



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)/23/002 |
| Batch No | B/MC-IPA/02/23/002 | Date of Analysis | 18.02.2023 |
| Batch Quantity | 1500.0 Kg | Mfg Date | FEBRUARY 2023 |
| Dispatched Quantity | 500.0 Kg | Expiry Date | JANUARY 2028 |
| No. of Containers | 10x50.0 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 | 94.1°C - 94.8°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 | 0.06% | Not more than 0.1% w/w. |
| 7 | Organic Impurities by HPLC | | |
| | a) Guaifenesin | *BLQ | 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 | Not detected | Not more than 0.05% w/w. |
| | f) Total Impurities | Not detected | Not more than 0.50% w/w. |

| | | |
|------------------------------|----------------------------|----------------------|
| Prepared by: | Approved by: | Released by: |
| Designation: Sr.Executive-QA | Designation: Dy.Manager-QC | Designation: AGM-QA |
| Name: S. Chakradhar | Name: P.Sreenivasu | Name: N. Mallikarjun |
| Date: 07/03/2023 | Date: 07/03/2023 | Date: 07/03/2023 |



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|------|---|---------|------------------------|
| 8 | Assay by HPLC (on dry basis) | 100.2% | 98.5% - 101.5% w/w. |
| 9 | Residual Solvents by Head Space GC (In-house) | | |
| | a) Methanol | ***BLQ | Not more than 250 ppm. |
| | b) Isopropyl alcohol | ****BDL | Not more than 500 ppm. |
| | c) Toluene | ****BDL | Not more than 100 ppm. |
| 10 | Particle Size (In-House) | | |
| | USS Sieve # 200 (75 microns) | 92% | NLT 65% passes through |
| | USS Sieve # 325 (45 microns) | 88% | NLT 45% passes through |

*BLQ: Below limit of Quantification (Guaifenesin LOQ:0.018%) & (Methocarbamol Isomer LOQ: 0.016%)

** BDL: Below Detection Limit (Guaifenesin β -Isomer LOD:0.004%) & (Methocarbamol Dioxolone LOD: 0.002%)

***BLQ:Below Limit of Quantification (Methanol LOQ:28 ppm)

**** BDL: Below Detection Limit (Isopropyl alcohol LOD: 9 ppm) & (Toluene LOD: 4 ppm)

Result: The product Complies as per the above specification.

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Compounding Chemicals You Can Trust

| | | |
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| Name: S. Chakradhar | Name: P.Sreenivasu | Name: N. Mallikarjun |
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