Does your container material meet regulatory requirements?

SCHOTT pharma services offers material conformity testing according to current USP, EP, and JP guidelines along with selected ISO, ASTM, and in-house methods.

The material conformity tests of pharmaceutical containers assist pharmaceutical companies in ensuring that the primary packaging container complies with pharmacopeia regulations. Samples are drawn from production lots and tested according to one or more of the methods described below:

Test Method	Regulation	Closure Type	# of Samples per Lot Required
Glass surface	EP 3.2.1. , USP <660> ISO 4802-2	Ampoule, cartridge, syringe, vial	30-45 pcs. (1-2 ml), 25-38 pcs. (2-5 ml), 20-30 pcs. (5-30 ml), 12-18 pcs. (30-100 ml), 7-11 pcs. (>100 ml)
Glass surface etching	EP 3.2.1. , USP <660>	Ampoule, cartridge, syringe, vial	30-45 pcs. (1-2 ml), 25-38 pcs. (2-5 ml), 20-30 pcs. (5-30 ml), 12-18 pcs. (30-100 ml), 7-11 pcs. (>100 ml)
Glass grains	EP 3.2.1., USP <660>	Ampoule, cartridge, syringe, vial	200 grams
Arsenic	EP 3.2.1. USP <211> & <660>	Ampoule, cartridge, syringe, vial	30-45 pcs. (1-2 ml), 25-38 pcs (2-5 ml), 20-30 pcs. (5-30 ml), 12-18 pcs. (30-100 ml), 7-11 pcs (>100 ml)
Transmission	EP, JP, USP	Ampoule, cartridge, syringe, vial	5 containers
Visual conformity	JP 7.01	Ampoule, cartridge, syringe, vial	10 containers
Soluble alkali	JP 7.01	Ampoule, cartridge, syringe, vial	200 grams
Soluble iron	JP 7.01	Ampoule, cartridge, syringe, vial	5 containers
Tungsten	In-house	Syringe	10 containers
Silicone oil	In-house	Syringe, cartridge	3 containers
Flange strength	In-house	Syringe	50 containers
Heavy metals Ba, Cd, Cr, Hg, Pb	EUR-Lex Article 11 94/62/EC	Ampoule, cartridge, syringe, vial	5 containers
Diameter & Composition	ISO 9626 & ISO 15350	Needle (syringe)	5 needles
Pull Out Force	In-house	Needle (syringe)	100 needles

SCHOTT
glass made of ideas

Does your elastomeric closure meet regulatory requirements?

SCHOTT pharma services offers material conformity testing according to current USP, EP, and JP guidelines along with selected ISO, ASTM, and in-house methods.

The material conformity tests of elastomeric closures for pharmaceutical packaging assist pharmaceutical companies in ensuring that the elastomeric closure complies with pharmacopeia regulations. Samples are drawn from production lots and tested according to one or more of the methods described below.

Test Method	Regulation	Container Type	# of Samples per Lot Required
UV	DIN EN ISO 8871-1	Plunger, tip cap	200 closures
Ash	DIN EN ISO 8871-2, ISO 247	Plunger, tip cap	40 closures
Density	DIN EN ISO 8871-2, ISO 2781	Plunger, tip cap	40 closures
Particle Count	DIN EN ISO 8871-3	Plunger, tip cap	100 closures
Total Ash	EP 3.2.9. + EP 2.4.16.	Plunger, tip cap	60 closures
Solution S Prep	EP 3.2.9.	Plunger, tip cap	200 closures
Solution S Appearance	EP 3.2.9.	Plunger, tip cap	From Solution S prep
Solution S Acidity or Alkalinity	EP 3.2.9.	Plunger, tip cap	From Solution S prep
Solution S Absorbance	EP 3.2.9.	Plunger, tip cap	From Solution S prep
Solution S Reducing	EP 3.2.9.	Plunger, tip cap	From Solution S prep
Solution S Heavy Metal	EP 3.2.9.	Plunger, tip cap	From Solution S prep
Solution S Extractable Zinc	EP 3.2.9.	Plunger, tip cap	From Solution S prep
Solution S Ammonium	EP 3.2.9.	Plunger, tip cap	From Solution S prep
Solution S Residue on Evaporation	EP 3.2.9.	Plunger, tip cap	From Solution S prep

SCHOTT
glass made of ideas

Locations:

SCHOTT pharma services provides the full compatibility testing from 2 sites working with harmonized analytical techniques and identical quality policies. One laboratory is located in North America (PA) and the other one is situated in Germany (Mainz). The shipment addresses are given below:

Laboratory address in Germany:

SCHOTT AG
SCHOTT pharma services
Hattenbergstraße 10
55122 Mainz
Germany

pharma.services@schott.com

Laboratory address in USA:

SCHOTT North America, Inc.
Attn. Dr. Dan Haines
201 South Blakely Street, #121
Dunmore, PA 18512
USA

Phone: +1 570 457-7485 x 653
daniel.haines@us.schott.com

Quality:

Laboratories of SCHOTT pharma services are DIN EN ISO/IEC 17025 accredited (DAkkS) and FDA registered.

SCHOTT pharma services can access more than 40 years experience in analytical testing of pharmaceutical packaging containers. All quality relevant documents are electronically available ensuring a hassle-free audit process.

Deutsche
Akkreditierungsstelle
D-PL-14645-01-00

For a quotation, a request or further information, please contact us:

SCHOTT AG
Hattenbergstraße 10
55122 Mainz
Germany

Phone: +49 (0)6131/66-7339
pharma.services@schott.com

Or please click here:

Quotation **Request**

Brochures, Sample Submission Form, Publications

SCHOTT AG
Hattenbergstraße 10
55122 Mainz
Germany
Phone: +49 (0)6131/66-7339
Fax: +49 (0)3641/2888-9125
pharma.services@schott.com

www.schott.com/pharmaceutical_systems

SCHOTT
glass made of ideas