



**TABRIZ PHARMA**  
Tabriz Chemical and Pharmaceutical Ind.

Date:  
No:  
Comments:

## Quality Control Laboratory

### Certificate of Analysis

**Product: Saccharin Sodium USP41-BP2017(Fine)**

**Batch No.: f-SAS00-107**

**Quantity: 1000 kg**

**Packing: 25 kg**

**Ref:USP41-BP2017**

**Lab No.: QC658**

**Mfg. date: 21/12/00**

**Exp. date: 21/12/02**

| No. | Chemical Analysis                       | Specifications   | Results                   |
|-----|---|--|---------------------------|
| 01  | Characteristics                         | A white, crystalline powder                                | White, crystalline powder |
| 02  | Solubility                              | Freely soluble in water, sparingly soluble in ethanol 96 % | Conforms                  |
| 03  | Identification A,B,C,D,E                | According to BP&USP requirements                           | Passes the test           |
| 04  | Color of Solution                       | According to USP requirement                               | Conforms                  |
| 05  | Clarity of solution                     | According to BP& USP requirement                           | Conforms                  |
| 06  | Melting Point                           | 226-230 °C   | 227 °C                    |
| 07  | Acidity or Alkalinity                   | According to BP&USP requirements                           | Passes the test           |
| 08  | Readily carbonisable substances         | According to BP&USP requirements                           | Passes the test           |
| 09  | Water                                   | Max. 15 %  | 13.8%                     |
| 10  | Limit of <i>p</i> - Toluenesulphonamide | Max. 10 ppm  | < 10 ppm                  |
| 11  | Limit of <i>o</i> - Toluenesulphonamide | Max. 10 ppm  | < 10 ppm                  |
| 12  | Heavy metals                            | Max. 10 ppm  | < 10 ppm                  |
| 13  | Limit of Benzoate & Salicylate          | No precipitate or violet color appears                     | Passes the test           |
| 14  | Assay                                   | 99 – 101 %   | 99.9%                     |

**Additional test:**

01 Bulk Density 0.75 g/cm<sup>3</sup>

**Date of Sampling:22/12/00**

**Approved**

**Rejected**

**Date of Analysis:23/12/00**

**Analyst**

**Q.C.Manager**

**Authorized by:**

We hereby certify that this product has been prepared under GMP regulation and tested according & conform to the requirements of USP41- BP2017. The raw materials, manufacturing process and product do not contain any of the solvents listed in organic volatile impurities (USP<467>) and residual solvents BP<5.4>