



## Below are some suggestions for Pharmaceutical & Process Air Testing.

In general there are no "hard and fast" air quality standards except for breathing air requirements. One such requirement is OSHA 1910.134, CGA Grade D + Moisture, for breathing air in the workplace.

The air used in manufacturing processes should be evaluated by a competent technical individual to determine the appropriate, current good manufacturing practices, cGMP, to protect the safety of the employees and the integrity of the products. For FDA regulated operations this is per CFR 210 & 211.

| <b>General Guidelines for:</b>  | <b>Employee</b><br><u>Breathing Air</u><br><u>CGA Grade D + Moisture</u><br><u>(OSHA 1910.134)</u> | <b>Indirect</b><br><u>Product Contact</u><br><u>Compressed Air</u><br>(Nitrogen or CO <sub>2</sub> extra cost) | <b>Direct</b><br><u>Product Contact</u><br><u>Compressed Air</u><br>(Nitrogen or CO <sub>2</sub> extra cost) | <b>USP</b><br><u>Medical Air Analysis</u> |
|---|--|--|--|---|
| Oil Mist & Particulate(matter)  | 5 mg/m <sup>3</sup> (Oil Mist)   | 1 mg/m <sup>3</sup>  | 0.1 mg/m <sup>3</sup>  | 0.1 mg/m <sup>3</sup>                     |
| Moisture/Dew Point  | 10 °F Lower than ambient temp.   | 1267ppmv/0 °F  | See Note 1   | 10 °F                                     |
| Gaseous Hydrocarbons<br>(minus methane)   | N/A  | 5ppm   | 2ppm   | N/A                                       |
| Halogenated Hydrocarbons  | N/A  | 5ppm   | 1ppm   | N/A                                       |
| Oxygen %, CO ppm, CO <sub>2</sub> ppm,<br>NO, NO <sub>2</sub> , SO <sub>2</sub> | O <sub>2</sub> 19.5-23.5%,<br>CO 10ppm, CO <sub>2</sub> 1000ppm,                                   | N/A  | N/A  | (See specifications for details)          |
| Order TRI test item #   | A3   | B1   | C23 or A82   | A33                                       |

Note 1: The user should select an appropriate value typically in the range of 0 °F (1267ppmv) to -50 °F (67ppmv) depending on sensitivity of the product to water vapor. A dew point of 0 °F requires a refrigerated drier (Use TRI test item C23). A dew point of -50 °F requires a desiccant drier be installed (Use TRI test item A82) in the compressed air system. Other gases such as nitrogen may have different system requirements.

TRI's analytical laboratory is accredited by the American Industrial Hygiene Association for breathing air testing. We perform analytical testing on air and the major components and contaminants of air. Below is a partial list. We often customize the customer's requirements to our ability. If you don't see the type of test you may require or have other questions please call us for further information. TRI offers 24 hour results and we now have FAST on-line laboratory reports.

| <b>Analyte</b>             | <b>How Typically Measured</b>   |
|----------------------------|---|
| <b>Analyte Analyzed</b>    | <b>Typical Range Measured by GC</b>   |
| Oxygen                     | 0.5% to 99+%(In H <sub>2</sub> or He call for price quote)  |
| Nitrogen                   | 0.5% to 99+%  |
| Nitrous Oxide              | 99+% (special 0.5ppm call for price quote)  |
| Carbon Dioxide             | 25ppm to 99+% (1 to 25ppm call for price quote)   |
| Carbon Monoxide            | 1ppm to 1000ppm   |
| Halogenated Hydrocarbons   | 1ppm and up in air and most gases   |
| Total Gaseous Hydrocarbons | 1ppm and up in Air, N <sub>2</sub> or Ar<br>(In O <sub>2</sub> , N <sub>2</sub> O, or CO <sub>2</sub> call for price quote) |
| Methane                    | 1ppm and up   |
| <b>Analyte Analyzed</b>    | <b>Typical Range Measured Gravimetrically</b>   |
| Oil Mist & Particulate     | 5.0 mg/m <sup>3</sup> Results reported combined   |
| Oil Mist & Particulate     | 0.1 mg/m <sup>3</sup> Results reported combined   |
| Oil Mist & Particulate     | Results always reported separately  |
| <b>Analyte Analyzed</b>    | <b>Typical Range Measured with Detection Tubes</b>  |
| Moisture                   | 2ppm(-95 °F) to >3900ppm(22 °F)   |
| Sulfur Dioxide             | 0.1ppm to 3ppm  |
| Nitrogen Dioxide           | 0.5ppm to 2ppm  |
| Nitric Oxide               | 0.5ppm to 2ppm  |
| Halogenated Solvents       | 0.1ppm to 10ppm   |
| <b>Analyte Analyzed</b>    | <b>Typical Range Measured by Culture</b>  |
| Mold & Bacteria, Viable    | <50 CFU/m <sup>3</sup>  |
| <b>TRI Test Equipment</b>  |   |
| Champion 35 Test Kit       | Champion 35 Test Equipment (one time purchase)  |