

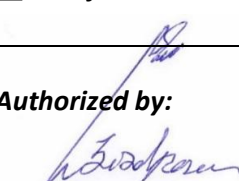




TABRIZ PHARMA
Tabriz Chemical and Pharmaceutical Ind.

Date:
No:
Comment:

Quality Control Laboratory

Certificate of Analysis			
Product: Saccharin Sodium USP39-BP2015			
Batch No.: g-SAS97-186			
Quantity: 1000 kg		Lab No.: QC667	
Packing: 25kg		Mfg. date: 18/11/97	
Ref:USP39-BP2015		Exp. date: 18/11/99	
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	227-229 °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 %	14.2 %
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 %	99.7 %
Additional test:			
01	Bulk Density	0.8 g/cm ³	
Date of Sampling:21/11/97			
		<input checked="" type="checkbox"/> Approved	<input type="checkbox"/> Rejected
Date of Analysis:23/11/97			
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 USP39- BP2015. 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>