peck and pack purity is 100%.

3.3 Accuracy:

Accuracy tested and accuracy was observed about 99.00%.

3.4 Linearity:

Under the above-described optimum conditions, the calibration curve obtained with standard showed good linear relationship in the interval 20 ppm to 80 ppm. The correlation coefficient was observed 0.9999 coefficient factor.

3.5 Robustness:

Flow rate change:
Flow rate was change 0.8ml/min, 1.0ml/min, 1.2ml/min and check the effect on assay of Sodium benzoate. No variation was observed in assay due to this change.

Wavelength change:
Wave length was change 252nm, 254nm, 256nm check the effect on assay of propyl paraben. No variation was observed in assay due to change in wavelength.

Acid Degradation:
Force acid degradation was done with 0.1M HCL on Sodium Benzoate & find out degradation effect on assay. Method was workable in force degradation also. No effect was observed.

Base Degradation:
Force base degradation was done with 0.1M NAOH on Sodium Benzoate & find out degradation effect on assay. Method was workable in force degradation also. No effect was observed.

Oxidation Degradation:
Force oxidation degradation was done with H_2O_2 on Sodium Benzoate & find out degradation effect on assay. Method was workable in force degradation also. No effect was observed.

Stress condition:

Sodium Benzoate was kept under stress condition at 105°C for 24 Hr. & checks the assay. Material was not affected or no degradation was observed due to heat.

Sodium Benzoate was kept under UV light stress condition for 24 Hr. & checks the assay. No effect was observed due to this stress conditions on sodium benzoate or no degradation was observed due to UV exposure.

4. CONCLUSION:

This work presents a simple and validated HPLC method for the determination of sodium benzoate. The method was validated showing satisfactory data for all parameters tested. Thus, it offers advantages over other analytical methods due to its rapidity, simplicity and lower cost.

5. REFERENCE:

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