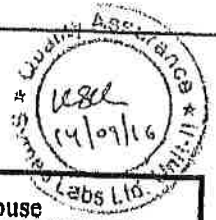


SYMED LABS LIMITED (UNIT-II)

Plot No. 25/B, Phase - III, IDA, Jeedimetla, Hyderabad - 500 055, Telangana, INDIA. Tel: +91 40 23191337
URL : <http://www.symedlabs.com>, CIN : U24231TG1998PLC029961

Certificate of Analysis



Product : IRON SUCROSE Reference : In-House
Batch No. : 2ISP(B)0140616 Batch Quantity : 302.00Kg
Date of Manufacture : May - 2016 Date of analysis : 09/07/2016
Re-test date : Apr' - 2020 A.R. No. : 02FP16000599
Storage conditions : Store in well closed, light resistant container.

S.No.	Test	Specifications	Results
1	Description	A homogenous brown powder.	A homogenous brown powder
2	Solubility	Freely soluble in water	Complies
3	pH at 20°C	Between 10.0 and 11.1	10.251
4	Loss on drying	Not more than 3.0%w/w	0.5%w/w
5	Identification (C=20mg of Fe/mL)		
	a) Iron	Should comply the test	Complies
	b) Sucrose	Should comply the test	Matches with the retention time of standard
	c) Molecular Weight	M _w =Between 34,000 Da and 60,000 Da M _n =Not less than 24,000 Da M _w /M _n =Not more than 1.7	54,533 Da 42,219 Da 1.3
6	Specific gravity (C= 20mg of Fe/mL)	Not less than 1.135 and not more than 1.165 at 20°C	1.148
7	Alkalinity (at pH 10.7) (C= 20 mg of Fe/mL)	Not less than 0.5mL and Not more than 0.8 mL of 0.1N HCl is consumed per mL of test solution.	0.68 mL/mL
8	Osmolarity (C= 20 mg of Fe/mL)	Not less than 1150 and Not more than 1350 mOsmol/L	1190 mOsmol/lit
9	Turbidity (C= 20 mg of Fe/mL)	The turbidity point (pH) of test solution is not less than 4.4 and not more than 5.3	4.802..
10	Content of chloride (C= 20 mg of Fe/mL)	Not more than 0.025%w/w	0.018%w/w
11	Assay for Sucrose by HPLC	Not less than 74.0%w/w and Not more than 97.0%w/w	83.0%w/w
12	Assay for Iron by AAS	Between 5.4%w/w and 6.0%w/w	5.7%w/w
13	Absence of Low molecular weight Fe (II) and Fe (III) complexes	Should be absent	Absent
14	Limit of Iron (II)	Not more than 1.08%w/w	Not detected

SYMED LABS LIMITED (UNIT-II)

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URL : <http://www.symedlabs.com>, CIN : U24231TG1998PLC029961

Certificate of Analysis



Product : IRON SUCROSE Reference : In-House
Batch No. : 2ISP(B)0140616 Batch Quantity : 302.00Kg
Date of Manufacture : May - 2016 Date of analysis : 09/07/2016
Re-test date : Apr' - 2020 A.R. No. : 02FP16000599
Storage conditions : Store in well closed, light resistant container.

S.No.	Test	Specifications	Results
15	Heavy metals		
	a) Arsenic content	Not more than 2 ppm	Less than 2 ppm
	b) Test for copper	Not more than 60 ppm	Less than 60 ppm
	c) Test for Lead	Not more than 20 ppm	Less than 20 ppm
	d) Test for Zinc	Not more than 150 ppm	Less than 150 ppm
16	Residual solvents by GC		
	Ethanol	Not more than 5000 ppm	2797 ppm
17	Bacterial Endotoxins	Not more than 1.0 USP Endotoxin units per mg of Iron	Less than 1.0 USP EU/mg of Iron
18	Microbial Limit		
	a) Total Aerobic Microbial Count	Not more than 100 cfu/g	Less than 10 cfu/g
	b) Total combined Yeasts and Molds Count	Not more than 10 cfu/g	Less than 10 cfu/g
	c) Test for Specified Micro organisms:		
	i) Test for Bile tolerant gram negative bacteria	Should be absent	Absent
	ii) Test for Pseudomonas aeruginosa	Should be absent	Absent
	iii) Test for Staphylococcus aureus	Should be absent	Absent
	iv) Test for Escherichia coli	Should be absent	Absent
	v) Test for Salmonella sps.	Should be absent	Absent

The product conforms to the above specification.

Approved signatory (QC)

Name : P.Srikanth

Designation: Asst. Manager

Date

14/09/16

Authorized signatory (QA)

Name : A.Laxmi prasanna

Designation: Manager

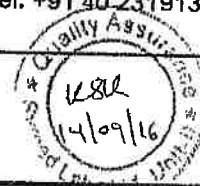
Date

14/09/2016

SYMED LABS LIMITED (UNIT-II)

Plot No. 25/B, Phase - III, IDA, Jeedimetla, Hyderabad - 500 055, Telangana, INDIA. Tel: +91 40 23191337
URL : <http://www.symedlabs.com>, CIN : U24231TG1998PLC029961

Certificate of Analysis



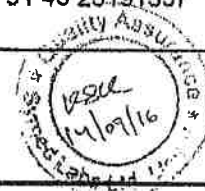
Product : **IRON SUCROSE** Reference : **In-House**
Batch No. : **2ISP(B)0150716** Batch Quantity : **302.00Kg**
Date of Manufacture : **Jun' - 2016** Date of analysis : **23/07/2016**
Re-test date : **May - 2020** A.R. No. : **02FP16000664**
Storage conditions : **Store in well closed, light resistant container.**

S.No.	Test	Specifications	Results
1	Description	A homogenous brown powder.	A homogenous brown powder
2	Solubility	Freely soluble in water	Complies
3	pH at 20°C	Between 10.0 and 11.1	10.181
4	Loss on drying	Not more than 3.0%w/w	0.5%w/w
5	Identification (C=20mg of Fe/mL)		
	a) Iron	Should comply the test	Complies
	b) Sucrose	Should comply the test	Matches with the retention time of standard
	c) Molecular Weight	M_w =Between 34,000 Da and 60,000 Da M_n =Not less than 24,000 Da M_w/M_n =Not more than 1.7	52,047 Da 36,109 Da 1.4
6	Specific gravity (C= 20mg of Fe/mL)	Not less than 1.135 and not more than 1.165 at 20°C	1.148
7	Alkalinity (at pH 10.7) (C= 20 mg of Fe/mL)	Not less than 0.5mL and Not more than 0.8 mL of 0.1N HCl is consumed per mL of test solution.	0.67 mL/mL
8	Osmolarity (C= 20 mg of Fe/mL)	Not less than 1150 and Not more than 1350 mOsmol/L	1160 mOsmol/lit
9	Turbidity (C= 20 mg of Fe/mL)	The turbidity point (pH) of test solution is not less than 4.4 and not more than 5.3	4.802
10	Content of chloride (C= 20 mg of Fe/mL)	Not more than 0.025%w/w	0.024%w/w
11	Assay for Sucrose by HPLC	Not less than 74.0%w/w and Not more than 97.0%w/w	83.0%w/w
12	Assay for Iron by AAS	Between 5.4%w/w and 6.0%w/w	5.6%w/w
13	Absence of Low molecular weight Fe (II) and Fe (III) complexes	Should be absent	Absent
14	Limit of Iron (II)	Not more than 1.08%w/w	0.20%w/w

SYMED LABS LIMITED (UNIT-II)

Plot No. 25/B, Phase - III, IDA, Jeedimetla, Hyderabad - 500 056, Telangana, INDIA. Tel: +91 40 23191337
URL : <http://www.symedlabs.com>, CIN : U24231TG1998PLC029061

Certificate of Analysis



Product	: IRON SUCROSE	Reference	: In-House
Batch No.	: 2ISP(B)0150716	Batch Quantity	: 302.00Kg
Date of Manufacture	: Jun' - 2016	Date of analysis	: 23/07/2016
Re-test date	: May - 2020	A.R. No.	: 02FP16000664
Storage conditions	: Store in well closed, light resistant container.		

S.No.	Test	Specifications	Results
15	Heavy metals		
	a) Arsenic content	Not more than 2 ppm	Less than 2 ppm
	b) Test for copper	Not more than 60 ppm	Less than 60 ppm
	c) Test for Lead	Not more than 20 ppm	Less than 20 ppm
	d) Test for Zinc	Not more than 150 ppm	Less than 150 ppm
16	Residual solvents by GC		
	Ethanol	Not more than 5000 ppm	2591 ppm
17	Bacterial Endotoxins	Not more than 1.0 USP Endotoxin units per mg of Iron	Less than 1.0 USP EU/mg of Iron
18	Microbial Limit		
	a) Total Aerobic Microbial Count	Not more than 100 cfu/g	20 cfu/g
	b) Total combined Yeasts and Molds Count	Not more than 10 cfu/g	Less than 10 cfu/g
	c) Test for Specified Micro organisms:		
	i) Test for Bile tolerant gram negative bacteria	Should be absent	Absent
	ii) Test for Pseudomonas aeruginosa	Should be absent	Absent
	iii) Test for Staphylococcus aureus	Should be absent	Absent
	iv) Test for Escherichia coli	Should be absent	Absent
	v) Test for Salmonella sps.	Should be absent	Absent

The product conforms to the above specification.

Approved Signatory (QC)	Authorized signatory (QA)
Name : P.Srikanth	Name : A.Laxmi prasanna
Designation: Asst.Manager	Designation: Manager
Date : 14/09/16	Date : 14/09/2016

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