SYNTHOKEM LABS PRIVATE LIMITED (UNIT-II)
Regd. Off. : P.B.No. 1911, B-5, INDUSTRIAL ESTATE, SANATHNAGAR, HYDERABAD - 500 018, TELANGANA STATE, INDIA.
PHONES : 0091-040-23702660, 23702061. website : www.synthokemlabs.com

CERTIFICATE OF ANALYSIS

Name of the Product	**METHOCARBAMOL USP**		
Customer Code	**EXP/S-95**	**QC No**	**FP/MC-IPA(AF)/23/080**
Batch No	**B/MC-IPA/12/23/080**	**Date of Analysis**	**28.12.2023**
Batch Quantity	**1500.0 kg**	**Mfg Date**	**DECEMBER 2023**
Dispatched Quantity	**300.0 kg**	**Expiry Date**	**NOVEMBER 2028**
No. of Containers	**12x25.0 kg**	**Reference**	**USP**

S.No	TEST	RESULT	SPECIFICATION
1	Description	White bulky powder, odourless	White bulky powder, odorless or having a slight characteristic odor.
2	Solubility	Complies	Sparingly soluble in water and in chloroform, Soluble in alcohol only with heating, Insoluble in benzene and in n - hexane.
3	Identification		
	a) Infrared absorption	Complies	IR spectrum of sample is concordant with reference sample spectrum.
	b) Assay (by HPLC)	Complies	The retention time of the Major peak of the sample solution corresponds to that of the standard solution as obtained in the assay.
4	Melting Range	94.5°C - 95.3°C	93°C - 96°C.
5	Loss on Drying (at 60°C for 2 hrs)	0.25%	Not more than 0.5% w/w.
6	Residue on Ignition	0.04%	Not more than 0.1% w/w.
7	Organic Impurities by HPLC		
	a) Guaifenesin	0.04%	Not more than 0.15% w/w.
	b) Guaifenesin β-Isomer	BDL	Not more than 0.05% w/w.
	c) Methocarbamol Isomer	BLQ	Not more than 0.05% w/w.
	d) Methocarbamol Dioxolone	BDL	Not more than 0.05% w/w.
	e) Any Individual Unspecified Impurity	0.01%	Not more than 0.05% w/w.
	f) Total Impurities	0.05%	Not more than 0.50% w/w.

Prepared by:	Approved by:	Released by:
Designation: Sr.Executive-QA	Designation: Asst.Manager-QC	Designation: DGM-QA
Name: S. Chakradhar	Name: K.Mangaiah	Name: M.V.V.Ramana
Date: 29/12/2023	Date: 29/12/23	Date: 29/12/2023

Factory : Plot No. 222 to 224 & 235 to 237, Phase - II, IDA Pashamylaram, Patancheru (Mandal), Sangareddy District -502319, Telangana State, India. Telephone : 0091-08455 - 224180

SYNTHOKEM LABS PRIVATE LIMITED (UNIT-II)
Regd. Off. : P.B.No. 1911, B-5, INDUSTRIAL ESTATE, SANATHNAGAR, HYDERABAD - 500 018, TELANGANA STATE, INDIA.
PHONES : 0091-040-23702660, 23702061. website : www.synthokemlabs.com

CERTIFICATE OF ANALYSIS

Name of the Product	**METHOCARBAMOL USP**		
Customer Code	**EXP/S-95**	**QC No**	**FP/MC-IPA(AF)/23/080**
Batch No	**B/MC-IPA/12/23/080**	**Date of Analysis**	**28.12.2023**
Batch Quantity	**1500.0 kg**	**Mfg Date**	**DECEMBER 2023**
Dispatched Quantity	**300.0 kg**	**Expiry Date**	**NOVEMBER 2028**
No. of Containers	**12x25.0 kg**	**Reference**	**USP**

S.No	TEST	RESULT	SPECIFICATION
8	Assay by HPLC (on dry basis)	100.4%	98.5% - 101.5% w/w.
9	Residual Solvents by Head Space GC (In-house)		
	a) Methanol	BDL	Not more than 250 ppm.
	b) Isopropyl alcohol	BLQ	Not more than 500 ppm.
	c) Toluene	BDL	Not more than 100 ppm.
10	Particle Size (In-House)		
	USS Sieve # 200 (75 microns)	90%	NLT 65% passes through
	USS Sieve # 325 (45 microns)	88%	NLT 45% passes through

BDL:Below Detection Limit and BLQ: Below Limit of Quantification.

LOD (Guaifenesin:0.006%, Guaifenesin β-Isomer:0.004%, Methocarbamol Isomer:0.005%,Methocarbamol dioxolone:0.002%)

LOQ(Guaifenesin:0.018%, Guaifenesin β-Isomer:0.01%, Methocarbamol Isomer:0.016%, Methocarbamol dioxolone:0.005%)

LOD (Toluene:4ppm, Methanol:10ppm, Isopropyl alcohol:9ppm)

LOQ (Toluene:11ppm, Methanol:28ppm,Isopropyl alcohol:26ppm)

Result: The product Complies as per the above specification.

Prepared by:	Approved by:	Released by:
Designation: Sr.Executive-QA	Designation: Asst.Manager-QC	Designation: DGM-QA
Name: S. Chakradhar	Name: K.Mangaiah	Name: M.V.V.Ramana
Date: 29/12/2023	Date: 29/12/23	Date: 29/12/2023

Factory : Plot No. 222 to 224 & 235 to 237, Phase - II, IDA Pashamylaram, Patancheru (Mandal), Sangareddy District -502319, Telangana State, India. Telephone : 0091-08455 - 224180