


**KARNATAKA ANTIBIOTICS &
PHARMACEUTICALS LIMITED**

(A Government of India Enterprise)

 ENQUIRY REF. NO. : PRM/28/137/489
 DATE : 26.9.19
 DUE DATE : 01.10.19

Dear Sir,

Please submit your lowest and competitive offer in a COURIER / POST DULY SUPERSCRIBING OUR ABOVE ENQUIRY REF. NO. DATE AND DUE DATE on it, with other details.

ITEM CODE	:	IPR1180
ITEM DESCRIPTION	:	Iron Sucrose complex
QUANTITY REQUIRED	:	7 stgs
DELIVERY SCHEDULE	:	W/I a week from P.O. date

RATE	:	
F.O.R. TERMS	:	DOOR DELIVERY PREFERRED
GST	:	
PACKING & FORWARDING CHARGES	:	
TAXES	:	
CREDIT PERIOD	:	90 DAYS REQUESTED
DELIVERY OFFERED	:	
PRICE VALIDITY	:	Should Be Valid For 07 working days from due date
NAME OF MANUFACTURER	:	Please Indicate the Name
OTHER DETAILS	:	Age of the material should not be more than three months on the date of despatch.

NOTE : 1. Incase of Sterile Raw Materials. Please provide MINIATURE Sample for each canister along with the consignment.
2. Incase you are not quoting please send a regret letter.

Please ensure that your offer reaches us on or before DUE DATE.

Thanking You,

Yours faithfully

 for **KARNATAKA ANTIBIOTICS &
PHARMACEUTICALS LIMITED.**

AUTHORISED SIGNATORY

KARNATAKA ANTIBIOTICS & PHARMACEUTICALS LIMITED, BANGALORE



**FORMULATION DEVELOPMENT
DEPARTMENT**

Specification No.	FD-API-1PR1180-001
Compendia	IH
Review Date	03-11-2019

NON-STERILE RAW MATERIAL SPECIFICATION

Item code	1PR1180	IRON SUCROSE COMPLEX
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#	Tests	Specifications
1	Description	Reddish brown to dark brown powder
2	Solubility	Freely soluble in water
3	Identification	
	a Test for Iron	Red color is discharged (Iron(III) salts)
	b Test for Sucrose	The retention time of the major peak obtained in the chromatogram of the assay preparation corresponds to that obtained in the chromatogram of the standard preparation as in the assay for sucrose
4	Molecular weight determination	
	a Weight average molecular weight(Mw)	34000 to 60000 Da
	b Number average molecular weight(Mn)	Not less than 24000 Da
	c Polydispersity Index Mw/Mn	Not more than 1.7
5	Assay of Iron (by Titrimetry)	4.8 to 6.0 % w/w
6	Assay of Sucrose (by HPLC)	70 to 90 % w/w
7	Specific Gravity at 20°C (2.0 % w/v of Iron Solution)	1.135 to 1.165 g/mL
8	pH at 20°C (2.0 % w/v of Iron Solution)	10.5 to 11.1
9	Loss on drying	Not more than 2.0 % w/w
10	Osmolarity (2.0 % w/v of Iron Solution)	1150 to 1350 mOsmol/L
11	Turbidity (2.0 % w/v of Iron Solution)	Turbidity should develop between pH 4.4 to 5.3
12	Alkalinity (2.0 % w/v of Iron Solution)	0.5 – 0.8 mL of 0.1 N HCl consumed/mL

Effective date 03.11.2017	Prepared by: E (RNG)-FD	Reviewed by: DGM (RNS) -R&D	Approved by: DCM (BUK) -QA
Signature/Date Page 1 of 2	 3/11/17	 3/11/17	 3/11/17

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Item code	1PR1180	IRON SUCROSE COMPLEX
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#	Tests	Specifications		
13	Absence of low molecular weight complexes of Fe(II) and Fe(III) (by Polarography) (2.0 % w/v of Iron Solution)	No additional peak should be found in the polarogram		
14	Limit test for Fe (II) (2.0 % w/v of Iron Solution)	Not more than 0.4 % w/v		
15	Chloride content (2.0 % w/v of Iron Solution)	0.012 to 0.025 %		
16	Residual solvent (by GC)			
	a	Methanol	Not more than 3000 ppm	
	b	Ethanol	Not more than 5000 ppm	
	c	Acetone	Not more than 5000 ppm	
17	Bacterial Endotoxin Test	Not more than 3.7 EU/mg of Iron		
18	Microbial Limit Test			
	a	Total Bacterial Count	Not more than 500 cfu/g	
	b	Total Fungi Count	Not more than 50 cfu/g	
	c	Total viable aerobic count	Not more than 100 cfu/g	
	d	Pathogens		
			Enterobacteriaceae	To be absent
			E. Coli	To be absent
			Salmonella	To be absent
			Staphylococcus aureus	To be absent
	Pseudomonas aeruginosa	To be absent		

Effective date 03.11.2017	Prepared by: E (RNG)-FD	Reviewed by: DGM (RNS) -R&D	Approved by: DGM (BUK) -QA
Signature/Date Page 2 of 2	 3/11/17	 3/11/17	 3/11/17