INTRODUCTION TO RECOMBINANT FACTOR C AND ITS FUTURE IN INDIA

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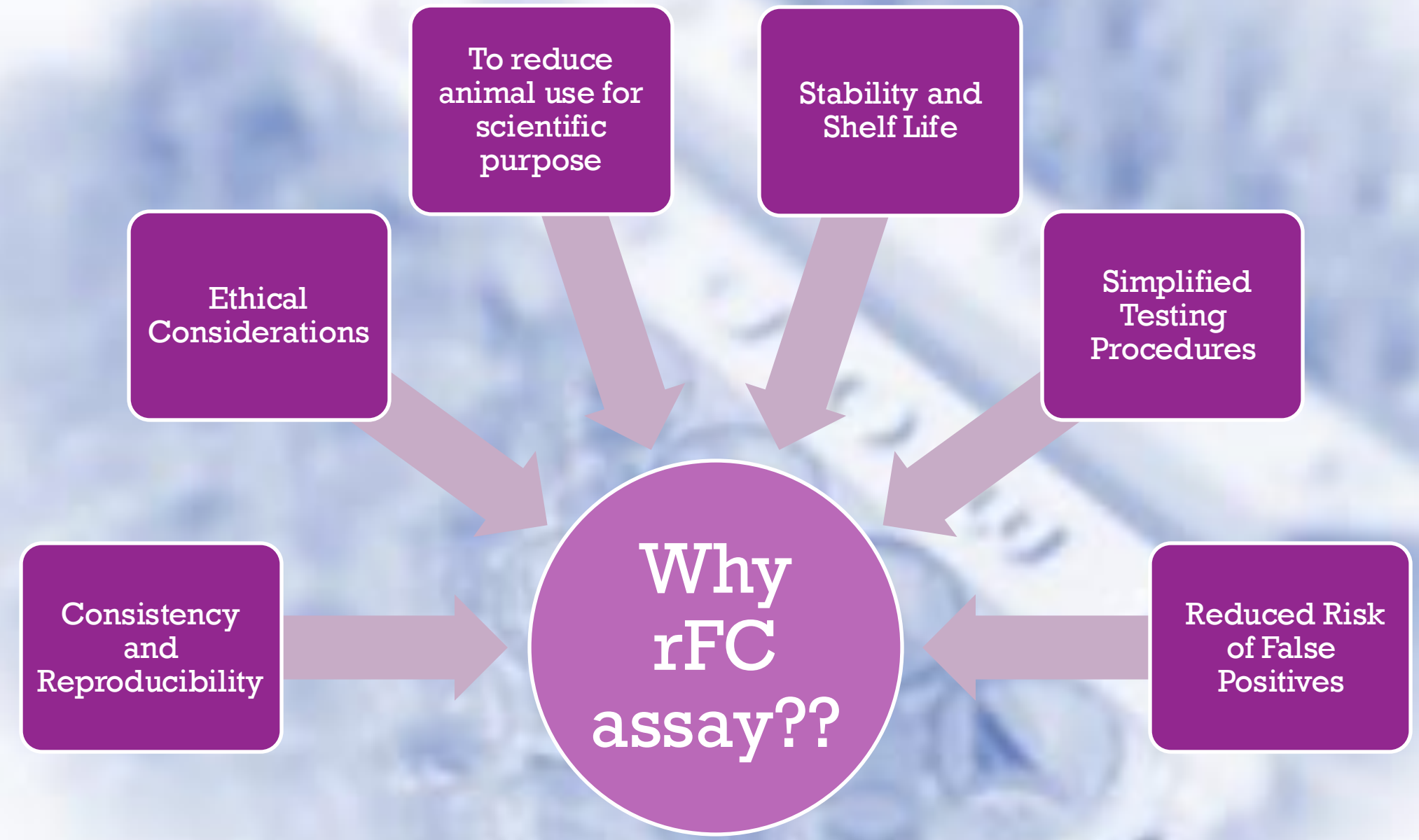
About Dr. Reddy's Laboratories

A global pharmaceutical company headquartered in Hyderabad, India. Founded by Dr. Anji Reddy.

Deals with wide range of product including API, generics, branded generics, biosimilars and Over-the-counter (OTC) pharmaceutical products around the world.

DRL is also involved in R&D, focusing on innovative solutions to address unmet medical needs.


To reduce animal use for scientific purpose
Stability and Shelf Life
Ethical Considerations
Simplified Testing Procedures
Consistency and Reproducibility
Why rFC assay??
Reduced Risk of False Positives

HOW AND WHY DID WE DECIDE TO EXPLORE rFC ASSAY

- **Replacement of animal use with biotechnological production:** Recombinant production without the use of animals is the basis of the biotechnology revolution and progress. rFC meets the European directive 2010/63/EU to reduce animal use for scientific purpose.
- **Consistency and Reproducibility:** Recombinant Factor C is a synthetic product, has greater consistency and reproducibility compared to LAL. This consistency is crucial for accurate and reliable endotoxin testing. More reliable in producing consistent results across different batches.
- **Ethical Considerations:** The use of recombinant Factor C eliminates the need for horseshoe crabs, which are harvested for LAL testing. This reduces the impact on wild populations and addresses ethical concerns related to animal welfare.
- **Stability and Shelf Life:** rFC tends to be more stable and has a longer shelf life compared to LAL reagents. This stability can lead to fewer issues with reagent degradation and variability over time.
- **Simplified Testing Procedures:** rFC assays are often simpler to perform and may require fewer steps compared to LAL tests. This can make the testing process more straightforward and less prone to errors.
- **Reduced Risk of False Positives:** rFC assays can be less susceptible to interference from non-endotoxin substances that might cause false positives in LAL assays. This can lead to more accurate detection of endotoxins.

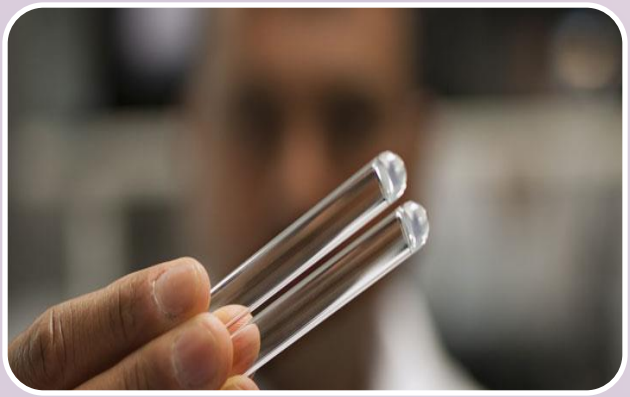
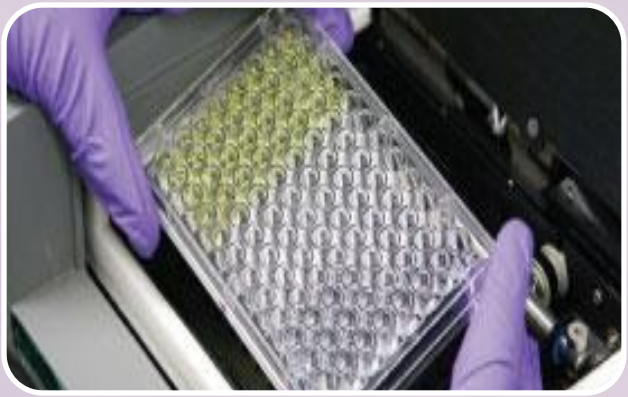
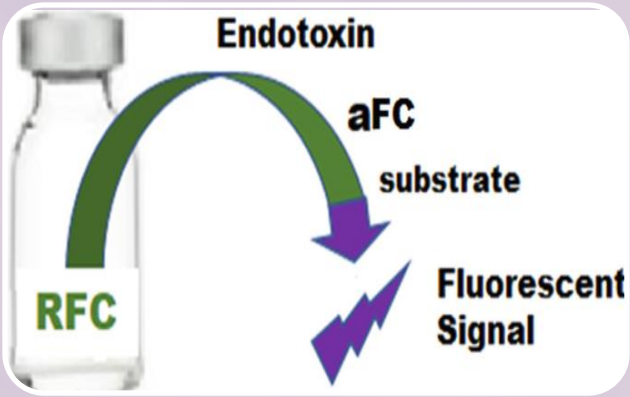
OUR EXPERIENCE SO FAR WITH rFC ASSAY

Our Quantitative Assessment: We have tested one of our product and found consistency & higher PPC recovery over 3 methods:

- Product : (API)
- Endotoxin Limit : 0.25 EU/mg
- Concentration : 100mg/mL

Bacterial endotoxin results of the product using different methods				
Method	Gel Clot		Kinetic Turbidimetric	rFC
Dilution	NPC	PPC	PPC recovery %	
MVD/8	Positive	Positive	280	54
MVD/4	Positive	Positive	220	76
MVD/2	Positive	Positive	190	94
MVD	Positive	Positive	183	98

OBSERVATION

Gel clot method	Kinetic method	rFC method
		
All the PPC shown positive and NPC shown positive, Even after addition of GlucaShield Buffer (Glucan inhibitory buffer)	Inconsistent PPC recovery was observed, which is beyond and close to 200%.	Consistent PPC recovery was observed and No enhancement was observed, without using Glucan inhibitory buffer

Our aim is to test more samples using rFC method

To eliminate LAL test in the next five years to save the animals

Using rFC has made it easier for us to validate samples since USP <86> was introduced

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Thank You....