



# Andhra Medi Pharma India Pvt Ltd

Manufacturer of Active Pharmaceutical Ingredients, Bulk Intermediates and nutraceuticals

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CERTIFICATE OF ANALYSIS					
Name of the Product: Glucosamine Hydrochloride USP-42					
Batch No	GLH05200198	Mfg.Date	MAY-2020	Expiry Date	APR-2024
Batch Quantity	2000 Kg	Analytical Report No	CBGLH200198	Released on	27-05-20
S.No	TEST	SPECIFICATION			Results
01	Origin	From Shrimp			From Shrimp
02	Appearance	White to off white crystalline powder			White crystalline powder
03	Identification				
	a) By Infrared absorption	The IR absorption spectrum of the sample should be concordant with the reference spectrum of Glucosamine Hydrochloride WS.			Complies
	b) By Chloride	Should meet the requirement			Complies
	c) By HPLC	The retention time of the Glucosamine peak of the sample solution corresponds to that in the standard solution			Complies
04	Solubility	Freely soluble in water			Complies
05	Loss on drying(% w/w) (2hrs at 105°C)	Not more than 1.0			0.16
06	Specific Optical rotation(25mg/mL)	Between +70.0° and +73.0°			71.05°
07	pH of 20mg/mL of test solution	Between 3.0 to 5.0			4.01
08	Residue on ignition(%w/w)	Not more than 0.1			0.03
09	Chloride & Sulfate, (%w/w)	Not more than 0.24			Complies
10	Arsenic(µg/g)	Not more than 3.0			Complies
11	Lead (ppm)	Not more than 0.5			Not detected
12	Cadmium(ppm)	Not more than 1.0			Not detected
13	Mercury(ppm)	Not more than 0.1			Not detected
14	Assay by HPLC (%w/w)(on dried basis)	98-102			99.6
15	Organic volatile impurities	Meets the requirements			Complies
16	Particle size	100% pass through 80mesh			Complies
Microbiology Tests					
17	Total aerobic microbial count	Not more than 500cfu/g			<10 cfu/g
18	Total yeasts & moulds count	Not more than 100cfu/g			<10 cfu/g
19	Escherichia coli	Absent/g			Absent
20	Salmonella species	Absent/10g			Absent
21	Pseudomonas aeruginosa	Absent/g			Absent
22	Staphylococcus aureus	Absent/g			Absent
Remarks: The above product complies as per USP-42 specifications					

	Prepared by	Checked by	Approved by
Signature			
Date	27/05/2020	27/05/2020	27/05/20

Works : Sy. No. 263, Veeravalli Village, Bapulapadu Mandal, Krishna Dist., Andhra Pradesh - 521 110.

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