	INNOVA PHARMACTIVE PVT. LTD.		MASTER COPY	
	TEST DATA SHEET			Authorized By /
	Specification No.	IP/QCD/PRS/006 (Revision No: 16)		Date : 16/10/2025
Product Name	CARBIMAZOLE IP (Blending Analysis)			Issued By /
Batch No.	CAR25149			Date : 05/10/2025
A.R.No.	QFI25214			Page No. 1 of 8

• Test Summary Report:


Sampling Date	05/10/2025	Batch size	26.40kg
Release Date	07/10/2025	Date of Mfg.	OCT 2025
		Date of Retest/Expiry	SEP 2029

Sr. No.	Test	Specification	Result
1	Description(*)	A white or creamy – white, crystalline powder.	white crystalline powder.
2	Solubility	Freely soluble in chloroform, soluble in acetone, sparingly soluble in ethanol (95%), slightly soluble in water and in ether.	complies
3	Identification		
	A) By Infrared Absorption Spectrophotometry	Compare the spectrum with that obtained with Carbimazole RS or with the reference spectrum Carbimazole.	* complies
	B) Chemical Test	A red precipitate is produced.	complies
	C) Thiamazole and other related substances	The principal peak in the chromatogram obtained with the test solution corresponds to that in the chromatogram obtained with reference solution (c).	complies
4	Thiamazole and other Related substance (By liquid chromatography)(*)		
	Impurity A	Not More Than 0.5%	ND
	Other related substances	Not More Than 0.1%	ND
	Total Impurity	Not More Than 0.6%	ND
5	Loss on drying(*) (In-house)	Not more than 0.3%	0.20%.
6	Sulphated ash	Not more than 0.1 %	0.02%.
7	Assay (By liquid chromatography)(*)	Not less than 98.0% and not more than 102.0% (Dried Substance)	99.9%.
8	Mesh size test	100% material passes through 85#	100.0%.
		Not Less Than 98% passes through 100#	99.0%.

Remark: The Sample Complies / ~~Does not complies~~ as per the specification No. IP/QCD/PRS/006.

Tested By/Date	Reviewed By/Date	Approved By/Date
M. S. K. N. S. 07/10/2025	R. Dekate 07/10/2025	N. S. 07/10/2025



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Product Name	CARBIMAZOLE IP (Blending Analysis)			Issued By /
Batch No.	CAR25149			Date : 05/11/2023
A.R.No.	QFI25214			Page No. 2 of 8

### 1.0 Description(\*):

Date : 06/10/2025

Balance No.: 512161237253

Weight of Sample: 1.0006g

Observation: white crystalline powder

(Complies / Not Complies)

Tested By/Date: M. Raju 06/10/2025

Reviewed By/Date: R. Dekate 07/10/2025

### 2.0 Solubility :

Date : 07/10/2025

Balance No.: IP/QCD/ELB/066

Sample Quantity	Solvent and Solvent Quantity	Observation	Result
1.0002g	Chloroform 10ml	Freely soluble	Complies
0.3014g	Acetone 10ml	Soluble	Complies
0.0108g	Ethanol (95%) 10ml	Sparingly Soluble	Complies
0.0104g	Water 10ml	Slightly soluble	Complies
0.0108g	Ether 10ml	Slightly soluble	Complies

(Complies / Not Complies)

Tested By/Date: Nial 07/10/2025

Reviewed By/Date: R. Dekate 07/10/2025

### 3.0 Identification Test:

#### A) Infrared Absorption Spectrophotometry :

- By using pallet:

Date :

Balance No.:

Instrument No.:

#### 1) For Standard:

Carbimazole WS Batch number :

	Weight(mg)
Weight of KBR	
Weight of WRS standard	

#### 2) For Test:

NA	Weight (mg)
Weight of KBR	
Weight of Test	

Observation:

(Complies / Not Complies)


Tested By/Date: Nial 06/10/2025

Reviewed By/Date:

IP/QAD/SOP/010/F03





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Product Name	CARBIMAZOLE IP (Blending Analysis)			Issued By /
Batch No.	<u>CA R 2 S 1 4 9</u>			Date : <u>05/10/2025</u>
A.R.No.	<u>QFI25214</u>			Page No. 3 of 8

• By using ATR:

Date : 06/10/2025

Balance No.: 06110 IP/QCD/ELB1053

Instrument No.: IPI/QCD/IFTR1048

Nial  
06/10/2025

Observation: IR Spectrum of test sample is concordant with spectrum of carbimazole working standard

Tested By/Date: Nial  
06/10/2025

Chromatogram No. 1 to 4

(Complies / Not Complies)

Reviewed By/Date: RDekate  
07/10/2025

B) Chemical Test:

Date: 07/10/2025

Balance No.: IPI/QCD/ELB1053

Preparation of Potassium iodobismuthate solution:

Batch Number Potassium iodobismuthate solution: Q R-18 1250 828

Date of Preparation: 28/08/2025

Test:

Take 0.01011 g of sample in a test tube. Dissolve it in a mixture of 0.05 ml of dilute hydrochloric acid and 50 ml of distilled water. Add 1 ml of potassium iodobismuthate solution.

Observation: A red precipitate produced

Tested By/Date: Nial  
07/10/2025

(Complies / Not Complies)

Reviewed By/Date: RDekate  
07/10/2025

C) Thiamazole and other related substances (#):

Date: 07/10/2025

Balance No.: SP12157 EUB1053

Instrument No.: SP12157 HPL1063

Observation: complies

(Complies / Not Complies)

Tested By/Date: M. Panik  
07/10/2025

Reviewed By/Date: RDekate  
07/10/2025

4.0 Thiamazole and other Related substance (By liquid chromatography)(\*)

Date: 07/10/2025

Balance No.: SP12157 EUB1053

Instrument No.: SP12157 HPL1063


Column ID: SP12157 (02118139)

Chromatographic system:

1	HPLC System	: <u>Solvent system</u>
2	Mobile phase	: <u>degassed Acetonitrile, water (10:90 v/v)</u>
3	Stationary phase:	: <u>octadecylsilane bonded to porous silica (5um)</u>
4	Column	: <u>C-18</u>
5	Column size	: <u>15 cm x 3.9 mm 5 micron</u>
6	Wavelength	: <u>254 nm</u>
7	Flow rate	: <u>1 ml/min</u>
8	Temperature	: <u>at Room temperature</u>
9	Run time	: <u>20 min</u>
10	Injection volume	: <u>20 ul</u>

Mobile Phase: Acetonitrile : water (10:90 v/v) degas through 0.45 um bubble



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Product Name	CARBIMAZOLE IP (Blending Analysis)			Issued By /
Batch No.	<u>CA R 2 S 1 4 9</u>			Date : <u>05/10/2025</u>
A.R.No.	<u>QFI 2 S 2 1 4</u>			Page No. 3 of 8

• By using ATR:

Date : 06/10/2025

Balance No.: 06110 IP/QCD/ELB1053

Instrument No.: IPI/QCD/IFTR1048

Nial  
06/10/2025

Observation: IR Spectrum of test sample is concordant with spectrum of carbimazole working standard

Tested By/Date: Nial  
06/10/2025

Chromatogram No. 1 to 4

(Complies / Not Complies)

Reviewed By/Date: RDekate  
07/10/2025

B) Chemical Test:

Date: 07/10/2025

Balance No.: IPI/QCD/ELB1053

Preparation of Potassium iodobismuthate solution:

Batch Number Potassium iodobismuthate solution: Q R-18 1250 828

Date of Preparation: 28/08/2025

Test:

Take 0.01011 g of sample in a test tube. Dissolve it in a mixture of 0.05 ml of dilute hydrochloric acid and 50 ml of distilled water. Add 1 ml of potassium iodobismuthate solution.

Observation: A red precipitate produced

Tested By/Date: Nial  
07/10/2025

(Complies / Not Complies)

Reviewed By/Date: RDekate  
07/10/2025

C) Thiamazole and other related substances (#):

Date: 07/10/2025

Balance No.: SPR 121 EUB1053

Instrument No.: SPR 121 HPL1063

Observation: complies

(Complies / Not Complies)

Tested By/Date: M. Pankaj  
07/10/2025

Reviewed By/Date: RDekate  
07/10/2025

4.0 Thiamazole and other Related substance (By liquid chromatography)(\*)

Date: 07/10/2025

Balance No.: SPR 121 EUB1053

Instrument No.: SPR 121 HPL1063


Column ID: SPR 121 (18/13)

Chromatographic system:

1	HPLC System	: <u>Solvent system</u>
2	Mobile phase	: <u>degassed Acetonitrile, water (10:90 v/v)</u>
3	Stationary phase:	: <u>octadecylsilane bonded to porous silica (5um)</u>
4	Column	: <u>C-18</u>
5	Column size	: <u>15 cm x 3.9 mm 5 micron</u>
6	Wavelength	: <u>254 nm</u>
7	Flow rate	: <u>1 ml/min</u>
8	Temperature	: <u>at Room temperature</u>
9	Run time	: <u>20 min</u>
10	Injection volume	: <u>20 ul</u>

Mobile Phase: Acetonitrile : water (10:90 v/v) degas through 0.45 um bitrite



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Product Name	CARBIMAZOLE IP (Blending Analysis)			Issued By /
Batch No.	<u>CAR25149</u>			Date : <u>05/10/2023</u>
A.R.No.	<u>QFI25214</u>			Page No. 4 of 8

Solvent Mixture : Acetonitrile : Water (20:80 v/v)

Carbimazole WS Batch number: CAR/WS/125/01

Thiamazole WS Batch number: MET/WS/24/01

Reference Solution (a): Dissolve 5.33 mg of Thiamazole WS (impurity A) in the solvent mixture and dilute to 100 ml with the solvent mixture. Mix 1 ml of the solution with 2 ml of the test solution (or preferably separate Carbimazole WS solution to be used) and dilute to 10 ml with the solvent mixture.

References Solution (b): Dissolve 5.43 mg of Thiamazole WS (impurity A) in the solvent mixture and dilute to 10 ml with the solvent mixture. Dilute 1 ml of the solution to 100 ml with the solvent mixture.

Test solution: Dissolve 0.22 mg of the of test sample in 10 ml of volumetric flask. Dissolve in solvent mixture and the volume up to 10 ml.

References Solution (c): Dissolve 25.58 mg of Carbimazole WS in the solvent mixture and dilute to 50 ml with the solvent mixture. And dilute 1 ml of the test solution to 100 ml with the solvent mixture. Dilute 5 ml of this solution to 10 ml with the solvent mixture.

System suitability:

Reference solution (a):

Sr. No	RT	Area (Thiamazole)	RT	Area (Carbimazole)	Resolution	Tailing Factor
1	2.163	15104.7167	12.632	15061.1232	28.03	1.03

Reference solution (b):

Sr. No	RT	Area(Thiamazole)
1	2.160	10552.8403

For Test:

Sr. No	RT	Area (Thiamazole)	RT	Area (Carbimazole)
1	0.000	0	12.323	75257.3892

Reference solution (c):

Sr. No	RT	Area (Carbimazole)
1	12.427	613.6915

Bracketing standard: (Reference Solution a)

Sr. No.	RT	Area (Thiamazole)	RT	Area (Carbimazole)	Resolution	Tailing factor
1	2.160	18310.5405	12.430	14696.3652	28.03	1.03 1.295

Calculation:


For Thiamazole and other related substance:

Impurity A:

$$= \frac{\text{Known}}{\text{Mean Astd}} \times \frac{\text{Wstd}}{10} \times \frac{1}{100} \times \frac{10}{\text{Wspl}} \times \frac{\% P}{100} \times 100$$

$$= \underline{1302}$$



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Product Name	CARBIMAZOLE IP (Blending Analysis)			Issued By /
Batch No.	CAR 25149			Date : 25/10/2025
A.R.No.	QFI 25214			Page No. 6 of 8

$$\begin{aligned} \text{\% Sulphated Ash} &= \frac{(\text{Wt. of crucible after H}_2\text{SO}_4 \text{ Ignition}) - (\text{Wt of Empty crucible})}{(\text{Wt. of sample})} \times 100 \\ &= \frac{35.0593 - 35.0591}{1.0007} \times 100 \\ &= 0.019 \approx 0.02 \% \end{aligned}$$

Tested By/Date: Mial 07/10/2025

(Complies / Not Complies)

Reviewed By/Date: RDebate 07/10/2025

#### 7.0 Assay (By liquid chromatography) :

Date: 06/10/2025

Balance No.: SP12 (67) E-31053  
Instrument No.: SP12 (67) H121052

Column ID: SP12 (67) C01 C18136

#### Chromatographic system:

1	HPLC System	: <u>Isco 600JL</u>
2	Mobile phase	: <u>De-gassed Acetonitrile, water (10:90 v/v)</u>
3	Stationary phase:	: <u>Octadecylsilane bonded to porous silica (5um)</u>
4	Column	: <u>C-18</u>
5	Column size	: <u>15 cm x 3.9 mm i.d. 5 micron</u>
6	Wavelength	: <u>254 nm</u>
7	Flow rate	: <u>1 ml/min</u>
8	Temperature	: <u>At Room temperature</u>
9	Run time	: <u>20 min</u>
10	Injection volume	: <u>20 µL</u>

Mobile Phase: Acetonitrile, water (10:90 v/v) De-gas through 0.45 µm filter.

Solvent Mixture: Acetonitrile, water (20:80 v/v)

Carbimazole WS Batch number: (AR) WJ2510

#### References Solution (d) :

Dissolve 5.10 mg of Carbimazole WS in the solvent mixture and dilute to 10 ml with the solvent mixture.

#### Test solution :


Dissolve 5.85 mg of the substance to be examined in the solvent mixture and dilute to 10 ml with the solvent mixture.

#### Observation:

For standard Reference solution (d):

Sr. No	RT	Area(Carbimazole)
1	13.027	62164.727
2	13.023	62115.997
Average		62140



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Product Name	CARBIMAZOLE IP (Blending Analysis)		Page No. 7 of 8	
Batch No.	<u>CAR25149</u>			
A.R.No.	<u>QFI25214</u>			

1. Tailing factor for Reference d : 0.84
2. Theoretical number of plates Reference d: 5223

For Test:

Sr. No	RT	Area (Carbimazole)
1	13.023	71126.4333
2	13.010	70995.1796
Average		71060.98645

For Bracketing standard ( Reference solution d):

Sr. No	RT	Area (Carbimazole)
1	13.077	62132.0138

Calculation :

For Assay:

Calculate the content of  $C_7H_{10}N_2O_2S$  on anhydrous basis.

$$\begin{aligned}
 &= \frac{\text{Mean Area of test sample} \times \text{Weight of Standard Sample}}{\text{Mean Area of ref (d)} \times \text{Weight of Test Sample}} \times 100 \\
 &= \frac{99.63}{100} \% \\
 &= \frac{\% \text{ Assay}}{(100 - \text{LOD})} \times 100 \\
 &= \frac{99.63}{99.80 (100 - 0.20)} \times 100 = 99.88 \approx 99.9 \%
 \end{aligned}$$

Result:

Assay Percentage	99.9%
------------------	-------

(Complies / Not Complies)

Tested By/Date: M. N. N. N. N.

Reviewed By/Date: R. Dekate  
07/10/2023

Chromatogram Page No.: 23 to 33

8.0 Mesh Size Test:

Date: 07/10/2023

Balance No.: IP/QCD/ELB/066

Instrument No. IP/QCD/STS/1025

Time Required: 5 min


$$\% \text{ sample pass} = \frac{A - C}{A} \times 100$$

	85#	100#
Weight of Sample taken(A)	10.0019g	9.9977g
Weight of sample Pass(B)	9.9977g	9.8945g
Weight of sample Retain(C)	0.0042g	0.1032g
% sample pass	99.95% $\approx$ 100.0%	98.96% $\approx$ 99.0%

(Complies / Not Complies)

IP/QAD/SOP/010/F03.0



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Tested By/Date: Nial  
07/10/2025

Reviewed By/Date: R Dekate  
07/10/2025

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

Comment: No

Conclusion: The above sample is Complies / ~~Does Not comply~~ with the tests as per Specification No. IP/QCD/PRS/006.

Approved By: Nial  
07/10/2025

Date :