



PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

ANALYTICAL SPECIFICATION FOR SODIUM STARCH GLYCOLLATE BP

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.:
Control No./ A.R. No.:		Retest Date:

Reference: BP 2001 pg 1503

Description: A white or almost white, fine, free-flowing powder, very hygroscopic; free from foreign particles. Examined under a microscope it is seen to consist of: granules, irregularly shaped, ovoid or pear-shaped, 30 μm to 100 μm in size, or rounded, 10 μm to 35 μm in size; compound granules consisting of two to four components occur occasionally; the granules have an eccentric hilum and clearly visible concentric striations; between crossed nicol prisms, the granules show a distinct black cross intersecting at the hilum; small crystals are visible at the surface of the granules. The granules show considerable swelling in contact with water.

Complies/Does Not Comply

Solubility: Practically insoluble in Methylene chloride (1 in More than 10000), It gives a translucent suspension in water.

Complies/Does Not Comply

SNo.	Test	Reference	Result	Specification	Remark
1.	Identification A. pH B. Reaction of Starch C. Reaction of starch D. Reaction of Sodium salts	BP		A) It complies with the test for pH B) A suspension forms that settles after standing. C) A dark blue colour is produced D) A dense, white precipitate is produced.	



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SNo.	Test	Reference	Result	Specification	Remark
2.	Appearance of solution S1	BP		Solution S1 is clear and colourless	
3.	pH	BP		5.5 to 7.5	
4.	Sodium glycollate	BP		The absorbance of the test solution is not greater than that of a reference solution (2.0 per cent).	
5.	Sodium chloride	BP		Not more than 7.0 %	
6.	Iron	BP		Not more than 20 ppm	
7.	Heavy metals	BP		Not more than 20 ppm.	
8.	Loss on drying	BP		Not more than 10.0 %	
9.	Microbial Contamination 1.E Coli 2.Salmonellae	BP		1. It complies with the test for Escherichia coli 2. It complies with the test for Salmonella	
10.	Assay as Na (on alcohol (80% v/v) washed and dried basis)	BP		Not Less Than 2.8 % and Not More Than 4.2%	

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 : _____