



**MECK PHARMACEUTICALS & CHEMICALS PVT LTD, SANAND, AHMEDABAD.**

FORMATE NO: QCS/F/029

**LONG TERM STABILITY DATA**

**QUALITY CONTROL DEPARTMENT**

Name of the product: **GLUCOSAMINE HYDROCHLORIDE USP**

Mfg date: Oct-2009  
Temperature: 25 ± 2°C

Stability chamber ID No: STCH/001

Exp/Retest date:-----  
Relative Humidity: 60 ± 5% RH  
Page no : 1 of 2

Sr No	Tests	Analysis after					Specifications
		INITIAL	3 Month	6 Month	9 Month	12 Month → 72M	
1	Description	Pass the test	Pass the test	Pass the test	Pass the test	Pass the test	Write to off white crystalline powder
2	Identification	Pass the test	Pass the test	Pass the test	Pass the test	Pass the test	Test b &c
3	Specific optical rotation ( 2.5% solution in & on dry basis)	+71.70°	+71.72°	+71.73°	+71.73°	+71.73°	+70° and +73°
4	Residue on ignition	0.08%	0.08%	0.08%	0.08%	0.082%	Not more than 0.1%
5	pH (2% w/v solution)	4.40	4.40	4.38	4.37	4.36	Between 3.0 and 5.0
6	Loss on drying at 105°C	0.21%	0.17%	0.20%	0.23%	0.18%	Not more than 1.0%
7	Sulphate content	Complies	Complies	Complies	Complies	Complies	Not more than 0.24%
8	Assay By HPLC on dried basis	99.80	99.78	99.76	99.76	99.74	Between 98.0% to 102.0%
Date of analysis		04/10/2009	08/01/2010	04/04/10	06/07/10	10/10/2010	
Analyzed by		<i>mehal</i>	<i>mehal</i>	<i>mevuss</i>	<i>mevuss</i>	<i>mevuss</i>	<p align="center"><b>A.C. APPROVED</b></p>
Reviewed by		<i>mehal</i>	<i>mehal</i>	<i>mevuss</i>	<i>mevuss</i>	<i>mevuss</i>	
Approved by		<i>mehal</i>	<i>mehal</i>	<i>mevuss</i>	<i>mevuss</i>	<i>mevuss</i>	



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Relative Humidity: 60 ± 5% RH

Page no : 2` of 2

Sr No	Tests	Analysis after						Specifications
		18 Month	24 Month	36 Month	48 Month	60 Month	72 Month	
1	Description	Pass the test	Pass the test	Pass the test	Pass the test	Pass the test	Pass the test	White to off white crystalline powder Test b &c  +70° and +73°  Not more than 0.1%  Between 3.0 and 5.0  Not more than 1.0%  Not more than 0.24%  Between 98.0% to 102.0%
2	Identification	Pass the test	Pass the test	Pass the test	Pass the test	Pass the test	Pass the test	
3	Specific optical rotation (2.5% solution in & on dry basis)	+71.33°	+71.30°	+71.73°	+71.70°	+71.30°	+71.30°	
4	Residue on ignition	0.082%	0.082%	0.085%	0.083%	0.085%	0.085%	
5	pH (2% w/v solution)	4.33	4.32	4.30	4.28	4.25	4.22	
6	Loss on drying at 105°C	0.198%	0.17%	0.19%	0.19%	0.18%	0.18%	
7	Sulphate content	Complies	Complies	Complies	Complies	Complies	Complies	
8	Assay by HPLC on dried basis	99.73	99.70	99.67	99.63	99.62	99.60	
Date of analysis		04/04/2011	05/10/2011	10/10/2012	12/10/2013	08/10/2014	04/10/2015	
Analyzed by		Milem.	Mayun.	Nehal	Nehal.	Mayun.	Milem.	
Reviewed by								
Approved by								

Q.C. APPROVED





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Mfg date: Oct-2009

Exp/Retest date:-----


Temperature: 25 ± 2°C

Relative Humidity: 60 ± 5% RH

Batch No.: GH/01/09/001

Stability chamber ID No: STCH/001

Page no : 1 of 2

Sr No	Tests	Analysis after					Specifications
		INITIAL	3 Month	6 Month	9 Month	12 Month → 72M	
1	Description	Pass the test	Pass the test	Pass the test	Pass the test	Pass the test	White to off white crystalline powder
2	Identification	Pass the test	Pass the test	Pass the test	Pass the test	Pass the test	Test b &c
3	Specific optical rotation (2.5% solution in & on dry basis)	+71.20°	+71.20°	+71.25°	+71.30°	+71.30°	+70° and +73°
4	Residue on ignition	0.08%	0.08%	0.08%	0.081%	0.082%	Not more than 0.1%
5	pH (2% w/v solution)	4.38	4.38	4.35	4.33	4.32	Between 3.0 and 5.0
6	Loss on drying at 105°C	0.18%	0.18%	0.18%	0.18%	0.18%	Not more than 1.0%
7	Sulphate content	Complies	Complies	Complies	Complies	Complies	Not more than 0.24%
8	Assay by HPLC on dried basis	99.72	99.69	99.68	99.65	99.60	Between 98.0% to 102.0%
Date of analysis		04/10/2009	08/01/2010	04/04/10	06/07/10	10/10/2010	
Analyzed by		Mehal.	Mehal.	Mayun.	Mayun.	Mayun.	
Reviewed by		Mehal.	Mehal.	Mayun.	Mayun.	Mayun.	
Approved by		Mehal.	Mayun.	Mayun.	Mayun.	Mayun.	



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Batch No.: GH/01/09/001

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Sr No	Tests	Analysis after						Specifications
		18 Month	24 Month	36 Month	48 Month	60 Month	72 Month	
1	Description	Pass the test	Pass the test	Pass the test	Pass the test	Pass the test	Pass the test	White to off white crystalline powder
2	Identification	Pass the test	Pass the test	Pass the test	Pass the test	Pass the test	Pass the test	Test b &c
3	Specific optical rotation (2.5% solution in & on dry basis)	+71.33°	+71.33°	+71.35°	+71.38°	+71.38°	+71.40°	+70° and +73°
4	Residue on ignition	0.082%	0.082%	0.084%	0.083%	0.084%	0.085%	Not more than 0.1%
5	pH (2% w/v solution)	4.30	4.30	4.28	4.30	4.28	4.25	Between 3.0 and 5.0
6	Loss on drying at 105°C	0.18%	0.18%	0.19%	0.19%	0.19%	0.19%	Not more than 1.0%
7	Sulphate content	Complies	Complies	Complies	Complies	Complies	Complies	Not more than 0.24%
8	Assay by HPLC on dried basis	99.57	99.57	99.55	99.53	99.52	99.50	Between 98.0% to 102.0%
Date of analysis		04/04/2011	05/10/2011	10/10/2012	12/10/2013	08/10/2014	04/10/2015	
Analyzed by		Nilesh	Mayur	Neel	Neel	Mayur	Nilesh	
Reviewed by		[Signature]	[Signature]	[Signature]	[Signature]	[Signature]	[Signature]	
Approved by		[Signature]	[Signature]	[Signature]	[Signature]	[Signature]	[Signature]	






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Name of the product: GLUCOSAMINE HYDROCHLORIDE USP		QUALITY CONTROL DEPARTMENT					Mfg date: Oct-2009		Exp/Retest date:-----	
Batch No.: GH/01/09/002		Stability chamber ID No: STCH/001					Temperature: 25 ± 2°C		Relative Humidity: 60 ± 5% RH	
		Analysis after					Page no : 1 of 2			
Sr No	Tests	INITIAL	3 Month	6 Month	9 Month	12 Month → 72M	Specifications			
1	Description	Pass the test	Pass the test	Pass the test	Pass the test	Pass the test	White to off white crystalline powder			
2	Identification	Pass the test	Pass the test	Pass the test	Pass the test	Pass the test	Test b & c			
3	Specific optical rotation (2.5% solution in & on dry basis)	+71.33°	+71.30°	+71.33°	+71.30°	+71.35°	+70° and +73°			
4	Residue on ignition	0.078%	0.078 %	0.08%	0.082%	0.082%	Not more than 0.1%			
5	pH (2% w/v solution)	4.40	4.38	4.40	4.39	4.37	Between 3.0 and 5.0			
6	Loss on drying at 105°C	0.198%	0.17%	0.19%	0.19%	0.18%	Not more than 1.0%			
7	Sulphate content	Complies	Complies	Complies	Complies	Complies	Not more than 0.24%			
8	Assay by HPLC on dried basis	99.60	99.57	99.56	99.54	99.54	Between 98.0% to 102.0%			
Date of analysis		04/10/2009	08/01/2010	04/04/10	06/07/10	10/10/2010				
Analyzed by		Nehal	Nehal	Maya	Maya	Maya				
Reviewed by		[Signature]	[Signature]	[Signature]	[Signature]	[Signature]				
Approved by		[Signature]	[Signature]	[Signature]	[Signature]	[Signature]	<div style="border: 1px solid black; border-radius: 50%; padding: 5px; display: inline-block;">Q.C. APPROVED</div>			



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1	Description	Pass the test	Pass the test	Pass the test	Pass the test	Pass the test	Pass the test	Write to off white crystalline powder
2	Identification	Pass the test	Pass the test	Pass the test	Pass the test	Pass the test	Pass the test	Test b & c
3	Specific optical rotation (2.5% solution in & on dry basis)	+71.35°	+71.35°	+71.37°	+71.36°	+71.38°	+71.36°	+70° and +73°
4	Residue on ignition	0.083%	0.085%	0.083%	0.083%	0.085%	0.086%	Not more than 0.1%
5	pH (2% w/v solution)	4.35	4.35	4.33	4.33	4.30	4.26	Between 3.0 and 5.0
6	Loss on drying at 105°C	0.19%	0.17%	0.19%	0.18%	0.18%	0.18%	Not more than 1.0%
7	Sulphate content	Complies	Complies	Complies	Complies	Complies	Complies	Not more than 0.24%
8	Assay by HPLC on dried basis	99.52	99.52	99.50	99.52	99.50	99.48	Between 98.0% to 102.0%
Date of analysis		04/04/2011	05/10/2011	10/10/2012	12/10/2013	08/10/2014	04/10/2015	
Analyzed by		Nilesh	Mayur	Mehal	Mehal	Mayur	Nilesh	
Reviewed by		Nilesh	Mehal	Mehal	Mehal	Mehal	Mehal	
Approved by		Mehal	Mehal	Mehal	Mehal	Mehal	Mehal	