

APTAR PHARMA REGISTERS ITS CONTRACT TEST LABORATORIES WITH THE U.S. FOOD AND DRUG ADMINISTRATION

Louveciennes, France – April 7th, 2011- Aptar Pharma's French manufacturing sites in Le Vaudreuil and Val-de-Reuil have been registered as **Contract Test Laboratories** for extractables testing with the U.S. Food and Drug Administration (FDA).

A number of pharmaceutical and biotechnology companies working with Aptar Pharma drug delivery devices have expressed a requirement to use Aptar Pharma extractables testing for batch release of their drug products. They can now benefit from this advantageous Aptar Pharma service.

Aptar Pharma enlarges its service scope

Through decades of experience working closely with its pharmaceutical and biotechnology customers in a spirit of continuous improvement, Aptar Pharma understands their evolving needs. As the world-leading supplier of innovative non-invasive drug delivery devices, Aptar Pharma has developed a variety of analytical capabilities, of which extractables data is critical for customers. Now that Aptar Pharma analytical laboratories have been registered with the FDA, customers can reduce their own testing burden, further enhancing the value of their partnership with Aptar Pharma.

Extractables are key to drug manufacturers

Pharmaceutical and biotechnology drug manufacturers are responsible for identifying and quantifying extractables and leachables and for evaluating any associated potential toxicity. Drug delivery device components are typically made of materials such as polymers and elastomers. The measurement of extractables from materials which are in contact with drug product is growing in importance due to increased regulatory scrutiny from organizations such as the FDA. Regulators are concerned about the interaction of the drug delivery device components with drug products. Extractables assessment of plastic and elastomeric components forms an integral part of the submission for approval, as well as for the routine controls used to release batches of the drug product.

Aptar Pharma manufacturing sites in France have been inspected by the FDA with an excellent outcome

The Aptar Pharma sites at Le Vaudreuil and Val-de-Reuil have been inspected twice by the FDA in recent years. These inspections were very satisfactory, with no observations being made (also known as the FDA 483 Inspectional Observations notice).

With this FDA registration Aptar Pharma French sites, which are already ISO-15378 certified and which operate with a robust and mature cGMP-compliant quality system, will further improve service and commitment to support their drug manufacturer customers.

About Aptar Pharma

Aptar Pharma is part of the Aptargroup family of companies, along with Aptar Beauty + Home and Aptar Food + Beverage. We create innovative drug delivery systems that meet the evolving needs of biotechnology, healthcare and pharmaceutical companies around the world. We provide our customers with a wide range of delivery technologies and analytical services backed by years of proven expertise.

Aptargroup (NYSE: ATR) is headquartered in the US and has manufacturing sites in North America, Europe, Asia and South America.

For more information, visit www.aptar.com.

Press Contacts

Elisa Eschylle, Events and Press relations manager

Tel.: +33 (0)1 39 17 20 41 - **Email :** elisa.eschylle@aptar.com

Marion Baschet Vernet, Press attache

Tel.: +44 (0)797 609 41 00 - **Email :** mbvernet@gmail.com