



Global Calcium
Adding Life to Life

QA

CERTIFICATE OF ANALYSIS

Name of the Product : MIDAZOLAM HYDROCHLORIDE-III
Batch No. : MIDZH-ND-III2409002
Analytical Report No. : FP24-MIDZH-ND-III-002
Item Code : 141
Quantity Dispatched/Sample Quantity : 1 Kg
Mfg. date : August 2024
Expiry date/Retest date : July 2027

RESULTS OF ANALYSIS

S.No.	TEST PARAMETERS	SPECIFICATION	RESULTS
1.	Appearance	White to yellowish, crystalline powder.	white crystalline powder.
2.	Solubility	Practically insoluble in acetone, Soluble in aqueous acidic solutions and in methanol, sparingly soluble in ethanol (96%).	Complies
3.	Identification A. Infrared absorption Spectrophotometry B. Chloride Test	A. The IR spectrum of sample should be concordant with IR spectrum of Midazolam Hydrochloride CRS or with the reference spectrum of Midazolam Hydrochloride or with the working standard. B. A curdy white precipitate should be produced	Complies Complies
4.	pH (0.2%w/v in water)	Between 3.7 and 4.7	3.96
5.	Related Substances (BY HPLC)	Impurity B : Not more than 0.2% Impurity A, : Not more than 0.15% Impurity E, : Not more than 0.15% Impurity G, : Not more than 0.15% Impurity H, : Not more than 0.15% Unspecified Impurity : Not more than 0.1% Total Impurities : Not more than 0.3%	*Below Disregard Limit *Below Disregard Limit *Below Disregard Limit 0.05% *Below Disregard Limit 0.12% 0.29%
6.	Loss on drying	Not more than 0.5%	0.34%
7.	Sulfated ash	Not more than 0.1%	0.03%
8.	Assay (On dried basis) (By Potentiometry)	98.5% to 101.5%	100.1%

Remarks: Complies with the above prescribed Specifications.

PREPARED BY: Geetha
OFFICER - QUALITY ASSURANCE
DATE: 20 Sep 24

CHECKED BY: p.p.
HOD - QUALITY CONTROL
DATE: 20 Sep 24

APPROVED BY: [Signature]
HOD - QUALITY ASSURANCE
DATE: 20 Sep 24

Format Rev.No.QA014-F09-00

Page 1 of 2

www.globalcalcium.com

Email : info@globalcalciumpharma.com

CIN : U02429TZ1979PLC009346

Global Calcium Pvt. Ltd.

Corporate Office: No. 882, 6th Cross, 6th Block, Koramangala, Bengaluru - 560 095, India
Tel : 080-25530807 Fax : 080-25530807

REGD. OFFICE & PLANT: 124, 125 & 126, SIPCOT Industrial Complex, Hosur - 635 126, TAMILNADU, INDIA
Tel : 04344-106000 Fax : 04344-276126



Global Calcium
Adding Life to Life

QA

CERTIFICATE OF ANALYSIS

Name of the Product : MIDAZOLAM HYDROCHLORIDE-IH
Batch No. : MIDZH-ND-IH2409002
Analytical Report No. : FP24-MIDZH-ND-IH-002
Item Code : 141
Quantity Dispatched/Sample Quantity : 1 Kg
Mfg. date : August 2024
Expiry date/Retest date : July 2027
RESULTS OF ANALYSIS

S.No.	TEST PARAMETERS	SPECIFICATION	RESULTS
9.	Residual solvents (BY GC) (In-House)	Methanol : Not more than 3000 ppm Ethanol : Not more than 5000 ppm Acetone : Not more than 5000 ppm Isopropyl alcohol : Not more than 5000 ppm Dichloromethane : Not more than 600 ppm Toluene : Not more than 890 ppm Xylene : Not more than 2170 ppm Dimethyl Sulphoxide : Not more than 5000 ppm	92 ppm Not Detected 206 ppm Not Detected Not Detected Not Detected Not Detected Not Detected
10.	Bacterial Endotoxins	Not more than 3.7 EU/mg of Midazolam Hydrochloride	Complies
11.	Microbial Contamination (A) Total aerobic microbial count (B) Total Combined Yeasts/Moulds count (C) Escherichia Coli	Not more than 100 cfu/g Not more than 10 cfu/g Should be absent	Less than 100 cfu/g Less than 10 cfu/g Absent
Remarks: Complies with the above prescribed Specifications. *Below disregard limit : < 0.05%			
PREPARED BY: Geetha OFFICER - QUALITY ASSURANCE DATE: 20 Sep 24		CHECKED BY: J. R. HOD - QUALITY CONTROL DATE: 20 Sep 24	APPROVED BY: [Signature] HOD - QUALITY ASSURANCE DATE: 20 Sep 24
Name of the Customer: M/s. PT. MERSIFARMA TIRMAKU MERCUSANA. Date of Issue: 20 th Sep 2024			

Format Rev.No.QA014-F09-00

Page 2 of 2

www.globalcalcium.com

Email: info@globalcalciumpharma.com

CIN: U02424TZ1979PTC-NY0000

Global Calcium Pvt. Ltd.

CORPORATE OFFICE: No. 882, 6th Cross, 6th Block, Koramangala, Bengaluru - 560 095, INDIA
Tel: 91-80-4055 4500 Fax: 91-80-25530807

REGD. OFFICE & PLANT: 124, 125 & 126, Sreejit Industrial Complex, Hosur - 515 126, TAMILNADU, INDIA
Tel: 91-4344-400007 Fax: 91-4344-276126