MECK PHARMACEUTICALS & CHEMICALS PVT LIMITED, SANAND, AHMEDABAD.

QUALITY ASSURANCE DPT.	FINISHED SPECIFICATION AND TESTING PROCEDURE		Page 1 of 12	
DOC. No: QC/GH38/145-00	Issue Date: 1/06/15	Effective date: 15/06/15	Next Review date: 15/06/18	CC No. 00
Ref.: In house/USP 38	Revision no:00		Supersedes no: 00	

	Prepared by	Reviewed by	Approved by
Name	Bhumika	Jigar	M.R.Patel
Designation	Chemist QA	Sr. Chemist QA	Quality Head
Signature			
Date	11/6/15	14/6/15	15/6/15

NAME OF PRODUCT: GLUCOSAMINE HYDRO CHLORIDE USP -38

Material/General Information:

Synonyms : Glucosamine Hydrochloride
Molecular Formula : $C_6H_{13}NO_5$ .HCl
Molecular weight : 215.63
CAS No. : 66-84-2
Storage condition : Preserve in tight, light-resistant containers.

MECK PHARMACEUTICALS & CHEMICALS PVT LIMITED, SANAND, AHMEDABAD.

DOC.NO.QAS/F/006
Rev.no.00

SPECIFICATION

NAME OF PRODUCT		GLUCOSAMINE HYDRO CHLORIDE USP 38
TQC NO		TQC/GH38/145-00
SR NO	TESTS	SPECIFICATION
01	Description	White to off white crystalline powder.
02	Identification	Should confirm to *A. Infrared meet the requirement B. It should meet the requirement of the test for chloride. C. The major peak in chromatogram should confirm to the standard solution.
03	Specific Optical Rotation (2.5% Solution in water)	Between +70.0° to +73.0°
04	Residue on ignition	Not More Than 0.1%
05	pH (2.0% solution in water)	Between 3.0 to 5.0
06	Loss On Drying. (at 105° for 2.0 Hrs.)	Not More Than 1.0%
07	Sulphate content	Not More Than 0.24%
08	Assay by HPLC	Between 98.0% to 102%
	Additional Test	
* 09	Chloride content	Between 15.5% to 17.5%
* 10	Particle size	100% pass through 80 mesh sieve
* 11	Heavy Metals	
	Lead	Not More Than 3 ppm
	Arsenic	Not More Than 3 ppm
	Cadmium	Not More Than 3 ppm
	Mercury	Not More Than 0.1 ppm
* 12	**Microbial Test**	
	Total Bacterial Count	NMT 500 cfu/gm
	Total yeast & mold count	NMT 100 cfu/gm
	Escherichia coli	Absent/gm
	Salmonella Spp.	Absent/gm
	Staphylococcus aureus	Absent/gm
	Pseudomonas aeruginosa	Absent/gm

* Tests do not perform at stability study.

	PREPARED BY	CHECKED BY	APPROVED BY
NAME	BHUMIKA	JIGAR	M. R. PATEL
DESIGNATION	QA CHEMIST	QA CHEMIST	INCHARGE QA/QC
SIGN	Bhumika	JPPatel	MRPatel
DATE	11/6/15	14/6/15	15/06/15

MECK PHARMACEUTICALS & CHEMICALS PVT LIMITED, SANAND, AHMEDABAD.

DOC.NO.QAS/F/003
Rev.no.00

FINISHED ANALYSIS REPORT

NAME OF PRODUCT	GLUCOSAMINE HYDRO CHLORIDE USP 38		
BATCH NO.		BATCH QUANTITY	
		A. R. NO.	
DATE OF TESTING		NAME OF PARTY	---
ANALYTICAL TQC NO .	TQC/GH38/145-00	DATE OF RELEASE	

SR NO	TESTS	SPECIFICATION	RESULT	DONE BY
01	Description	White to off white crystalline powder.		
02	Identification	Should confirm to A. Infrared meet the requirement B. It should meet the requirement of the test for chloride. C. The major peak in chromatogram should confirm to the standard solution.		
03	Specific Optical Rotation	Between +70.0° to +73.0°		
04	Residue on ignition	Not More Than 0.1%		
05	pH (2.0% solution)	Between 3.0 to 5.0		
06	Loss On Drying. (at 105° for 2.0 Hrs.)	Not More Than 1.0%		
07	Sulphate content	Not More Than 0.24%		
08	Assay by HPLC	Between 98.0% to 102%		
	Additional Test			
09	Chloride content	Between 15.5% to 17.5%		
10	Particle size	100% pass through 80 mesh sieve		
11	**Heavy Metals**			
	Lead	Not More Than 3 ppm		
	Arsenic	Not More Than 3 ppm		
	Cadmium	Not More Than 3 ppm		
	Mercury	Not More Than 0.1 ppm		
12	**Microbial Test**			
	Total Bacterial Count	NMT 500 cfu/gm		
	Total yeast & mold count	NMT 100 cfu/gm		
	Escherichia coli	Absent/gm		
	Salmonella Spp.	Absent/gm		
	Staphylococcus aureus	Absent/gm		
	Pseudomonas aeruginosa	Absent/gm		

REPORT: The Material Complies/Does Not Complies as per the prescribed Specifications of IP/BP/IH and is Approved / Rejected.

ANALYSED BY: DATE:	APPROVED BY: DATE:

MECK PHARMACEUTICALS & CHEMICALS PVT LIMITED, SANAND, AHMEDABAD.

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Ref.: In house/USP 38	Revision no:00		Supersedes no: 00	

	Prepared by	Reviewed by	Approved by
Name	Bhumika	Jigar	M.R.Patel
Designation	Chemist QA	Sr. Chemist QA	Quality Head
Signature			
Date	11/6/15	14/06/15	15/06/15

NAME OF PRODUCT: GLUCOSAMINE HYDRO CHLORIDE USP -38

Sr no.	Test	Specifications	Reference
01	Appearance	White to off white crystalline powder.	As per STP
02	Identification	Should confirm to A. Infrared meet the requirement B. It should meet the requirement of the test for chloride. C. The major peak in chromatogram should confirm to the standard solution.	As per STP
03	Specific Optical Rotation (2.5% Solution in water)	Between +70.0° to +73.0°	As per STP
04	Residue on ignition	Not More Than 0.1%	As per STP
05	pH (2.0% solution in water)	Between 3.0 to 5.0	As per STP
06	Loss On Drying. (at 105° for 2.0 Hrs.)	Not More Than 1.0%	As per STP
07	Sulphate content	Not More Than 0.24%	As per STP
08	Assay by HPLC	Between 98.0% to 102%	As per STP
	Additional Test		
09	Chloride content	Between 15.5% to 17.5%	As per STP
10	Particle size	100% pass through 80 mesh sieve	As per STP
11	**Heavy Metals**		
	Lead	Not More Than 3 ppm	As per ICPMS
	Arsenic	Not More Than 3 ppm	
	Cadmium	Not More Than 3 ppm	
	Mercury	Not More Than 0.1 ppm	
12	**Microbial Test**		
	Total Bacterial Count	NMT 500 cfu/gm	As per TQC/MBL/135-00
	Total yeast & mold count	NMT 100 cfu/gm	
	Escherichia coli	Absent/gm	
	Salmonella Spp.	Absent/gm	
	Staphylococcus aureus	Absent/gm	
	Pseudomonas aeruginosa	Absent/gm	

MECK PHARMACEUTICALS & CHEMICALS PVT LIMITED, SANAND, AHMEDABAD.

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	Prepared by	Reviewed by	Approved by
Name	Bhumika	Jigar	M.R.Patel
Designation	Chemist QA	Sr. Chemist QA	Quality Head
Signature	Bhumika	H P Patel	
Date	11/06/15	14/06/15	15/06/15

NAME OF PRODUCT: GLUCOSAMINE HYDRO CHLORIDE USP -38

Sr No	Test	Standard testing procedure
01	Appearance	White to off white crystalline powder. **Procedure:** Take the _____ (5.0 g) of the material in Petri dish and record its appearance.
		Observation:
		Remark :
02	Identification	**Infrared Absorption <197K>** **By HPLC test:** **Procedure:** The retention time of the principal peak in the sample preparation is match with the Standard preparation in the test of Assay by HPLC.
		Observation: UNCONTROLLED RT of 1st Standard injection _____ RT of 1st Sample Injection _____ RT of 2nd Sample Injection _____
		Remark :
		Identification by Chloride test: **Reagents:** 10 % w/w solution of Nitric Acid . 25 % w/w solution of 13.5 M Ammonia solution, 5 % w/v solution of silver nitrate **Procedure:** Weighing the accurately _____(0.0122 g) substance in ____(2 ml) water and acidify with the 10 % w/w solution of Nitric Acid , add _____(0.5 ml) of 5 % w/v solution of silver nitrate, shake and allow to stand ; a curdy ,white precipitate is formed , which is insoluble in Con. Nitric acid but soluble , after being well washed with water, in 25 % w/w solution of 13.5 M Ammonia solution, from which it is precipitate by the addition of 10 % w/w solution of Nitric Acid.
		Observation:
		Remark:

MECK PHARMACEUTICALS & CHEMICALS PVT LIMITED, SANAND, AHMEDABAD.

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Ref.: In house/USP 38	Revision no:00		Supersedes no: 00	

	Prepared by	Reviewed by	Approved by
Name	Bhumika	Jigar	M.R.Patel
Designation	Chemist QA	Sr. Chemist QA	Quality Head
Signature			
Date	11/06/15	14/06/15	15/06/15

NAME OF PRODUCT: GLUCOSAMINE HYDRO CHLORIDE USP -38

Sr No.	TEST	Standard testing procedure
03	Specific Optical Rotation (2.5 % Solution in water.)	Between +70.0° and +73.0° **Procedure:** Accurately weighing _____(2.5g) of the substance in _____(100ml) clean and dried volumetric flask. And dissolve it in _____(water) and dilute up to the mark with the water. And corrected for the solvent blank, measurements the optical rotation in _____(1 dm) Polarimeter tube for the Blank solution and sample solution at 589nm at _____(25° ± 0.5°) for five time and take the average reading for the calculation.

No. of Reading	Blank Reading	No. of Reading	Sample Reading
01		01	
02		02	
03		03	
04		04	
05		05	
Average		Average	

Calculation:

$$[\alpha]_D^{25} = \frac{100 \times \alpha}{l \times c \times (100 - LOD)} \times 100$$

α - Average corrected observation rotation, in degrees at 25°
L - Length of the Polarimeter tube – 1 dm
LOD - Loss on drying of sample.
c - Concentration of substance in % w/v
D- D line of sodium light (λ= 589.3nm)

$$= \frac{100 \times \quad}{\times 1 \times (100 - \quad)} \times 100$$

Observation:_____
Remarks:_____

MECK PHARMACEUTICALS & CHEMICALS PVT LIMITED, SANAND, AHMEDABAD.

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Ref.: In house/USP 38	Revision no:00		Supersedes no: 00	

	Prepared by	Reviewed by	Approved by
Name	Bhumika	Jigar	M.R.Patel
Designation	Chemist QA	Sr. Chemist QA	Quality Head
Signature			
Date	14/06/15	14/06/15	15/06/15

NAME OF PRODUCT: GLUCOSAMINE HYDRO CHLORIDE USP -38

Sr No.	TEST	Standard testing procedure
04	Residue on ignition	Not More Than 0.1 % w/w **Procedure:** Take the Silica crucible and ignite at _____ (650°± 25°C) for 30 minutes. Allow to cool in a desiccator over silica gel and weigh.(W1) Place the _____(1.0 g) of substance in the crucible and weigh (W2). Moisten the substance to be examined with a small amount of Sulphuric acid (usually_____ 2 ml) and heat gently at as low temperature as practicable until the sample is thoroughly charred. After cooling moisten the residue with a small amount of Sulphuric acid, heat gently until white fumes are no longer evolved and ignite at 650°C±25°C until the residue is completely incinerated. Ensure that flames are not produced at any time during the procedure. Allow the crucible to cool in a desecrator over silica gel, weigh again (W3), ignite for _____(15 minutes) and repeat this procedure until two successive weighing do not differ by more than 0.5 mg / g. and calculate the wt of the residue. And calculate the residue by following formula. $$\% \text{ of ROI} = \frac{W3 - W1}{W2 - W1} \times 100$$ W1 Weight of crucible in g _____ W2 Weight of crucible + sample in g (Before ignition) _____ W3 Weight of crucible + sample in g (After ignition) W1 _____ W2 _____ $$\% \text{ of ROI} = \frac{\quad}{\quad} \times 100$$ Observation:_____ Remarks:_____

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	Prepared by	Reviewed by	Approved by
Name	Bhumika	Jigar	M.R.Patel
Designation	Chemist QA	Sr. Chemist QA	Quality Head
Signature			
Date	12/06/15	14/06/15	15/06/15

NAME OF PRODUCT: GLUCOSAMINE HYDRO CHLORIDE USP -38

Sr No.	TEST	Standard testing procedure
05	pH (2.0 % solution in water)	Between 3.0 and 5.0 **Procedure:** Weighing the accurately _____(2.0 g) of the substance in _____(100 ml) clean and dried volumetric flask. Dissolve it _____water up to the mark. And measured the pH of the solution at _____ (25°±2° C). Observation:_____ Remarks:_____
06	Loss on Drying (at 105°C for 2 Hrs.)	Not more than 1.0% w/w **Procedure:** Take the weighing bottle (bottom flat) complete with the lid previously dried at _____(105°±2° C) for 30 minute (W1) After drying is completed put the bottle in desiccator at room temperature to avoid the moisture. Weighing accurately the LOD bottle and transfer the _____(1.0 g) substance in LOD bottle and take the gross weight (W2) . Then transfer the LOD bottle in drying oven and keep the lid aside at 105°±2°C temperature for 2 hr. After the drying is completed, open the drying oven closed the bottle promptly and allow it to cool to room temperature in a desecrator before weighing. Weight the bottle and the contents (W3) , for conformation of the LOD, further put the LOD bottle in drying oven and keep it above condition for 30 minute. The difference of the constant weight should not be more than 0.5 mg/g and calculate the LOD by following formula. $\%\text{Loss on Drying} = \frac{W2 - W3}{W2 - W1} \times 100$ W1= Weighing of the LOD bottle in g W2 = Weighing of the LOD bottle + sample (Before drying) In g

MECK PHARMACEUTICALS & CHEMICALS PVT LIMITED, SANAND, AHMEDABAD.

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	Prepared by	Reviewed by	Approved by
Name	Bhumika	Jigar	M.R.Patel
Designation	Chemist QA	Sr. Chemist QA	Quality Head
Signature			
Date	11/06/15	14/06/15	15/06/15

NAME OF PRODUCT: GLUCOSAMINE HYDRO CHLORIDE USP -38

Sr No.	TEST	Standard testing procedure
		W3= Weighing of the LOD bottle + sample (After drying) in g Observation:_____ Remarks:_____
07	Sulfate content	**Sulfate:** **Not more than 0.24%** Reagents: **3N HCl solutions.** 25 % w/v of Barium Chloride solution. 0.02 N Sulphuric acid solutions. **Sample preparation:** Weighing accurately _____ (0.1 g) of substance in _____(50 ml) colour comparison tube, add _____(30 to 40 ml) of water and if necessary neutralize the solution with hydrochloride to litmus. Add _____(1 ml) of 3 N hydrochloride acid, _____(3 ml) of 25 % w/v of Barium chloride solution and sufficient water to make _____(50 ml). Mix and allow to stand for _____(10 minutes) **Standard preparation:** Pipette out _____(0.25 ml) of 0.02 N Sulphuric acid in ____(50 ml) colour Comparison tube, add _____(30 to 40 ml) of water and Add _____(1 ml) of 3 N hydrochloride acid, _____(3 ml) of 25 % w/v of Barium chloride solution and sufficient water to make _____(50 ml). Mix and allow to stand for ____(10 minutes **Procedure:** Compare the turbidity of sample preparation against the standard preparation. The turbidity of the sample is not more than the standard preparation. Observation:_____ Remarks:_____

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	Prepared by	Reviewed by	Approved by
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Designation	Chemist QA	Sr. Chemist QA	Quality Head
Signature	Bhumi Rve	JP Patel	
Date	11/06/15	14/06/15	15/06/15

NAME OF PRODUCT: GLUCOSAMINE HYDRO CHLORIDE USP -38

Sr No.	TEST	Standard testing procedure
08	Assay by HPLC (On dried Basis)	Between 98.0% and 102.0% Glucosamine hydrochloride WRS B. No. _____ **Buffer:** In a 1 – L **Volumetric** flask, .dissolve 3.5 g of dibasic potassium phosphate in water. Add 0.25 ml of ammonium hydroxide, dilute with water to volume, and mix. Adjust with phosphoric acid to a pH of 7.5. Mobile phase : Acetonitrile and Buffer (75 : 25) Diluent : Acetonitrile and water (50 : 50) Standard Solution : 3.8 mg/ml of USP Glucosamine Hydrochloride RS in Diluent Sample Solution: 3.8 mg/ml of Glucosamine Hydrochloride in Diluent. [NOTE – Shake by mechanical means to aid dissolution.] **Chromatographic system** Mode : LC Detector : UV 195 nm Column : 4.6 mm × 15 cm ; 5 µm packing L8 (NH_2 Inertsil) C/N 5020 – 05545 S/N 3B180002 IN HOUSE NO . CL – 01 Column temperature : 35° Flow rate : 1.5 ml/min Injection size : 10 µl **System suitability :** Sample : Standard solution [NOTE – The peak for the glucosamine moiety elutes at above 10 min. The chromatogram shows a large additional peak near the void volume , due to the chloride ion.] **Suitability requirements :** Tailing factor : NMT 2.0 for the glucosamine peak-_____ Efficiency ; NLT 1000 theoretical plates-_____ RSD of replicate five standard injection: NMT 2%-_____

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	Prepared by	Reviewed by	Approved by
Name	Bhumika	Jigar	M.R.Patel
Designation	Chemist QA	Sr. Chemist QA	Quality Head
Signature	Bhumika	Jigar	
Date	11/06/15	14/06/15	15/06/15

NAME OF PRODUCT: GLUCOSAMINE HYDRO CHLORIDE USP -38

Sr No.	TEST	Standard testing procedure

Analysis

Sample : Standard solution and sample solution

Calculate the percentage of glucosamine hydrochloride ($C_6H_{13}NO_5$. HCL) in the portion of Glucosamine Hydrochloride taken :

Result $= (r_U/r_S) \times (C_S/C_U) \times 100$

r_U	=	peak response from the sample solution.
r_S	=	peak response from the standard solution.
C_S	=	concentration of USP Glucosamine Hydrochloride RS in the Standard solution (mg/ml)
C_U	=	concentration of Glucosamine Hydrochloride in the sample solution (mg/ml)

Standard Details		Sample Details	
Standard	Standard Area	Sample	Sample Area
Std-1		Sample Inj.-1	
Std-2		Sample Inj.-2	
Std-3		Sample Inj.-3	
Std-4		Average	
Std-5			
Average			
RSD			

% of Assay = ---------- x ----------x 100

Observation: _____ % Assay

Remark:

MECK PHARMACEUTICALS & CHEMICALS PVT LIMITED, SANAND, AHMEDABAD.

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	Prepared by	Reviewed by	Approved by
Name	Bhumika	Jigar	M.R.Patel
Designation	Chemist QA	Sr. Chemist QA	Quality Head
Signature	Bhumika	JPatel	
Date	12/06/15	14/06/15	15/06/15

NAME OF PRODUCT: GLUCOSAMINE HYDRO CHLORIDE USP -38

Sr No.	TEST	Standard testing procedure
09	Chloride Content	**Chloride:** Between 15.5% - 17.5% **Reagents:** 1N $AgNO_3$(Silver nitrate) Solution, Eosin Procedure: Take About 0.2 gm weight of the test sample in conical flask. Add 5 ml distilled water dissolve it , Add 5 ml Acetic acid & 50 ml methanol. Then add 2-3 drops of Eosin Indicator titrate against 0.1N $AgNO_3$. % of chloride = $\frac{B.R \times Normality \times 35.55}{Wt \times 10}$ Where, B.R = Burette reading N = Normality of 0.1 N $AgNO_3$ Wt = Weight of Sample in g Observation:_____ Remarks:_____
10	Particle size	As per party specification. Take 10 gm sample and pass through selected mesh sieve and calculate the return wet. Observation:_____ Remark:_____

MECK PHARMACEUTICALS & CHEMICALS PVT LIMITED, SANAND, AHMEDABAD.

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	Prepared by	Reviewed by	Approved by
Name	Bhumika	Jigar	M.R.Patel
Designation	Chemist QA	Sr. Chemist QA	Quality Head
Signature			
Date	11/06/15	14/06/15	15/06/15

NAME OF PRODUCT: GLUCOSAMINE HYDRO CHLORIDE USP -38

Sr No.	TEST	Standard testing procedure
11	Heavy Metals	*As per ICPMS Lead Arsenic Cadmium Mercury
12	Microbial Test	As per TQC/MBL/135-00

QUALITY ASSURANCE DPT.	FINISHED SPECIFICATION AND TESTING PROCEDURE		Page 12 of 12	
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	Prepared by	Reviewed by	Approved by
Name	Bhumika	Jigar	M.R.Patel
Designation	Chemist QA	Sr. Chemist QA	Quality Head
Signature	Bhumika	JPatel	
Date	11/06/15	14/06/15	15/06/15

NAME OF PRODUCT: GLUCOSAMINE HYDRO CHLORIDE USP -38

Review by: _____ **Date:** _____

Approved by: _____ **Date:** _____

Remark: _____

* = Third party report

HISTORY CARD

ATP NAME	Revision No	Effective Date	Supersedes No.	Reason for revision	*Remark*
GLUCOSAMINE HYDROCHLORIDE (TQC/GH38/145-00)	00	15/06/15	00	----	NEW DOCUMENT

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