MECK PHARMACEUTICALS & CHEMICALS PVT LIMITED, SANAND, AHMEDABAD.

| QUALITY ASSURANCE DPT. | FINISHED SPECIFICATION AND TESTING PROCEDURE | | Page 3 of 12 | |
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| DOC. No: TQC/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 | Bhumika | H.Patel | Mpatel |
| Date | 11/06/15 | 14/06/15 | 15/06/15 |

NAME OF PRODUCT: GLUCOSAMINE HYDRO CHLORIDE USP -38 Rm/01/17/006

| Sr No | Test | Standard testing procedure |
|---|---|---|
| 01 | Appearance | White to off white crystalline powder.<br>**Procedure:**<br>Take the 5.0009 (5.0 g) of the material in Petri dish and record its appearance.<br>Observation: White crystalline powder ~ @<br>Remark : Complies Mb - 02/07/17 02/07/17 |
| 02 | Identification | **Infrared Absorption <197K>**<br>**By HPLC test:**<br>**Procedure:**<br>The retention time of the principal peak in the sample preparation is match with the Standard preparation in the test of Assay by HPLC.<br>Observation: RT of 1st Standard injection 3.704; RT of 1st Sample Injection 3.706; RT of 2nd Sample Injection 3.708<br>Remark : Complies Mb - 02/07/17 @ 02/07/17<br>**Identification by Chloride test:**<br>**Reagents:**<br>10 % w/w solution of Nitric Acid .<br>25 % w/w solution of 13.5 M Ammonia solution,<br>5 % w/v solution of silver nitrate<br>**Procedure:**<br>Weighing the accurately 0.0122 (0.0122 g ) substance in 2 (2 ml) water and acidify with the 10 % w/w solution of Nitric Acid , add 0.5 (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.<br>Observation: A curdy White ppt is Formed ~<br>Remark: complies Mb - 02/07/17 @ 02/07/17 |

**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** Q.H.01117006

| Sr No. | TEST | Standard testing procedure |
|---|---|---|
| 03 | Specific Optical Rotation (2.5 % Solution in water.) | Between +70.0° and +73.0° |

**Procedure:**

Accurately weighing 2.5230 (2.5g) of the substance in 100 (100ml) clean and dried volumetric flask. And dissolve it in water (water) and dilute up to the mark with the water. And corrected for the solvent blank, measurements the optical rotation in 1 (1 dm) Polarimeter tube for the Blank solution and sample solution at 589nm at 25° ( 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 | 0.00° | 01 | 1.78° |
| 02 | 0.00° | 02 | 1.77° |
| 03 | 0.00° | 03 | 1.78° |
| 04 | 0.00° | 04 | 1.78° |
| 05 | 0.00° | 05 | 1.79° |
| Average | 0.00° | Average | 1.78° |

**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)

$$= \frac{100 \times 1.78^\circ}{2.5230 \times 1 \times (100 - 0.22)} \times 100$$

Observation: +70.70°
Remarks: complies

02/07/17 02/07/17

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 GLH/01/H1006

| Sr No. | TEST | Standard testing procedure |
|---|---|---|
| 04 | Residue on ignition | Not More Than 0.1 % w/w<br>**Procedure:**<br>Take the Silica crucible and ignite at 650° (650°± 25°C) for 30 minutes.<br>Allow to cool in a desiccator over silica gel and weigh.(W1) Place the 1.1312 (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 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 (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.<br><br>$$\% \text{ of ROI} = \frac{W3 - W1}{W2 - W1} \times 100$$<br><br>W1 Weight of crucible in g: 34.9469<br>W2 Weight of crucible + sample in g (Before ignition): 36.0781<br>W3 Weight of crucible + sample in g (After ignition): W1 34.9479, W2 34.9479<br><br>% of ROI = $\frac{0.0010}{1.1312} \times 100$<br>Observation: 0.088 %.<br>Remarks: Complies<br>02/07/17<br>Reviewed 02/07/17 |

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 | 12/06/15 | 14/06/15 | 15/06/15 |

NAME OF PRODUCT: GLUCOSAMINE HYDRO CHLORIDE USP -38 QAH/01/17006

| Sr No. | TEST | Standard testing procedure |
|---|---|---|
| 05 | pH (2.0 % solution in water) | Between 3.0 and 5.0<br>**Procedure:**<br>Weighing the accurately 2.0010(2.0 g) of the substance in 100 (100 ml) clean and dried volumetric flask. Dissolve it Water water up to the mark. And measured the pH of the solution at 25° (25°±2° C).<br><br>Observation: 3.98<br>Remarks: Complies<br>02/07/17 Review 02/07/17 |
| 06 | Loss on Drying (at 105°C for 2 Hrs.) | Not more than 1.0%w/w<br>**Procedure:**<br>Take the weighing bottle (bottom flat) complete with the lid previously dried at 105°(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 1.0013 (1.0 g) substance in LOD bottle and take the gross weight (W2) .<br>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.<br><br>The difference of the constant weight should not be more than 0.5 mg/g and calculate the LOD by following formula.<br>$\%\text{Loss on Drying} = \frac{W2 - W3}{W2 - W1} \times 100$<br>W1= Weighing of the LOD bottle in g<br>W2 = Weighing of the LOD bottle + sample (Before drying) In g |

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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** QAH/GI/17/006

| Sr No. | TEST | Standard testing procedure |
|---|---|---|
| | | W3= Weighing of the LOD bottle + sample (After drying) in g<br><br>Observation: 0.22 %<br>Remarks: Complies<br>02/07/17 Review 02/07/17 |
| 07 | Sulfate content | **Sulfate:**<br><br>**Not more than 0.24%**<br><br>Reagents:<br><br>**3N HCl solutions.**<br>25 % w/v of Barium Chloride solution.<br>0.02 N Sulphuric acid solutions.<br><br>**Sample preparation:**<br>Weighing accurately 0.1001 (0.1 g) of substance in 50 (50 ml) colour comparison tube, add 30 (30 to 40 ml) of water and if necessary neutralize the solution with hydrochloride to litmus. Add 1 (1 ml) of 3 N hydrochloride acid, 3 (3 ml) of 25 % w/v of Barium chloride solution and sufficient water to make 50 (50 ml). Mix and allow to stand for 10 (10 minutes)<br>**Standard preparation:**<br>Pipette out 0.25 (0.25 ml) of 0.02 N Sulphuric acid in 50 (50 ml) colour Comparison tube, add 30 (30 to 40 ml) of water and Add 1 (1 ml) of 3 N hydrochloride acid, 3 (3 ml) of 25 % w/v of Barium chloride solution and sufficient water to make 50 (50 ml). Mix and allow to stand for 10 (10 minutes<br>**Procedure:**<br>Compare the turbidity of sample preparation against the standard preparation.<br>The turbidity of the sample is not more than the standard preparation.<br><br>Observation: Complies<br>Remarks: Complies<br>02/07/17 Review 02/07/17 |

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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 | Bhumi Rke | JP Patel | |
| Date | 11/06/15 | 14/06/15 | 15/06/15 |

**NAME OF PRODUCT: GLUCOSAMINE HYDRO CHLORIDE USP -38** GH/01/F/006

| Sr No. | TEST | Standard testing procedure |
|---|---|---|
| 08 | Assay by HPLC (On dried Basis) | Between 98.0% and 102.0%<br>Glucosamine hydrochloride WRS B. No. WS/GH/15/002<br><br>**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. Mobilephase Annexure Attached<br><br>Mobile phase : Acetonitrile and Buffer (75 : 25)<br>Diluent : Acetonitrile and water (50 : 50)<br>Standard Solution : 3.8 mg/ml of USP Glucosamine Hydrochloride RS in Diluent<br>Sample Solution: 3.8 mg/ml of Glucosamine Hydrochloride in Diluent.<br>[NOTE – Shake by mechanical means to aid dissolution.]<br>**Chromatographic system**<br><br>Mode : LC<br>Detector : UV 195 nm<br>Column : 4.6 mm × 15 cm ; 5 µm packing L8 ($NH_2$ Inertsil)<br>C/N 5020 – 05545 S/N 3B180002<br>IN HOUSE NO . CL – 01<br>Column temperature : 35°<br>Flow rate : 1.5 ml/min<br>Injection size : 10 µl<br>**System suitability :**<br>Sample : Standard solution<br>[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.]<br><br>**Suitability requirements :**<br>Tailing factor : NMT 2.0 for the glucosamine peak- 1.285<br>Efficiency ; NLT 1000 theoretical plates- 4706.614<br>RSD of replicate five standard injection: NMT 2%- 0.101672<br>PDS 02/01/17 |

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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** GH/01/17/006

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

★ calculation sheet attached

| | | |
|---|---|---|
| $r_U$ | = | 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 | 755319 | Sample Inj.-1 | 753345 |
| Std-2 | 754641 | Sample Inj.-2 | 753234 |
| Std-3 | 753526 | Sample Inj.-3 | 753842 |
| Std-4 | 753792 | Average | 753474 |
| Std-5 | 753666 | | |
| Average | 754188.8 | | |
| RSD | 0.10167 2 | | |

% of Assay = $\frac{753474}{754188.8} \times \frac{190.0}{190.1} \times 100$

**Observation:** ~~99.83~~ 99.61 % Assay $\times \frac{100}{100-0.22} = 99.83$

**Remark:** Complies

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|---|---|---|---|
| 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 |
|---|---|---|
| 09 | Chloride Content | **Chloride:**<br>Between 15.5% - 17.5%<br>**Reagents:**<br>1N $AgNO_3$(Silver nitrate) Solution, Eosin<br>Procedure:<br>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 $AgNO_3$.<br><br>$\% \text{ of chloride} = \frac{B.R \times \text{Normality} \times 35.55}{Wt \times 10}$<br><br>Where,<br>B.R = Burette reading 16.6 ml<br>N = Normality of 0.1 N $AgNO_3$ 0.1015 N<br>Wt = Weight of Sample in g 0.3790 g<br><br>Observation: 16.10 %<br>Remarks: Complies<br>02/07/17 Review 02/07/17 |
| 10 | Particle size | As per party specification.<br>Take 10 gm sample and pass through selected mesh sieve and calculate the return wet.<br><br>Observation: Complies<br>Remark: Complies<br>02/07/17 Review 02/07/17 |

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<br>Lead<br>Arsenic $ COA Attached<br>Cadmium<br>Mercury $ B. No CTH/01/17/006<br>Report No ÷ CTLF/2806017012 |
| 12 | Microbial Test | As per TQC/MBL/135-00<br>CTLF/2806017G15 |

# Gujarat Laboratory

**AN ISO 9001 : 2008 CERTIFIED LABORATORY**

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**APPROVED BY :**
- "Agmark" Directorate of Marketing and Inspection, Govt. of India.
- Solvent Extractors Association of India.

## TEST REPORT

| | | | |
|---|---|---|---|
| Report No. | GL/F/2806017012 | | |
| Sample submitted by | Meck pharmaceutical & chemical p. ltd.<br>606,Harikrupa Tower,<br>S. M. Road Ellisbrige,<br>Ahmedabad - 380006 | Date of Receipt<br>Batch No. | 28/06/17<br>GH/01/17/006 |
| Sample Described as | GLUCOSAMINE HYDROCHLORIDE USP | | |
| Mode of packing | Sample packed in plastic bag | Mfg. Date | NM |
| Sample condition | Satisfactory | Exp. Date | NM |
| | | Sample Qty.: | 25gm |
| Marking | ------ | | |
| Analysis Date | 04/07/17 | | |

| Sl. | Test Name | Result | Test Method |
|---|---|---|---|
| | **Heavy metals** | | |
| 1 | Arsenic (as As) ppm | ND (D.L.=0.005) | GL/SOP/I-120 |
| 2 | Cadmium (as Cd) ppm | N.D.(D.L.=0.01) | GL/SOP/I-119 |
| 3 | Mercury (as Hg) ppm | N.D.(D.L.=0.02) | GL/SOP/I-120 |
| 4 | Lead (as Pb) ppm | 0.1 (D.L.=0.08) | GL/SOP/I-119 |

N.M. = Not Mentioned, N.D. = Not Detected, D.L. = Detection Limit

For GUJARAT LABORATORY

Date of Issue : 04/07/17

Rupesh Desai

Autho. Signatory

***End of Report***

Note

1. The result refer only to be tested sample & applicable parameters, endorsement of product is neither inferred nor implied.
2. Total liability of our institution to be invoice amount/testing charges.
3. This report is not to be reproduced wholly or in part and cannot be used as an evidence in the court of law and should not be used in any advertising media without our special permission in writing.
4. Sample drawn & submitted by the party for analysis unless otherwise stated.
5. Gujarat laboratory maintains strict confidentiality of all the analysis and test result and customer supplied product and will not reveal this information to third party unless required by the statutory or legal requirement.
6. Subject to Ahmedabad jurisdiction.
7. Perishable sample will be destroyed after testing, others after three weeks from the data of issue of the report, unless otherwise agreed with the customer.
8. The sample is accepted by us subject to our general condition of services which is displayed at reception notice board & is also available on request.
9. Customer requested for the above test only.

# Gujarat Laboratory

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APPROVED BY :
- "Agmark" Directorate of Marketing and Inspection, Govt. of India.
- Solvent Extractors Association of India.

## TEST REPORT

| | | | |
|---|---|---|---|
| Report No. | GL/F/2806017015 | | |
| Sample submitted by | Meck pharmaceutical & chemical p. ltd.<br>606,Harikrupa Tower,<br>S. M. Road Ellisbrige,<br>Ahmedabad - 380006 | Date of Receipt<br>Batch No. | 28/06/17<br>GH/01/17006 |
| Sample Described as | GLUCOSAMINE HYDROCHLORIDE USP | Mfg. Date | NM |
| Mode of packing | Sample packed in plastic bag | Exp. Date | NM |
| mple condition | Satisfactory | Sample Qty.: | 25gm |
| Marking | ------ | | |
| Analysis Date | 03/07/17 | | |

## MICRO REPORT

| Sr. No. | Test | Result | Specification |
|---|---|---|---|
| 1 | Total Aerobic Microbial count | 30 cfu / gm | Not more than 500 cfu / gm |
| 2 | Total yeast & mold count | 10 cfu / gm | Not more than 100 cfu / gm |
| 3 | Escherichia coli | Absent | Should be absent |
| 4 | Pseudomonas aeruginosa | Absent | Should be absent |
| 5 | Salmonella spp. | Absent | Should be absent |
| 6 | Staphylococcus aureus | Absent | Should be absent |
| 7 | Bile tolerant gram negative bacteria | Absent | Should be absent |

N.M. = Not Mentioned, N.D. = Not Detected, D.L. =Detection Limit

For GUJARAT LABORATORY

Date of Issue : 03/07/17

Rupesh Desai
Autho. Signatory

Note:

1. The result refer only to be tested sample & applicable parameters, endorsement of product is neither inferred nor implied.
2. Total liability of our institution to be invoice amount/testing charges.
3. This report is not to be reproduced wholly or in part and cannot be used as an evidence in the court of law and should not be used in any advertising media without our special permission in writing.
4. Sample drawn & submitted by the party for analysis unless otherwise stated.
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6. Subject to Ahmedabad jurisdiction.
7. Perishable sample will be destroyed after testing, others after three weeks from the data of issue of the report, unless otherwise agreed with the customer.
8. The sample is accepted by us subject to our general condition of services which is displayed at reception notice board & is also available on request.
9. Customer requested for the above test only.