 <b>INNOVA PHARMACTIVE PVT. LTD.</b>		<b>MASTER COPY</b>	
<b>TEST DATA SHEET</b>			
Specification No.		IP/QCD/IPS/002 (Revision No. 13)	
Product Name	Methylaminoacetaldehyde Dimethyl Acetal (Stage II) (MAMA)		Authorized By / Date : <i>M 23/11/2013</i>
Batch No.	<i>MAM 25321</i>		Issued By / Date : <i>Pt 12/09/2025</i>
A.R.No.	<i>CI 251302</i>		Page No. 1 of 3

• Test Summary Report:

Sampling Date	<i>12/09/2025</i>	Batch size	<i>30.10 kg</i>
Release Date	<i>12/09/2025</i>	Date of Mfg.	<i>SEP 2025</i>
		Date of Retest/Expiry	<i>FEB 2026</i>

Sr. No.	Test	Specification	Result
1	Appearance (*#)	Clear, Colorless to Pale Yellow, irritant liquid with characteristics, Ammonical odors.	<i>clear colorless irritant liquid with ammoniacal odors</i>
2	Specific Gravity at Room temperature (*).	Not Less than 0.92 – Not More than 0.96	<i>0.93</i>
3	Purity By GC (By area normalization) (*#)		
	MAMA	Not Less Than 89.0% area of Principle peak by area normalization.	<i>98.0%.</i>
	Stage 1 impurity:		
	BAMA at about RRT 1.03	Not More Than 0.2%	<i>ND</i>
	VAM at about RRT 0.37	Not More Than 0.1%	<i>ND</i>
	Methyl acetate at about RRT 0.35	Not More Than 0.1%	<i>ND</i>
	Methanol at about RRT 0.22	Not More Than 5.0%	<i>ND</i>
	Specified impurities		
	Impurity at about RRT 1.31	Not More Than 5.0%	<i>2.05%.</i>
	Largest Individual Unspecified impurity	Not More Than 0.2%	<i>ND</i>
	Total impurity	Not More Than 11.0%	<i>2.05%.</i>

Remark: The sample complies / ~~Does not complies~~ as per the specification No. IP/QCD/IPS/002.

Tested By/Date	Reviewed By/Date	Released By/Date
<i>R Dekate</i> <i>12/09/2025</i>	<i>[Signature]</i> <i>12/09/2025</i>	<i>[Signature]</i> <i>12/09/2025</i>



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TEST DATA SHEET			
Specification No.		IP/QCD/IPS/002 (Revision No. 13)	
Product Name	Methylaminoacetaldehyde Dimethyl Acetal (Stage II) (MAMA)		Authorized By / Date : <u>12/09/2025</u>
Batch No.	<u>MAM25321</u>		Issued By / Date : <u>PI-1 12/09/2025</u>
A.R.No.	<u>CI 251302</u>		Page No. 2 of 3

### 1.0 Appearance(\*#):

Date : 12/09/2025

Observation :

Drum Number	sample volume	Observation
<u>01</u>	<u>5 ml</u>	<u>clear colorless intermediate liquid with ammoniacal odour</u>

Tested By / Date : 12/09/2025 (Complies / Not Complies)

Reviewed By / Date : 12/09/2025

### 2.0 Specific Gravity at Room temperature (\*):

Date : 12/09/2025

Balance No.: IP/QCD/ELB1054

Specific gravity =  $\frac{\text{Weight of Pycnometer and sample (W2)} - \text{Weight of Empty Pycnometer (W1)}}{\text{Wt of Water (W4)}}$

Sample Name	Wt. of Pycnometer (W1)	Wt. Of sample and Pycnometer (W2)	Wt. Of Actual Sample (W3) = (W2-W1)	Specific gravity = $\frac{\text{Wt. of sample}}{\text{Wt. of water}}$
<u>MAMA</u>	<u>24.6848 g</u>	<u>49.6855 g</u>	<u>25.0007 g</u>	<u>0.933</u>
<u>water</u>	<u>24.6838 g</u>	<u>51.4728 g</u>	<u>26.7890 g</u>	<u>0.93</u>

Tested By / Date : 12/09/2025 (Complies / Not Complies)

Reviewed By / Date : 12/09/2025

### 3.0 Purity By GC (By area normalization) (\*#):

Date : 12/09/2025

Balance No.: IP/QCD/ELB1053

Instrument No.: IP/QCD/GC/049

Column ID: IP/QCD/COL/28-50/06

Chromatographic condition:

Equivalent column also used for GC analysis.

1	Analytical Column	Capillary ZB-50(0.25mm X 30 meter)
2	Carrier Gas	Nitrogen
3	Carrier gas flow	1.5ml/min
4	Column Oven temperature	35 °C (5.0min) to 250°C (15.0 min) @ 30 °C
5	Detector (FID) temperature	250 °C
6	Injector temperature	150°C
7	Split ratio	6.6 :1
8	Run time	27.17min.
9	Sample Size	0.5 µl

Procedure :

Preparation of Solution:

Preparation of System Suitability of mix standard solution (2000ppm) :

Weigh accurately of 20.47 mg of BAMA; 20.71 mg VAM, 20.42 mg Methyl acetate and 20.77 mg Methanol in 10 ml volumetric flask make up the volume up to 10 ml with Chloroform.



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TEST DATA SHEET		Authorized By / Date : <u>12/09/2025</u>	
Specification No.	IP/QCD/IPS/002 (Revision No. 13)		
Product Name	Methylaminoacetaldehyde Dimethyl Acetal (Stage II) (MAMA)		Issued By / Date : <u>12/09/2025</u>
Batch No.	<u>MAM 25321</u>		
A.R.No.	<u>QI 251302</u>		Page No. 3 of 3

**Test preparation(5000ppm):**

Weigh accurately of 50.38 mg sample in 10 ml volumetric flask make up the volume up to 10 ml with Chloroform.

Blank: Chloroform

For system suitability:

Name of peak	RT	Area
BAMA	8.601	28.5529
VAM	2.885	15.3386
Methanol	1.818	7.0233
Methyl acetate	2.636	6.8032

For Test:

Calculation :

For purity:

$$\% \text{ Purity} = \frac{\text{Area Test chromatogram} \times 100}{\text{Sum of area of all peak in Test chromatogram}}$$

For impurity:

$$\% \text{ Impurity} = \frac{\text{Area of impurities in test chromatogram} \times 100}{\text{Sum of area of all peak in Test chromatogram}}$$

Purity and Impurity will calculated by area normalization using above formula.

Observation:

Name of peak	RT	Area	percentage
MAMA Test	8.230	32.2430	97.95 $\approx$ 98.0%
BAMA at about RRT 1.03	ND	ND	ND
VAM at about RRT 0.37	ND	ND	ND
Methyl acetate at about RRT0.35	ND	ND	ND
Methanol at about RRT 0.22	ND	ND	ND
Impurity at about RRT 1.31	10.813	0.6754	2.05%
Largest Individual Unspecified impurity	ND	ND	ND

Total impurity : Sum of all impurities = 1 to 5

(Complies / Not Complies)

Tested By / Date: RD kate  
12/09/2025

Reviewed By / Date: 12/09/2025

Raw data, chromatograms, Titration Report are attached with the Test Data Sheet. If applicable.


Comment: No

Conclusion: The above sample is Complies / ~~Does not complies~~ with the tests as per Specification No. IP/QCD/IPS/002.

Released By :

Date :

12/09/2025




	INNOVA PHARMACTIVE PVT. LTD.		MASTER COPY		
	TEST DATA SHEET			Authorized By / Date : 10/09/2025	
Specification No.		IP/QCD/IPS/002 (Revision No. 13)		Issued By / Date : 07/09/2025	
Product Name	Methylaminoacetaldehyde Dimethyl Acetal (MAMA) (Stage II) (Inprocess MAMA)				
Batch No.	MAM25321				
A.R.No.	Q251278			Page No.	1 of 3

• Test Summary Report:


Sampling Date	07/09/2025	Batch size	50.0kg
Release Date	07/09/2025	Date of Mfg.	NA
		Date of Retest/Expiry	NA

Sr. No.	Test	Specification	Result
1	Appearance (*#)	Colorless to Pale Yellow, irritant liquid with characteristics, Ammonical odors.	pale yellow irritant liquid with characteristics Ammonical odors
2	BAMA Content (*)	Not More Than 5% area of BAMA.	BAMA content not detected

Remark : The sample ~~Does not~~ complies as per the specification No. IP/QCD/IPS/002.

Tested By/Date	Reviewed By/Date	Released By/Date
 07/09/2025	 07/09/2025	 07/09/2025



 <b>INNOVA PHARMACTIVE PVT. LTD.</b>		<b>MASTER COPY</b>	
<b>TEST DATA SHEET</b>			
Specification No.		IP/QCD/IPS/002 (Revision No. 13)	
Product Name	Methylaminoacetaldehyde Dimethyl Acetal (MAMA) (Stage II) (Inprocess MAMA)		Authorized By / Date : <u>07/09/2025</u>
Batch No.	<u>MAM 25321</u>		Issued By / Date : <u>07/09/2025</u>
A.R.No.	<u>QI251278</u>		Page No. 2 of 3

### 1.0 Appearance (\*#):

Date: 07/09/2025 07/09/2025

Observation: pale yellow irritant liquid with  
characteristic Ammoniacal odors

(Complies / Not Complies)

Tested By / Date : 07/09/2025

Reviewed By / Date : 07/09/2025

### 2.0 BAMA Content (\*):

Date: 07/09/2025

Balance No.: IP/QCD/ELB/053

Instrument No.: IP/QCD/GC/1036

Column ID: IP/QCD/COL/PAC/18

#### Chromatographic condition:

Equivalent column also used for GC analysis.

1	Analytical Column	5% Carbowax X 2M and 1%, KOH, chromosorb GHP 80-100#
2	Carrier Gas	Nitrogen
3	Carrier gas flow	30ml/min
4	Column Oven temperature	50 °C (30sec) to 200 °C(0.0 min) @ 8.0 °C
5	Detector (FID) temperature	200 °C
6	Injector temperature	200 °C
7	Run time	19.25 min.
8	Sample Size	0.5 µl

#### Procedure:

##### Preparation of Solution:

##### Preparation of 50% Potassium hydroxide:


Weigh accurately 5.00178 g of Potassium hydroxide in 10 ml volumetric flask and make up the volume up to 10 ml with distilled water.

##### Blank Preparation:

Dissolve 10 ml diethyl ether and 5 ml 50% potassium hydroxide solution in test tube

##### Test Preparation:

Take 5 ml of sample in separating funnel add 5 ml 50% potassium hydroxide solution and allow cooling and then add 10 ml diethyl ether. Shake the sample properly to Separate the layer. Discard the aqueous layer and collect the upper organic layer for analysis.

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	TEST DATA SHEET			Authorized By / Date : <u>23/12/2025</u>	
Specification No.		IP/QCD/IPS/002 (Revision No. 13)		Issued By / Date : <u>07/09/2025</u>	
Product Name	Methylaminoacetaldehyde Dimethyl Acetal (MAMA) (Stage II) (Inprocess MAMA)				
Batch No.	MAM25821				
A.R.No.	01251278			Page No.	3 of 3

For Test:

Calculation :

1. First Sample:

Name of peak	RT	Area	Percentage
BAMA	ND	ND	ND

Observation: BAMA not detected

(Complies / ~~Not Complies~~)

Tested By / Date : 07/09/2025

Reviewed By / Date : 07/09/2025

2. Second Sample:

Name of peak	RT	Area	Percentage
BAMA			

Observation: \_\_\_\_\_

(Complies / Not Complies)

Tested By / Date: NA

Reviewed By / Date:

3. Third Sample:

Name of peak	RT	Area	Percentage
BAMA			

Observation: \_\_\_\_\_

(Complies / Not Complies)

Tested By / Date:

Reviewed By / Date: 07/09/2025

Raw data, chromatograms, Titration Report are attached with the Test Data Sheet. If applicable.

Comment : NO

Conclusion: The above sample is Complies / ~~Does not complies~~ with the tests as per Specification No. IP/QCD/IPS/002.

Released By : NA

Date : 07/09/2025