

Hi,

LOTUS LABS - MIDYEAR UPDATES:

Inspection at Lotus Labs:

- Lotus Labs completed inspection from NPCB, Malaysia in May and its 2nd MHRA Inspection in July 2015 taking total number of inspections to 65.
- ANVISA approval for Lotus Labs Bangalore sites (Clinical & Analytical) has now been approved up to October 2017.

Lotus Assay Bank

Search for analytical method availability

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Ongoing CTs – PK & end point studies:

- Lotus has recently completed two studies in the segments of CNS (PK) & Dermatology.
- Two clinical trials are currently ongoing in Oncology (PK) and Ophthalmology (Glaucoma & Cataract) therapeutic segments respectively.
- Two Studies in the areas of Dermatology and Urology are scheduled to be initiated shortly.

Capabilities

Explore our resources

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Premium analytical methods developed recently:

- Treprostinil
- Bazedoxifent + Metabolite
- Conjugated Estrogens (Unconjugated and Total)
- Calcifediol
- Nicotine (0.8ng/mL LOQ)
- Formoterol (0.4pg/mL LOQ)
- Alitretinonin
- Levothyroxine
- Levothyronine
- Testosterone
- Alpha Tocoferol
- Paclitaxel (Unbound and Total)

Contact us

Get in touch we would like to hear from you.

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INDUSTRY UPDATES:

WHO issues draft norms for surveys to assess drug quality & efficacy of medicines

In an effort to ensure access to high quality drugs in the market, the World Health Organization (WHO) has issued draft guidelines outlining steps to consider when preparing and conducting a survey of medicines quality.

Source: <http://www.pharmabiz.com/NewsDetails.aspx?aid=89478&sid=1>

US FDA issues norms on Allowable Excess Volume & Labeled Vial Fill Size in injectable drugs

US FDA has issued a guidance on Allowable Excess Volume and Labeled Vial Fill Size in injectable drug and biological products. These norms are essentially issued to clarify the Center for Drug Evaluation and Research's and the Center of Biologics Evaluation and Research's recommendations to allow excess volume and labeled vial fill size in injectable drugs and biologics.

Source: <http://www.pharmabiz.com/NewsDetails.aspx?aid=89391&sid=1>

News & Events

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