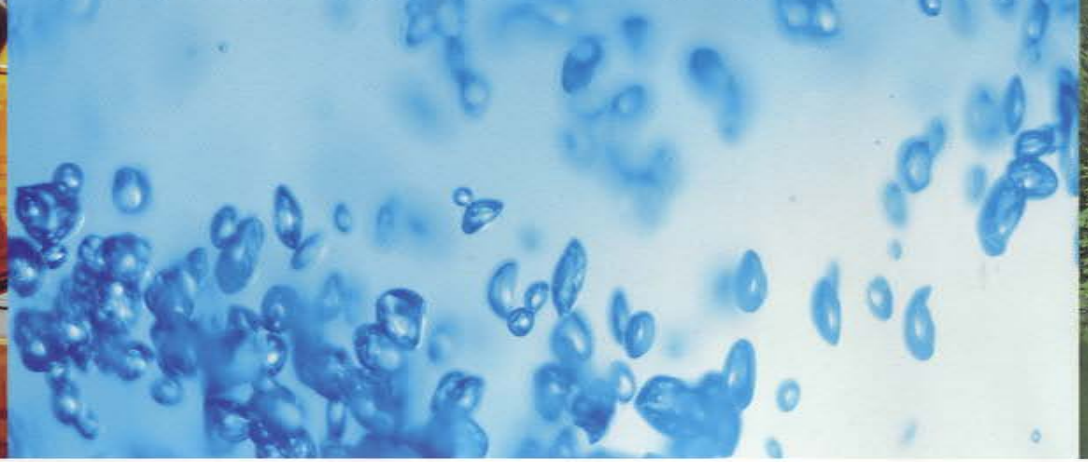
Purimox™

DSM Anti-Infectives

Unlimited. DSM



"GREEN" PROCESS, PURE AMOXICILLIN

As a producer, you face a number of significant challenges these days. Challenges arising from increasingly strict environmental and pharmaceutical regulations. And from a tight market that makes it ever more necessary to keep a firm rein on costs. Purimox™, the first enzymatically produced amoxicillin trihydrate, helps you to meet both these challenges head on. With exceptional purity that increases your yields, cuts your costs and contributes to patient safety. And fewer residual solvents so you comply with today's—and tomorrow's—most stringent environmental and pharmaceutical policies (e.g. ICH-guidelines).

Produced in DSM's brand-new facility in Almeria, Spain, Purimox™ will be available worldwide at the end of 2002. In five grades, so it can be used in all traditional amoxicillin applications: capsules, tablets and suspensions. In addition, of course, it's the ideal grade for the manufacture of amoxicillin/clavulanic acid dosage forms.

The Certificate of Suitability to the European Pharmacopoeia (CEP) will be available well before the end of 2002. Completion of the FDA approval process is targeted for 2004.

PURITY REDUCES SYSTEM COSTS AND INCREASES YIELD

Rarely has your market been as sensitive as it is today. With competition forcing prices down and regulatory, labour and other expenses pushing costs higher and higher. Leaving you and your profits squeezed. Purimox™ helps you to cope with margin pressure in two ways. You'll reduce your analytical system costs. And, because of higher yield, you'll simply have more product to sell.

Decrease your testing costs
Testing costs can really eat into your profits, and this is getting worse every year as regulations intensify. Purimox™ cuts testing costs in several ways;

- By decreasing testing frequency, since batch sizes will be up to 5000 kgs
- By reducing the amount of testing necessary, thanks to the substance's inherent purity
- By reducing the labour required to test, trial and document for QA and RA
- By eventually reducing the amount of testing equipment needed—for significant long-term cost savings

Increase your yield
Improving your yield immediately impacts your bottom line. You'll see as much as a 0.5 % - 1% increase in your yield with every batch. In other words, you'll get at least 5 kilograms extra per metric ton of bulk product. The reason for this is Purimox™'s high purity. Since Purimox™ is free of many of the impurities — methylene cloride (dichloromethane), isopropylalcohol, butylacetate, pyridin, etc. — found in amoxicillin currently on the market.

THE "GREEN" PRODUCT OF THE FUTURE

It's a huge question mark for everyone. What will the future bring in terms of environmental and pharmaceutical requirements? More importantly, how will you be able to comply with them? Purimox™ will give you one less thing to worry about since it's a "green" product. One that will allow you to easily comply with all future pharmaceutical regulations.

Meet ICH Guideline Q3C

Purimox™ is free of class 1 and 2 residual solvents and contains only a small amount of methanol. In fact, the methanol formed during enzymatic synthesis is considerably below the limit recommended by ICH Guideline Q3C. This substantially reduces your regulatory work in terms of administrative and paper costs.

Another benchmark in environmental responsibility

We chose to develop Purimox™ because it also allows us to manufacture in the most environmentally responsible way. And to pass along this "green" product to you, so you'll also participate in and contribute to protecting the world's precious environment. This enzymatic process guarantees our license to produce, and thus to supply, for the coming decades of the 21st century. Perhaps this comes as no surprise. After all, DSM Anti-Infectives was the first to develop an enzymatic process for producing cephalexin monohydrate. And is constantly alert for new opportunities to promote responsible environmental care.