BIOCHEMICAL & SYNTHETIC PRODUCTS LTD.

(An ISO 9001:2008 CERTIFIED COMPANY)

The Drugs Act 1940 and Rules thereunder

QUALITY ASSURANCE DEPARTMENT

CERTIFICATE OF ANALYSIS

Name of the Product: SODIUM AMINO SALICYLATE DIHYDRATE BP

(CAS NO: 6018-19-5)

Batch No : PSB/071/13-14
Batch Size : 500.0 Kgs
Date of Analysis : 08.08.2013
Dispatch Quantity : 25.0 Kgs

Date of Release : 09.08.2013
Date of Mfg : July'2013
Date of retest : Dec'2014

S.No	Tests	Results	Specification
1.	Appearance	White crystalline powder.	White or almost white crystalline powder or crystals, slightly hygroscopic.
2.	Solubility	Pass the test	Freely soluble in water; sparingly soluble in alcohol; practically insoluble in methylene chloride.
3.	Identification	A. 123-124°C	A. The Melting point of the sublimate shall between 120°C and 124°C
		B. Pass the test.	B. A 0.1% solution in water should gives reddish-brown color on addition with ferric chloride solution.
		C. Pass the test.	C.A 2 ml of 2% solution should give the test for primary aromatic amines.
		D. Pass the test.	D.A 5% solution should give reaction of sodium.
		E. Pass the test.	E. The infrared absorption spectrum of the sample should be concordant with the spectrum obtained with the working standard.
4.	Appearance of solution	Pass the test	A freshly prepared solution shall be clear not more intense than B6 reference solution.
5.	pH of 2% w/v solution	6.6	Between 6.5 and 8.5
6.	Related substances by (HPLC)		
	i)Impurity A (3- amino phenol)	0.05 %	Not more than 0.10 %.
	ii)Impurity B (Mesalazine)	Not detected	Not more than 1.0 %.
	iii) Any other impurity	0.08 %	Not more than 0.10 %.
	iv)Total impurities	0.14 %	Not more than 1.0 %.
7.	Heavy metals	Less than 10 ppm	Not more than 10 ppm.
8.	Loss on drying at 105°C	16.8 % w/w.	Between 16.0 and 17.5 % w/w.
9.	Assay (on dried basis	99.6 %w/w	Not less than 99.0 % and Not more than 101.0 % w/w
*10.	Residual solvents		
	i) Methanol	Not detected	Not more than 500 ppm
	ii) Ethanol	Not detected	Not more than 5000 ppm
	iii)Aceticacid	Not detected	Not more than 5000 ppm

FAGRON IBÉRICA, S.A.U
Corresponde al lote de Fagron:
C13090072
18.9.13 Director Técnico

REPORT: The Batch submitted Complies with BP specification

* Inhouse additional test

Storage: Preserve in an air tight container, protected from light.

Prepared by	Reviewed by	Approved & Released by
(K. Jaya Prakash Narayana)	(T.Karunakar Reddy)	(Y.Hanuma Reddy)
Manager-QC	Asst.Manager –QA/RA	Dy.Manager –QA/QC
Sign :	Sign :	Sign :
Date : 09/08/13	Date : 09/08/13	Date : 09/08/13

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