PHARMA DEVILS

QUALITY CONTROL DEPARTMENT

ANALYTICAL SPECIFICATION FOR SODIUM STARCH GLYCOLLATE 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. 701, 702

Description: Very, fine white or off white, free flowing powder; odourless or amlost odourless; free from foreign particles.
Complies/Does Not Comply

Solubility: Practically insoluble in Distilled Water (1 in More than 10000), insoluble in most of inorganic solvents (1 in More than 10000).
Complies/Does Not Comply

SNo.	Test	Reference	Result	Specification	Remark
1.	**Identification** **A. IR** **B. Reaction of Starch** **C) Reaction of Sodium salts**	IP		A) IR absorption specctrum of test is concordant with WRS. B) A dark blue colour is produeced. C) Reaction of Sodium salts (a) A dense white Precipitate is formed.	
2.	**Identification (continued)** **C) Reaction of Sodium salts**	IP		b) A yellow Crystalline precipitate is formed	
3.	**pH**	IP		Between 5.5 and 7.5	
4.	**Heavy metals**	IP		Not more than 20 ppm.	
5.	**Iron**	IP		Not more than 20 ppm	
6.	**Sodium chloride**	IP		Not more than 10.0 %	
7.	**Sodium glycollate**	IP		Not more than 2.0 %	
8.	**Microbial limits** **1. E Coli**	IP		1. Absent per g	

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SNo.	Test	Reference	Result	Specification	Remark
	2. Salmonellae			2. Absent per g	
9.	**Loss on drying**	IP		Not more than 10.0 %	
10.	**Assay as Na**	IP		Not Less Than 2.8 % and Not More Than 4.5%	

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:** _____