



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

ANALYTICAL SPECIFICATION FOR SACCHARIN SODIUM IP

Manufacturer Name :		Supplier Name :
Manufacturer's Batch No. :		Manufacturer's Batch Size :
Manufacturing Date :		Expiry Date :
Quantity Received :		Test Quantity :
Document No. :	Effective Date :	Change Control No. : N/A
Control No./ A.R. No. :		Retest Date :

Reference: IP 1996 Page No. 668

Description: White, crystalline powder or colourless crystals; efflorescent in dry air, free from foreign particles.

Complies/Does Not Comply

Solubility: Freely soluble in Water (1 in 10), sparing soluble in Ethanol (95%) (1 in 30-100); practically insoluble in Ether(1 in More than 10,000).

Complies/Does Not Comply

SNo.	Test	Reference	Result	Specification	Remark
1.	Identification (A,E) or (B,C,D, E) A. IR B. Colour reaction	IP		Note : Routinely identification B,C,D,E followed. (A) IR absorption spectrum of test concordent with refrance spectrum of WRS B) A violet colour is produced	
1.	Identification (IP) (continued) C. Colour reaction D. Melting range F. Reaction of Sodium Salt	IP		C) A fluorescent green liquid is produced. D) Between 226° and 230°C.	



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SNo.	Test	Reference	Result	Specification	Remark
				F) A yellow crystalline precipitate is formed.	
2.	Acidity or alkalinity	IP		Not less than 4.5 ml and not more than 5.5 ml of 0.01 M Sodium hydroxide is required to change colour of solution to pink.	
3.	Clarity and Colour of Solution.	IP		Solution is clear and colourless.	
4.	Arsenic	IP		Not more than 2 ppm	
5.	Heavy Metals	IP		Not more than 20 ppm	
6.	Readily carbonisable substance	IP		The solution is not more intensely coloured than Reference solution BS6	
7.	Related Substances	IP		Any secondary spot corresponding to Toluene -2- sulphamide in the chromatogram obtained with solution (1) is not more intense than the spot in the chromatogram obtained with solution (2)	
8.	Water	IP		Not More Than 15.0 %	
9.	Assay as $C_7H_4NNaO_3S$, HCl (On anhydrous Basis)	IP		Not Less Than 99.0 % and Not More Than 101.0%	



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SNo.	Test	Reference	Result	Specification	Remark

Raw Data Reference :

Analyst Name:

Analyst Name:

Analyst Name:

Analyst Hard Book No. :

Page No. :

Analyst Hard Book No. :

Page No. :

Analyst Hard Book No. :

Page No. :

Results: Sample Conforms / Does Not Conform to Specification

Analyzed By : _____

Date : _____

Checked By : _____

Date : _____

Approved By : _____

Date : _____