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Ref:USP-38	Revision no:02		Supersedes no: TQC/GSPC/080-01	

	Prepared by	Reviewed by	Approved by
Name	Hardik	J P PATEL	M.R.Patel
Designation	Chemist QA	Sr. Chemist QA	Incharge QA/QC
Signature	Hardik	J.P.Patel	
Date	03/05/15	07/05/15	07/05/15

NAME OF PRODUCT: GLUCOSAMINE SULPHATE POTASSIUM CHLORIDE GP/01/17/014

Sr No	Test	Standard testing procedure
01	Appearance	White to off white crystalline powder. **Procedure:** Take the 5.0016 (5.0 g) of the material in Petri dish and record its appearance. Observation: White Crys. Powder Remark : Complies Analyzed by & Date: 10/08/17 Reviewed by: 10/8/17
02	Identification Test	**a) Identification by IR** **Sample:** transfer 50mg of glucosamine sulphate potassium chloride to a centrifuge tube, and dissolve in 2ml of water. Add 0.5ml of barium chloride TS, and centrifuge. Collect the supernatant, and evaporate to dryness. Dry the residue at 105° for 2 h. **Acceptance criteria:** The IR spectrum of the sample matches that of a similar preparation of USP glucosamine hydrochloride RS, except that the addition of barium chloride TS is omitted. **b) Identification by Chloride test / potassium** **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:** **Chloride-**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 13.5M Ammonia solution, from which it is precipitate by the addition of 10 % w/w solution of Nitric Acid. Complies, Curdy white precipitate observed Sachin. 10/08/17 10/08/17

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Signature	Hardik	J.P.Patel	
Date	03/05/15	05/05/15	07/05/15

NAME OF PRODUCT: GLUCOSAMINE SULPHATE POTASSIUM CHLORIDE GSP/01/17/014

Potassium—Potassium compounds impart a violet color to a nonluminous flame, but the presence of small quantities of sodium masks the color unless the yellow color produced by sodium is screened out by viewing through a blue filter that blocks emission at 589 nm (sodium) but is transparent to emission at 404 nm (potassium). Traditionally, cobalt glass has been used, but other suitable filters are commercially available. In neutral, concentrated or moderately concentrated solutions of potassium salts (depending upon the solubility and the potassium content), sodium bitartrate TS produces a white crystalline precipitate that is soluble in 6 N ammonium hydroxide and in solutions of alkali hydroxides and carbonates. The formation of the precipitate, which is usually slow, is accelerated by stirring or rubbing the inside of the test tube with a glass rod. The addition of a small amount of glacial acetic acid or alcohol also promotes the precipitation.

c) 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:	RT of 1st Standard injection 3.953 ✓ RT of 1st Sample Injection 3.974 ✓ RT of 2nd Sample Injection 3.974 ✓
Remark : Complies	
Analyzed by & Date:	JMh - 10/08/17 RLP 10/08/17

d) Sulfate :

In the test for content of sulfate , after the addition of barium chloride TS a white precipitate is formed.

Observation:	A White ppt is formed
Remark :	Complies
Analyzed by & Date:	JMh - 10/08/17 RLP 10/08/17

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Designation	Chemist QA	Sr. Chemist QA	Incharge QA/QC
Signature	Hardik	J.P.Patel	
Date	03/05/15	05/05/15	07/05/15

NAME OF PRODUCT: GLUCOSAMINE SULPHATE POTASSIUM CHLORIDE GP/01/17/014

Sr No.	TEST	Standard testing procedure
3	Optical Rotation	Between +47° and +53° **Procedure:** Accurately weighing 3.4934 (3.5 g) of the substance in 100 (100-ml) 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) Polari meter 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	1.75°
02	0.00	02	1.75°
03	0.00	03	1.75°
04	0.00	04	1.74°
05	0.00	05	1.76°
Average	0.00	Average	1.75°

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 Polari meter 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)

$$= \frac{100 \times 1.75}{3.4934 \times 1 \times (100 - 0.21)} \times 100$$

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Designation	Chemist QA	Sr. Chemist QA	Incharge QA/QC
Signature	Hardik	J P Patel	
Date	03/05/15	05/05/15	07/05/15

NAME OF PRODUCT: GLUCOSAMINE SULPHATE POTASSIUM CHLORIDE GP/01/17/014

		Observation +50.20° Remarks Complies Analyzed by & Date: HB - 10/08/17 RDM 10/08/17

Sr No.	TEST	Standard testing procedure
4	pH (2.0 % solution)	Between 3.0 and 5.0 **Procedure:** 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). Observation 4.68 Remarks Complies Analyzed by & Date: HB - 10/08/17 RDM 10/8/17
5	Loss on drying 105°c for 2 h	Not more than 1.0%w/w **Procedure:** 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 1.0019 (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.

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Designation	Chemist QA	Sr. Chemist QA	Incharge QA/QC
Signature	Hardik	J P Patel	
Date	03/05/15	05/05/15	07/05/15

NAME OF PRODUCT: GLUCOSAMINE SULPHATE POTASSIUM CHLORIDE Gp101/9/014

Sr No.	TEST	Standard testing procedure
		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 W3= Weighing of the LOD bottle + sample (After drying) in g W1 31.1706 W2 31.1706 % of LOD = 0.0021 / 1.0019 x 100 Observation: 0.21 % Remark: Complies Analyzed by & Date: MB - 10/08/17 ROD 10/08/17
6	Residue on. Ignition	26.5% - 31.0% **Procedure:** Take the Silica crucible and ignite at 650° (650°± 25°C) for 30 minutes. Allow to cool in a desiccator over silica gel and weigh. (W1) Place the 1.0090 (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

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Signature	Hardik	J.P.Patel	
Date	03/05/15	05/05/15	07/05/15

NAME OF PRODUCT: GLUCOSAMINE SULPHATE POTASSIUM CHLORIDE Grp 01/17/014

Sr No.	TEST	Standard testing procedure
		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. $\% \text{ of ROI} = \frac{W3 - W1}{W2 - W1} \times 100$

W1	Weight of crucible in g	34.5995
W2	Weight of crucible + sample in g (Before ignition)	35.6085
W3	Weight of crucible + sample in g residue(After ignition)	W1 34.8875 W2 34.8875

ROI

Observation: ~~LOD~~ 28.54 % w/w

Remarks: - 10/08/17 10/08/17

7	Sulphate	15.5 % – 16.5 % **Reagents:** 6 N Hydrochloric Acid. Barium Chloride TS. Silver Nitrate TS. **Procedure:** Transfer about 1 g of Glucosamine Sulfate Potassium Chloride, accurately Weighed, to a 250 ml beaker, and dissolve in about 100 ml of water. Add 4 ml of 6N Hydrochloric acid. Heat the solution to boiling, and add, with constant stirring, sufficient boiling barium chloride TS to completely precipitate the sulfate. Add an additional 2 ml of barium chloride TS, and digest on a steam bath for 1 hour.

Sr No.	TEST	Standard testing procedure
		Pass the mixture through ashless filter paper, transferring the residue quantitatively to the filter, and wash the residue with hot water until no precipitate is obtained when 1 ml of Silver nitrate TS is added to 5ml of Washing. Transfer the paper containing the residue to a tared crucible. Char the paper, Without burning ,and ignite the crucible and its contents to constant Weight. Calculate the content of Sulfate by multiplying the weight obtained by 0.4116. The content of sulfate is between 15.5 and 16.5% Observation: I 16.16 % w/w Remark: Complies Analyzed by & Date: HB - 10/08/17 RDP 10/08/17
8	Sodium Content	Should be absent (As per USP) A Solution (1 in 10), tested on a Platinum wire, does not impart a pronounced yellow color to a nonluminous flame. Observation: Complies Not impart pronounced yellow color Remark: Complies Analyzed by & Date: HB - 10/08/17 RDP 10/08/17

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Signature	Hardik	J.P.Patel	
Date	03/05/15	05/05/15	07/05/15

NAME OF PRODUCT: GLUCOSAMINE SULPHATE POTASSIUM CHLORIDE GP/01/17/014

Sr No.	TEST	Standard testing procedure
9	Assay by HPLC	Between 98.0% and 102.0% **Buffer:** In a 1 – L Volumetric flask, .dissolve 3.5 g of diabasic 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 Anaxure Attached Mobile phase : Acetonitrile and Buffer (75 : 25) Diluent : Acetonitrile and water (50 : 50) **Standard Solution** : 3.8mg/ml of USP Glucosamine Hydrochloride RS in Diluent 193 mg working standard in 50 ml diluent. **Sample Solution** : Transfer 263 mg of Glucosamine Sulfate potassium chloride to a 50-ml volumetric flask .Dissolve in 30 ml of Diluent, and shake by mechanical means. Dilute with Diluent to volume. 259.3 sample in 50 ml 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

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Signature	Hardik	J.P Patel	
Date	03/05/15	05/05/15	07/05/15

NAME OF PRODUCT: GLUCOSAMINE SULPHATE POTASSIUM CHLORIDE GSP/01/17/014

Sr No.	TEST	Standard testing procedure
		Suitability requirements : Tailing factor : NMT 2.0 for the glucosamine peak 1.36 Efficiency ; NLT 1200 theoretical plates - 2284.387 Relative standard deviation : NMT 2.0 % - 1.07214 Analysis **Sample** : Standard solution and sample solution Calculate the percentage of glucosamine Sulfate potassium chloride $[(C_6H_{14}NO_5)_2SO_4 .2KCL]$ in the portion of Glucosamin Sulfate potassium Chloride taken : Result $= (ru/rs) \times (Cs/Cu) \times (M_{r1}/M_{r2}) \times 100$ ru = peak response from the sample solution. rs = peak response from the standard solution. Cs = concentration of USP Glucosamine Hydrochloride RS in the Standard solution (mg/ml) Cu = concentration of Glucosamine Hydrochloride in the sample solution (mg/ml) M_{r1} = molecular weight of glucosamine sulfate potassium chloride,(605.52) M_{r2} = twice the molecular weight of glucosamine hydrochloride(431.26) * Excel Sheet Attached LOD: 0.21 % **Calculation** (ru) 2151287 x (cs) 193 x (Mr_1) 605.52 x n 100 x 99.76 / 100 (rs) 2251287 (cu) 259.3 (Mr_2) 431.26 (100 - LOD 0.21)

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NAME OF PRODUCT: GLUCOSAMINE SULPHATE POTASSIUM CHLORIDE GP/01/17/014

Sr No.	TEST	Standard testing procedure
*10	Particles size	As per party spec. Take 10 gm sample and pass through selected sieve and calculate the return. Observation: 100 % Pass through 80 Mesh Remark : Complies Analyzed by & Date: - 10/08/17 10/08/17
*11	Heavy metals Lead Arsenic Cadmium Mercury	By ICPMS Instrument QL/F/040801702 2 Attached
*12	Microbiological	As per TQC MOA: TQC/MBL/135-00 QL/F/040801702 3 Attached

Gujarat Laboratory

AN ISO 9001 : 2008 CERTIFIED LABORATORY

F-17, MADHAVPURA MARKET, SHAHIBAUG, AHMEDABAD - 380 004.
Tele Fax : (079) 25626040, 25624821, 25625436, 25620753
Email : gujlab@gmail.com • Website : www.gujaratlaboratory.com

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

TEST REPORT

Report No.	GL/F/0408017022		
Sample submitted by	Meck pharmaceutical & chemical p. ltd. 606,Harikrupa Tower, S. M. Road Ellisbrige, Ahmedabad - 380006	Date of Receipt Batch No.	04/08/17 GP/01/17/014
Sample Described as	GLUCOSAMINE SULFATE POTASSIUMCHLORIDE USP	Mfg. Date Exp. Date	NM NM
Mode of packing	Sample packed in plastic bag	Sample Qty.:	20gm
Sample condition	Satisfactory		
Marking	------		
Analysis Date	07/08/17		

Sl.	Test Name	Result	Test Method
	Heavy metals		
1	Arsenic (as As) ppm	N.D.(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

Date of Issue : 07/08/17

For GUJARAT LABORATORY

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.

08/08/17

Gujarat Laboratory

AN ISO 9001 : 2008 CERTIFIED LABORATORY

F-17, MADHAVPURA MARKET, SHAHIBAUG, AHMEDABAD - 380 004.
Tele Fax : (079) 25626040, 25624821, 25625436, 25620753
Email : gujlab@gmail.com • Website : www.gujaratlaboratory.com

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

TEST REPORT

Report No.	GL/F/0408017023		
Sample submitted by	Meck pharmaceutical & chemical p. ltd. 606,Harikrupa Tower, S. M. Road Ellisbrige, Ahmedabad - 380006	Date of Receipt Batch No.	04/08/17 GP/01/17/014
Sample Described as	GLUCOSAMINE SULFATE POTASSIUM CHLORIDE USP	Mfg. Date Exp. Date	NM NM
Mode of packing	Sample packed in plastic bag	Sample Qty.:	20gm
Sample condition	Satisfactory		
Marking	------		
Analysis Date	09/08/17		

MICRO REPORT

Sr. No.	Test	Result	Specification
1	Total Aerobic Microbial count	25 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 : 10/08/17

Rupesh Desai
Autho. Signatory

End of Report

Note:

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2. Total liability of our institution to be invoice amount/testing charges.
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9. Customer requested for the above test only.

10/08/17