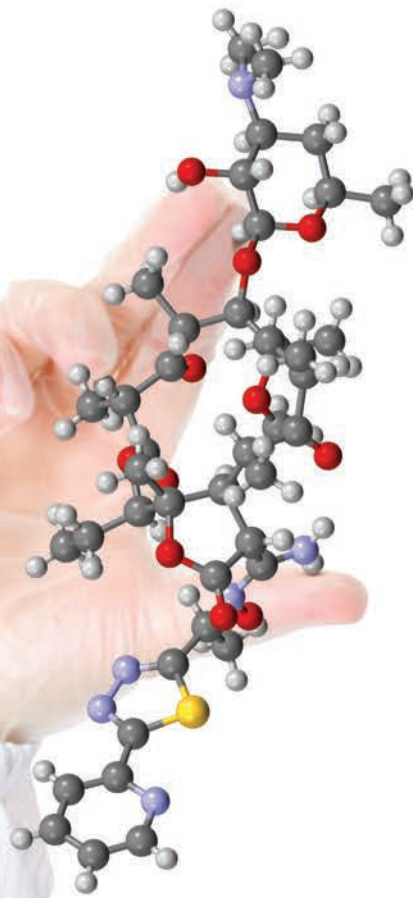


RESEARCH WINS. LIFE WINS.



WOCKHARDT | **LIFE WINS**



Annual Report 2015-16



Globally, drug-resistant infections have been recognised and acknowledged as a clear and present danger. The US Centers for Disease Control and Prevention (CDC) estimated that antibiotic resistance is responsible for more than 2 million infections and 23,000 deaths each year in the United States, at a direct cost of \$20 billion and additional productivity losses of \$35 billion (CDC 2013). In Europe, an estimated 25,000 deaths are attributable to antibiotic-resistant infections, costing €1.5 billion annually in direct and indirect costs (EMA and ECDC 2009). The worldwide estimates of global antibiotic resistance, published by the World Health Organisation (WHO) in 2014, list *Escherichia coli*, *Klebsiella pneumoniae*, and *Staphylococcus aureus* as the three agents of greatest concern, associated with both hospital and community-acquired infections.

The current global concern and efforts to survive the 'post-antibiotic era' vindicates Wockhardt's research focus on the anti-infectives space over two decades ago. While other global drug manufacturers at that time displayed waning interest in antibiotics, intuition and a competitive analysis of potential market dynamics was reason enough for Wockhardt to create a conceptual framework to focus on antibiotics. And two decades of unwavering focus and diligence has come to fruition.

Today, Wockhardt has the unique distinction of being the only pharmaceutical company in the world to have 5 of its new drugs under development accorded the coveted Qualified Infectious Disease Product (QIDP) status from USFDA.

Considering our corporate credo and given our strong focus and heavy investment on R&D, it is only fitting to say that when Research Wins, Life Wins.

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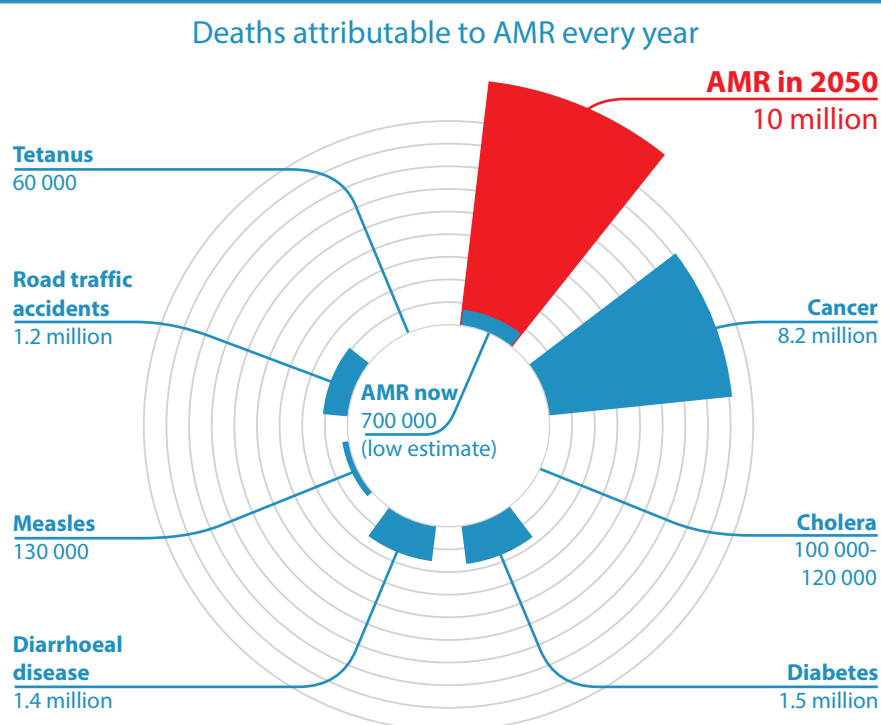
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Antimicrobial Resistance (AMR): A global crisis

The Review on AMR, published in May, 2016, cites a current average of 700,000 deaths attributable to AMR every year and estimates that by 2050, 10 million lives every year, and a cumulative USD 100 trillion of economic output will be at risk due to the rise of drug-resistant infections.

The US Centers for Disease Control and Prevention (CDC) has identified and classified several 'Urgent', 'Serious' and 'Concerning' resistance threats that require focus and attention. They include Carbapenem-resistant Enterobacteriaceae (CRE), Multi drug-resistant Acinetobacter, Extended Spectrum β -lactamase producing Enterobacteriaceae (ESBLs), Vancomycin-resistant Enterococcus (VRE), Methicillin-resistant Staphylococcus aureus (MRSA), Vancomycin-resistant Staphylococcus aureus (VRSA) etc.



Source: The Review on Antimicrobial Resistance, Jim O'Neill, 2016

Wockhardt's New Drug Discoveries to counter AMR

Wockhardt's New Drug Discovery Programme has focused on novel solutions to these very threats for over two decades and has achieved significant successes to fulfill unmet medical needs. Assigned International Nonproprietary Names (INN) by the World Health Organisation, Wockhardt has 5 new drugs, accorded Qualified Infectious Disease Product (QIDP) status by US FDA, in various stages of development.

WCK 5222 is a life-saving combination of Cefepime and Zidebactam (INN for WCK 5107) for MDR blood, lung and urinary tract infections not treatable with most available therapies.

Levonadifloxacin (INN for WCK 771) and Alalevonadifloxacin (INN for WCK 2349) are broader spectrum bactericidal anti-MRSA drugs.

Nafithromycin (INN for WCK 4873) is being developed for community-origin pneumonia, as well as for the treatment of upper respiratory tract infections such as bronchitis and pharyngitis.

WCK 4282 is a combination of Cefepime and Tazobactam which leads to coverage of Multidrug Resistant (MDR) gram negative infections caused by E.coli, Klebsiella and Enterobacter infections in hospital settings.



CHAIRMAN'S STATEMENT

My Dear Shareowners

Last year, we adopted Life Wins as the underlying philosophy and driving principle of everything that we do at Wockhardt. As our corporate credo, Life Wins will continue to characterise what we do and reiterate our commitment to do it the right way.

Research that Wins

Albert Einstein said, "To raise new questions, new possibilities, to regard old problems from a new angle, requires creative imagination and marks real advance in science." I am happy to inform you that Wockhardt's Research & Development division has made significant advances in the pharmaceutical sciences. This year, 3 more of our new drugs under development received breakthrough discovery status by US FDA, taking our tally to 5 new drugs in the anti-infectives space to receive the coveted QIDP (Qualified Infectious Disease Product) status by US FDA.

This makes Wockhardt the only pharmaceutical company in the world to have 5 experimental antibiotic drugs given QIDP status by US FDA, making way for an accelerated drug development cycle in addition to providing a five-year extension of the exclusivity period, post approval.

This momentous achievement catapults Wockhardt amongst a group of select global drug makers that include Roche, Merck, Allergan and AstraZeneca. It validates our long and consistent R&D focus by our New Drug Discovery Programme on antibiotics. Given the global concern over drug-resistant infections, our early focus and recent achievements translate into a tremendous opportunity in the near future.

At Wockhardt, we have always believed that R&D is the key to the future. Naturally, we continue to increase our industry-leading investment in R&D as a percentage of total sales every year. In FY 2015-16, our R&D spend of ₹ 669 crore at 15% of total sales is almost 30% higher

than our investment in R&D of ₹ 515 crore at 11.5% of total sales in FY 2014-15. This financial year, we filed 311 patents and were granted 100 patents, taking cumulative patents filed to 2,579 and patents granted to 441.

Performance that Wins

For the year under review, FY 2015-16, our operations worldwide yielded consolidated revenues of ₹ 4,461 crore and a Profit After Tax of ₹ 326 crore. The marginally lower numbers as compared to FY 2014-15 increased our Net Debt to ₹ 932 crore as compared to ₹ 437 crore in FY 2014-15. Currently, Net Debt to Equity Ratio is 0.24 as compared to 0.12 as on March 31, 2015. Our US business declined by 11% and our EU market declined by 11%.

But there are several wins too. Our Emerging Markets business grew by 36% and our India business grew by 16%. We launched 48 new products in India. We filed 17 ANDAs with US FDA and have received 2 approvals in FY 2015-16, with 84 ANDAs pending approval. Of course, QIDP status for 3 new drugs under development by US FDA, adding to the 2 that got QIDP status in FY 2014-15, is a huge win by itself. At Wockhardt, we are constantly seeking to grow our business, expand our markets and launch new products.

Compliance that Wins

"The only way around is through." Simple and practical words of wisdom by American poet Robert Frost reflect

our approach to regulatory compliance. We have invested significant resources to deploy people, processes and technology to ensure regulatory compliance and I am happy to announce steady progress on that front.

During the year, our L1-Chikalthana, Aurangabad, manufacturing facility was inspected by UK MHRA and they have confirmed the closure of the inspection and issued an unrestricted GMP certificate. Accordingly, supplies have been resumed from L1 facility to UK Market. US FDA has also recently completed inspections of our manufacturing units at Ankleshwar, Gujarat, and Shendra, Aurangabad, and made some observations. They have been responded to. The Shendra manufacturing unit is a new facility supplying to India, UK & Irish markets. Currently we are not supplying any product from the Shendra facility to the US market. Also, our manufacturing facility at Waluj received the Establishment Inspection Report (EIR) from US FDA. We constantly seek and implement measures towards remediation and compliance and are confident of achieving full regulatory compliance soon.

Healthcare that Wins

You will be pleased to know that Wockhardt Hospitals' reputation as a provider of state-of-the-art healthcare services continues to grow. The new-age Wockhardt Hospital that was opened in FY 2014-15 is characteristic of our vision of operating a chain of super specialty hospitals delivering world-class tertiary healthcare and establishing a benchmark in clinical care. We constantly seek to employ experienced professionals, implement advanced treatment regimens and deploy best-in-class technology to offer healthcare services designed to improve and save lives. Every successful procedure that we carry out in all our hospitals is a big win for us.

CSR that Wins

"I slept and dreamt that life was joy. I awoke and saw that life was service. I acted and behold, service was joy." Our joy of giving couldn't be better expressed than by this truly beautiful thought by Rabindranath Tagore. At Wockhardt, our approach to Corporate Social Responsibility (CSR) goes beyond compliance and we initiate and implement social projects and activities with the same zeal and professionalism as we conduct our business.

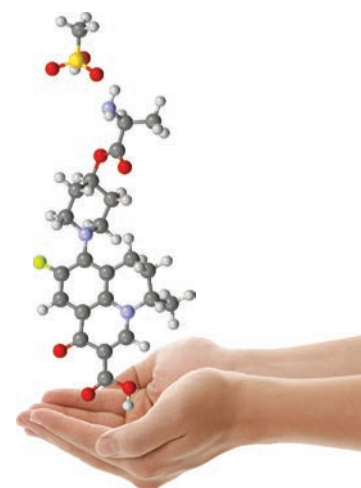
Driven by Wockhardt Foundation in tandem with Wockhardt Hospitals, our social initiatives include mobile medical services, toy libraries, potable water, sanitation, e-learning, skill development etc. Last year, we initiated an ambitious social project by adopting a village and transforming it into an ideal community that lacks nothing. It is a work in progress. At Wockhardt, we constantly seek to enhance and improve the quality of life of underprivileged communities. For us, every smile generated and every life touched is a huge win.

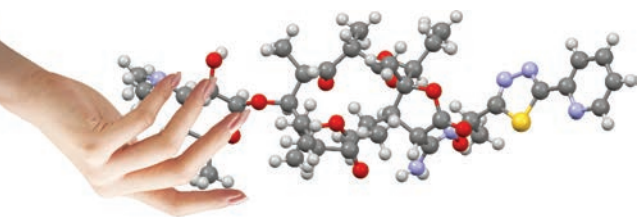
Excellence that Wins

I am happy to announce that excellence has become a byword for Team Wockhardt. 10,000 Wockhardians across 6 continents and 21 nationalities with a global work culture and a global mindset make Wockhardt a truly global organisation. Leadership champion and former CEO of the iconic Campbell Soup Company, Douglas Conant gets it right when he says, "To win in the marketplace you must first win in the workplace." Wockhardt's work culture that considers human capital to be its most valuable asset has ensured that Wockhardt, Wockhardt Hospitals and Wockhardt Foundation have all won leading ranks in the prestigious 'Great Place to Work' Survey. Notable amongst this year's awards are awards won by Dr. Murtaza Khorakiwala, Managing Director, Wockhardt; Dr. Huzaifa Khorakiwala, Executive Director, Wockhardt and Trustee & CEO, Wockhardt Foundation; and Ms. Zahabiya Khorakiwala, Managing Director, Wockhardt Hospitals. We also received the 'Niryat Shree' Award conferred by the Federation of Indian Export Organisations (FIEO) at the hands of the Hon'ble President of India Mr. Pranab Mukherjee. Bound by a common thread of a passion for excellence, Team Wockhardt has surpassed itself this year. They have added to their FY 2014-15 tally of 54 awards for excellence, by winning 64 awards for excellence in FY 2015-16 across functions and departments, on an individual as well as at the organisational level. Team Wockhardt constantly seeks to excel and every win is a measure of their success.

I will conclude with a profound quote by eminent 19th century French physiologist and medical researcher Claude Bernard. "Art is I; science is we." Wockhardt will continue to focus on R&D and innovation. We will continuously seek and strive to do good, act better and do what is best for us and our stakeholders. In this endeavor, every success and every achievement, on an individual as well as on an organisational level, will be a big win.

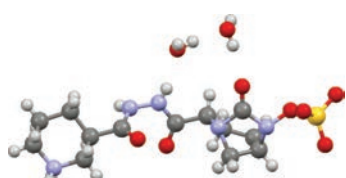
Dr. Habil Khorakiwala,
Founder Chairman & Group CEO



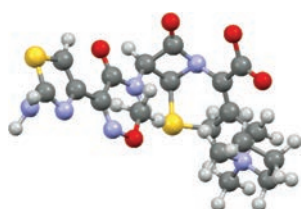


Breakthrough Drugs Under Development with QIDP Status from US FDA

WCK 5222



Zidebactam



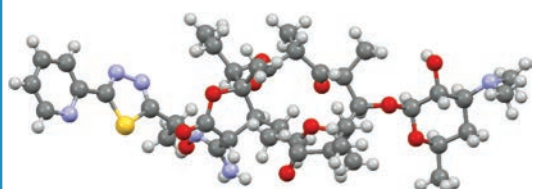
Cefepime

This is a unique Gram-negative targeted product based on a novel mechanism of action driven by one of its constituents, Zidebactam (INN for WCK 5107), a β -lactam enhancer, combined with a cephalosporin (Cefepime).

It has the broadest ever coverage of life threatening infections including Extensively drug-resistant (XDR) pathogens, Metallo- β -lactamase, Multi-Drug Resistant (MDR) *Pseudomonas* and *Acinetobacter*.

It is a high-efficacy product for high-mortality indications like Hospital-Acquired Bacterial Pneumonia (HABP), Bloodstream Infections (BSI), intra-abdominal and urinary tract infections.

Nafithromycin (INN for WCK 4873)

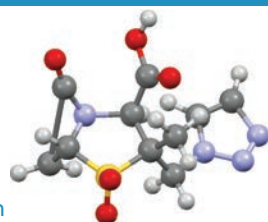


This is a novel lactone ketolide antibiotic designed to target MDR pneumococci, a bacterial pathogen contributing to the highest number of deaths globally.

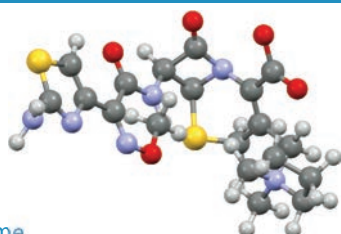
Clinically attractive attributes of WCK 4873 include best-in-class oral pharmacokinetics, highest level of lung tissue and alveolar macrophage penetration and good hepatic safety.

It is being developed to treat community-acquired pneumonia, pneumococcal bacteraemia, otitis media, chlamydial urethritis and upper respiratory tract infections

WCK 4282



Tazobactam

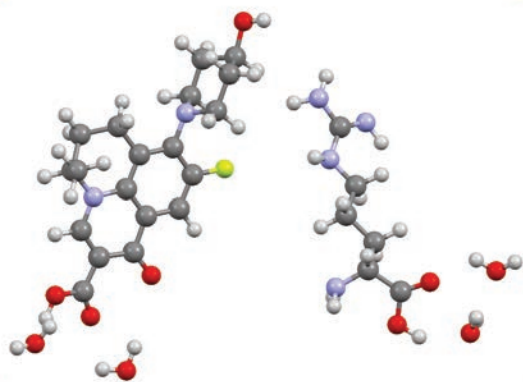


Cefepime

This is a first ever high-proportion combination of a well-established cephalosporin (Cefepime) with clinically validated β -lactamase inhibitor (Tazobactam). This combination yields superior Extended Spectrum β -lactamase producing Enterobacteriaceae (ESBL) pathogen coverage extending up to some of the Carbapenem-resistant Enterobacteriaceae (CRE).

It is suitable as a first line empiric therapy for Complicated Urinary Tract Infections (cUTI), Complicated Intra-Abdominal Infections (cIAI), Hospital-Acquired Bacterial Pneumonia (HABP) and Bloodstream Infections (BSI).

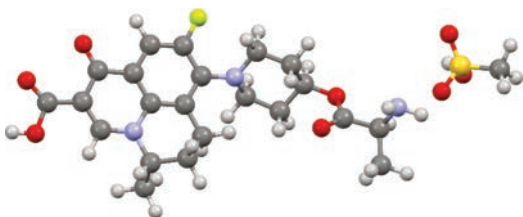
Levonadifloxacin (INN for WCK 771)



It is a broader spectrum bactericidal anti Methicillin-resistant Staphylococcus aureus (MRSA) drug whose novel structural attributes of Levonadifloxacin leads to a differentiated mechanism of action against MRSA. Its resistant pathogen coverage includes MRSA, Community-Acquired MRSA, Vancomycin-resistant Staphylococcus aureus (VRSA), Multi drug-resistant (MDR) Pneumococci, Clindamycin-resistant Group B Streptococci, E.coli, Klebsiella, Enterobacter, Salmonella and Gram-positive & Gram-negative anaerobes.

Its treatment potential includes acute bacterial skin and skin structure infections, hospital-acquired pneumonia caused by MRSA, diabetic foot infections and community-acquired pneumonia.

Alalevonadifloxacin (INN for WCK 2349)



It is a novel L-alanine ester prodrug of Levonadifloxacin with remarkably high oral bioavailability. It is being developed as an oral fluoroquinolone antibacterial agent that displays excellent coverage for Methicillin-resistant Staphylococcus aureus (MRSA). Its resistant pathogen coverage includes MRSA, Community-Acquired MRSA, Vancomycin-resistant Staphylococcus aureus (VRSA), Multi drug-resistant (MDR) Pneumococci, Clindamycin-resistant Group B Streptococci, E.coli, Klebsiella, Enterobacter, Salmonella and Gram-positive & Gram-negative anaerobes.

This agent is being developed for the treatment of Acute bacterial skin and skin structure infections (ABSSSI), Hospital-acquired bacterial pneumonia (HABP) caused by MRSA, diabetic foot infections and community-acquired pneumonia.

Wockhardt NCEs Addressing Several Resistance Threats Identified by CDC

URGENT THREATS

Clostridium difficile

-

Carbapenem-resistant Enterobacteriaceae (CRE)

WCK 5222, WCK 4282

Drug-resistant Neisseria gonorrhoeae

-

SERIOUS THREATS

Multidrug-resistant Acinetobacter

WCK 5222

Extended spectrum β -lactamase producing Enterobacteriaceae (ESBLs)

WCK 5222, WCK 4282

Vancomycin-resistant Enterococcus (VRE)

-

Drug-resistant Salmonella typhi

WCK 5222, WCK 4282

Multidrug-resistant Pseudomonas aeruginosa

WCK 5222, WCK 4282

Methicillin-resistant Staphylococcus aureus (MRSA)

WCK 771, WCK 2349

Drug-resistant Streptococcus pneumoniae

WCK 4873, WCK 2349

CONCERNING THREATS

Vancomycin-resistant Staphylococcus aureus (VRSA)

WCK 771, WCK 2349

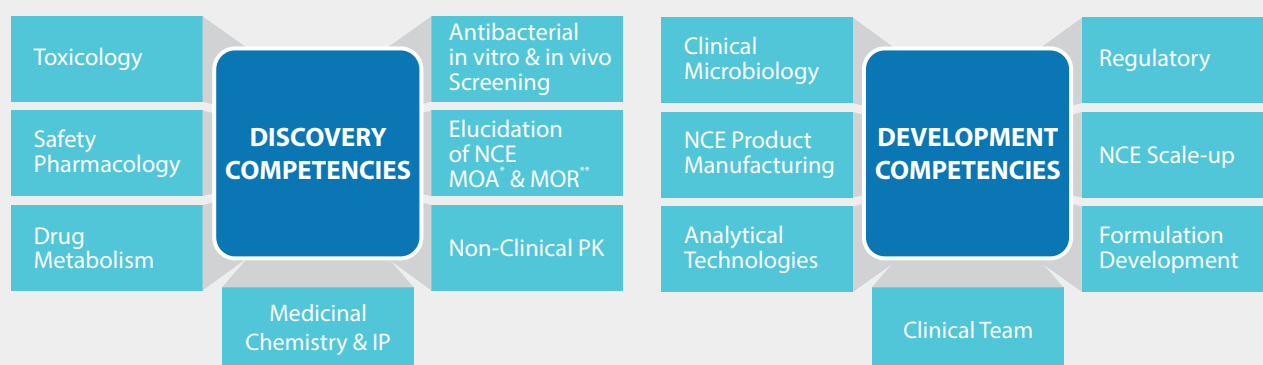
Erythromycin-resistant Group A Streptococcus

WCK 4873, WCK 2349

Clindamycin-resistant Group A Streptococcus

WCK 4873, WCK 2349

End-to-End Discovery Research & NCE Development Competencies



*Mechanism of action | **Mechanism of resistance

3
R&D Centres
in India, UK & USA

99
DOCTORATES
IN

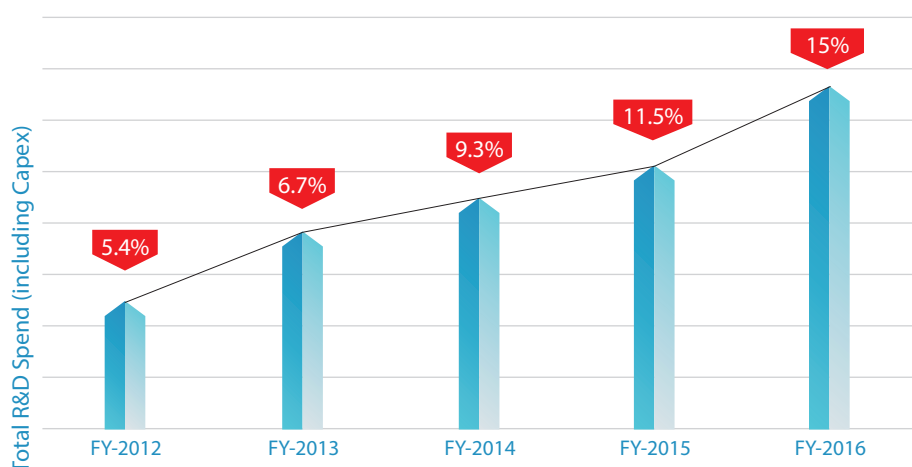
- Chemistry
- Pharmaceutics
- Pharmacology
- Biotechnology
- Medicinal Chemistry
- Synthetic Organic
- Organic Synthesis
- Microbiology
- Molecular biology
- Clinical Microbiology
- Clinical Research
- Analytical Chemistry
- Regulatory Affairs

822 Professionals
comprise a
committed
Research Team

Research Areas

- Generics
- Novel Drug Delivery
- New Drug Discovery
- Recombinant Biopharmaceuticals

Year-on-Year increase in industry-leading investment in R&D as a percentage of total sales



EVERY PATENT & APPROVAL IS A WIN. LIFE WINS.

At Wockhardt, our comprehensive R&D capabilities include end-to-end drug discovery competencies, developed in-house, right from concept to drug discovery to clinical development to approvals to manufacturing and marketing.

As a result of our long and steady focus on community and hospital acquired infections for over two decades, we pride ourselves on having one of the most comprehensive anti-bacterial R&D programmes in the world.

Our year-on-year increasing investment in R&D as a

percentage of sales is vindicated by our successes and achievements. In FY 2015-16, we won QIDP status by US FDA for 3 more new drugs, making it a total of 5 new drugs under development with QIDP status, a feat unmatched by any pharmaceutical company in the world.

This year we also added to our Intellectual Property (IP) base by filing 311 patents out of which 100 patents were granted, taking cumulative patents filed to 2,579 and patents granted to 441.

FY 2015-16 Performance Highlights

SALES

US\$ 673 million

₹ 4,461 crore

OPERATING PROFIT (EBITDA)

US\$ 78 million

₹ 518 crore

PROFIT AFTER TAX

US\$ 49 million

₹ 326 crore

EBITDA MARGIN

11.6%

