



## Passepartout Studies

a wide worst-case extractables profile

The pharmaceutical industry demands safe, reliable, and versatile packaging solutions that can withstand the rigors of diverse drug products.

Passepartout Studies offer an innovative approach to extractables profiling, providing a comprehensive view of potential chemical compounds that may leach from packaging materials. Dedicated to packaging manufacturers and pharmaceutical companies, MxNS Passepartout Studies are designed to support the Sponsor in regulatory requirements efficiently and cost-effectively, while ensuring broad applicability of packaging across multiple drug products.

### WHAT ARE PASSEPARTOUT STUDIES?

Passepartout Studies are focused on **delivering a wide worst-case extractables profile**. Unlike traditional extractables studies, which are tied to specific drug products, **Passepartout Studies generate data that can be applied across a variety of formulations**. By exploring a broader range of extraction conditions and solutions, Passepartout Studies help determine the suitability of packaging materials for multiple products, offering unparalleled flexibility and efficiency in the development and validation of packaging.

#### KEY BENEFITS

**Comprehensive Profiling.** Obtain a detailed worst-case extractables profile applicable to various drug products.

**Resource Efficiency.** A single study can support multiple drug product applications for the same packaging, saving time and costs.

**Tailored Results.** Use Analytical Evaluation Threshold (AET) to tailor the extractables profile for specific drug products, ensuring precise regulatory compliance.

## MXNS PASSEPARTOUT STUDIES: TAILORED SOLUTIONS FOR EVERY PACKAGING NEED

At Mérieux NutriSciences we understand that every drug product and its packaging pose unique challenges. That's why our Passepartout Studies are designed to offer a flexible, adaptable solution to extractables testing.

### OUR SERVICE INCLUDES

- **Complete Extractables Profiling.** Offering a full extractables analysis based on Limit of Quantitation (LoQ), suitable for packaging manufacturers and pharmaceutical companies.
- **Tailored Regulatory Compliance.** Tailor your extractables profile based on Analytical Evaluation Threshold (AET) to meet specific regulatory demands.
- **One Study, Multiple Applications.** Conduct one study and use it as the foundation for multiple extractables profiles, streamlining your packaging validation process.

### EXTRACTABLES V. PASSEPARTOUT

EXTRACTABLES STUDY	PASSEPARTOUT STUDY
Drug product specific	Unrelated to drug product
Results reported on AET	Results reported on LoQ
Specific extractables profile (valid for just one drug product configuration)	Wide-range extractables profile (results can be applied to several drug products)
Required by pharmaceutical companies	Required by packaging/components manufacturers



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