PHARMACEUTICAL GAS ANALYSIS

SGS

Compressed air, oxygen, nitrogen and carbon dioxide are often used in pharmaceutical production environments and are subject to the Good Manufacturing Practices.

Analyzing gases within a production environment involves testing them upon receipt at the facility as well as subsequent tests when the system is operational and after any changes or intervention to the production systems are made. The aim is to verify the absence of any potentially hazardous or disruptive materials.

SGS Life Science Services provides advice, sampling and GMP compliant analysis of media in a pharmaceutical environment based on the requirements of the pharmacopoeias (e.g. EP, JP, BP, USP).

TESTS PERFORMED

- Air, oxygen, carbon dioxide and nitrogen testing
- Purity testing
- Particle testing
- Microbial testing
- Dewpoint testing
- Tests for oil residues, aerosol oil and remainders of aeration and disinfectants - see tables 1 and 2.

QUALITY AND PROXIMITY

Compliant with all the international and local pharmacopoeias, our analyses are done in specially equipped laboratories, however some tests can be conducted onsite, using mobile analysis systems, enabling quick access to results. SGS uses spectroscopic techniques to identify contamination as well as molecular biological techniques for germ identification (important for sterile production methods).

Tests are conducted on samples selected before use in production, and results are recorded on Certificate of Analysis to demonstrate that regulatory standards have been achieved.

SAMPLE MANAGEMENT

- Tailored logistic solutions
  - Collection of samples from the production sites
  - Partnerships with certifi ed health specialist carriers
- Analysis performed D+1
- Internet tracking of samples available

TABLE 1: COMPRESSED AIR OR BREATHING AIR

GAS	ANALYSIS	SPECIFICATIONS			
COMPRESSED AIR OR BREATHING AIR	O_2 Content	ISO 8573	-	EN 12021	21% ± 1
	Humidity		According to ISO 8573		Dewpoint ≤ 11°C or 5°C ≤ T° of use
	Traces of oil		According to ISO 8573		≤ 0.5 mg/m^3
	CO_2		Optional		≤ 500 ppm (500 ml/m^3)
	CO		Optional		≤ 15 ppm (15 ml/m^3)
	Other gaseous pollutants		Optional		-
	Particles		According to ISO 8573 from BPF		Optional
	Viable microorganisms		Optional (ex < 5 ufc/m^3)		Optional

TABLE 2: TESTS FOR DISTRIBUTION NETWORKS

GAS	ANALYSIS	SPECIFICATIONS			
ALL GAS	Viable microorganisms and particulate count	GMP	According to the class of the area use	GMP	According to the class of the area use
MEDICINAL AIR	O_2 content	EP 01/2009 : 1238	20.4 – 21.4%	USP35-NF30	19.5 – 23.5%
	Water		≤ 67 ppm		No traces on mirrors
	Traces of oil (aerosol)		≤ 0.1 mg/m^3		No traces on mirrors
	CO_2		≤ 500 ppm		≤ 0.05%
	CO		≤ 5 ppm		≤ 0.001%
	NO/NO_2		≤ 2 ppm		≤ 2.5 ppm
	SO_2		≤ 1 ppm		≤ 5 ppm
NITROGEN	Purity	EP 01/2008 : 1247	> 99.5%	USP35-NF30	> 99.0%
	Water		≤ 67 ppm		-
	CO		≤ 5 ppm		≤ 0.001%
	CO_2		≤ 300 ppm		-
	O_2		≤ 50 ppm		≤ 1.0%
OXYGEN	Purity	EP 01/2010 :0417	> 99.5%	USP35-NF30	> 99.0%
	Water		≤ 67 ppm		
	CO		≤ 5 ppm		≤ 0.001%
	CO_2		≤ 300 ppm		≤ 0.03%
CARBON DIOXIDE	Purity	EP 01/2008 : 0375	> 99.5%	USP35-NF30	> 99.0%
	Water		≤ 67 ppm		≤ 150 mg/m^3
	CO		≤ 5 ppm		≤ 0.001%
	Total sulfur		≤ 1 ppm au total		≤1 ppm
	H_2S		≤1 ppm at the total		≤1 ppm
	NO/NO_2		≤2 ppm at the total		≤2.5 ppm
	Ammonia		-		≤0.0025%
	SO_2		≤ 2ppm		≤ 5 ppm

ABOUT SGS

Part of the SGS Group, SGS Life Science Services is a leading contract service organization providing, analytical development, biologics characterization, biosafety, quality control testing and clinical research.

Operating 27 facilities in 14 countries across Europe, the Americas and Asia with 1,500 employees, SGS represents the world's largest, state-of-the-art network of GMP compliant laboratories.

Delivering solutions for pharmaceutical, biologics, and medical-device manufacturers, SGS offers GMP/GLP contract laboratory services that include analytical chemistry, microbiology, stability studies, bioanalysis, extractables and leachables, virology, and protein analysis.

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WHEN YOU NEED TO BE SURE