

 **COLOUR-CODED TABS — EASIER TO READ AND EASIER TO FOLLOW**

News & Updates

Updates, news, upgrades & personal messages from NxGen Wholesaling.

Marketing

Marketing tips & suggestions from some of the industry leaders. They are here to help your compounding business grow.

Industry News

Stay up to date with the latest news, rules & regulations from the compounding industry.

Compounding Corner

Formulas, tips, discussion & pharmaceutical articles, everything for the compounder.



t: 1300 738 306
f: +612 9540 0399
wholesaling@nxgen.com.au

NxGen Wholesaling
PO Box 2502 Taren Point
NSW Australia 2229

NxGen Wholesaling news

Issue 14
SEPTEMBER—OCTOBER 2010

NxGen Wholesaling — pharmaceutical, medical, dental & veterinary wholesale distributor



Accredited  PSA
www.psa.org.au

*Earn 11.25
CPD points*

1 WEEK TO GO!

NxGen Wholesaling is proud to bring you the inaugural Australasian Conference for Compounding Pharmacists, the **first compounding specific conference in Australia** open to all pharmacists in the country.

Speakers & their topics at the conference:

- Patricia Storey** — Exploiting your compounding facility and increasing your sales and market share
- T.S. Wiley** — The Wiley Protocol®
- Jim Rowe** — 1. Beyond use-by dates in compounded products 2. BHRT in compounding
- Daryll Knowles** — 1. An introduction to compounding. 2. Compounding as a business
- Bill Anton** — Biochemistry behind BHRT
- Andrew McLachlan** — Future of individualised medicine and compounding in Australia
- John Mitchell** — Regulation in pharmaceutical compounding in Australia
- Cathrine Dahlgren** — Standard operating procedures and quality management
- Dr Helen Mackie** — Pain management
- Ric Williams** — Advanced formulation techniques for compounding

LAST CHANCE TO REGISTER FOR

**Sat 11th — Sun 12th
September, 2010**

Swissôtel Sydney, Australia

1300 738 306

info@accp.net.au

www.accp.net.au



Brought to you by NxGen Wholesaling
www.nxgen.com.au



Dear valued customer

September is here and our Australasian Conference for Compounding Pharmacists is just around the corner on the 11th and 12th September! Please get all your registrations in so you do not miss out on this great event. Spots are filling fast!

What a couple of months it has been. We have had our biggest sale ever and our key customer service and sales guru Vladimir off on annual leave!! Great timing Vladimir! I must take my hat off to our newest member of staff Jordi who has done a fantastic job of getting all our orders out on time.

I am pleased to see that customers are now realising that they do not have to send their formulation studies and assays overseas to the US! Some of our customers have already been getting their products tested and asking technical advice which we are more than happy to provide through our NxGen Pharmaceutical Company.

Once again I'm always interested in feedback on our company, services or the industry as a whole. The best was to

service you better is by telling us how! So pick up the phone and give me a call or drop me an email, I would love to hear from you.

Wishing you and your team a great month as always

Andrew Rowe

SEE INSERT
FOR THE
**COLOSSAL
CHEMICAL
CLEAROUT**

IN THIS ISSUE

■ **Meet the team!** Time to put a picture to that voice on the other end.
Page 3

■ **Article:** "Product formulations"
Pages 1 & 2

■ **Make your own caffeine citrate!** Find out how.
Page 3

■ **Don't miss ACCP,** the first compounding conference in Australia.
Visit www.accp.net.au

Product formulations

Daryll Knowles

People all over the world are constantly bombarded with emails making claims that are completely unsubstantiated in order to make a quick buck. Unfortunately, most consumers don't have

a medical degree or 20 years' experience in the healthcare field to rely upon when deciding whether to buy.

This leads me my point; the dose delivery considerations and formulation is

just as important as the active ingredient when selecting solutions for an ailment or supplement.

Continued on page 2

Product formulations (continued from page 1)

Daryll Knowles

...continued from page 1

■ Delivery as important as dose

Besides providing a mechanism for the safe and convenient delivery of accurate dosage forms may also provide:

1. Protection of the drug substances from the destructive influences of atmospheric oxygen or humidity (coated tablets for example)

2. Protection of the drug substance from gastric acid after oral administration (enteric coated tablets)

3. Concealment of the bitter, salty or offensive taste or odour of a drug substance (flavoured syrups)

4. Liquid preparations of substances that are either insoluble or unstable in the desired vehicle (suspensions)

5. Clear liquid dosage forms of substances (syrups)

6. Rate controlled drug action (various controlled-release medications)

7. Optimal drug action from topical administration sites (ointments, creams etc)

8. For internal insertion of a drug into one's body's orifices (suppositories or pessaries)

9. Direct placement of drugs directly into the bloodstream or body tissue (injections)

10. Optimal drug action through inhalation therapy (inhalants)

■ Formulation variables to consider

When looking at a formulation of a single ingredient produced under CGMP, the questions that need to be asked are:

1. What is the aim of the therapy?

2. What is the target area of the medication?

Can we deliver the medicine directly to

the area without involving the entire body system? Topical skin applications, nasal sprays, buccal, sublingual lozenges and eye drops are examples of direct delivery systems that, for the large part, avoid the body's systemic and hepatic metabolism, thus allowing a smaller dose to be applied and a lesser side-effect profile. The molecules that lend themselves to these dose forms are, on whole, low molecular-weight and water soluble, but this inhibits the ability for molecules to cross the dermal barrier.

3. What is the dose regime of the medication required?

By simply changing the type or molecular weight of the excipient or bulking agent in a capsule or tablet, you are able to alter significantly the release rate of the active ingredient. For example, excipients such as rice starch, ascorbic acid or lactose give a quicker releasing preparation, whereas the cellulose family of filler tend to slow the release (depending on the molecular weight of the cellulose).

4. Stability considerations of dose forms

Many vitamins are very unstable if exposed to water or air and are significantly metabolised by the liver. This limits the formulation methods due to stability aspects to sublingual, non aqueous formulations and injections. Vitamins C, E and B12 are susceptible to oxidation.

5. Are the actives dangerous if delivered by some routes?

Active ingredients that are corrosive, acidic, caustic or just plain irritant must be given special attention when formulating.

6. How long is the course of the treat-

ment?

Is a preservative required? The pH, dose form and duration of therapy all determine the preservative selected. Hormone therapies would not use parabens that are currently under investigation for oestrogen-like activity. Benzyl alcohol is a versatile preservative that to date has avoided bad press. Eye preparations are very restricted due to irritancy factors and generally use benzalkonium. Sensitivity to active ingredients and colours should be taken into account.

7. What is the pH of the formulation? pH affects every aspect of formulation, from the ability to penetrate the skin, irritability of eye preparations, nasal preparations and gastric irritability.

8. Choice of delivery system? Looking at the nature of the molecule we are trying to deliver is important in the choice of carrier.

■ Getting under the Skin

The most effective and suitable carrier molecules are usually hydrocarbon entities with carbon chain lengths between nine and 12. Unfortunately, however, penetrating agents are amongst the potentially most irritating chemicals to skin because they disrupt the order of the protective dermal barrier.

So, armed with the above information, the same basic rules apply when looking at dose delivery systems. If a medicine is only available in a limited range of dose forms it is probably because it is not suited to be delivered any other way.

If you have any questions regarding formulations or drug delivery please call NxGen and speak to an experienced compounder.

MEET THE TEAM



Name?

Vladimir 'The Impaler' Holusa.

Where are you from?

A beautiful little Village called Nova Ves, 4 hours east of Prague in the real God's Country, Czech Republic!

What is your current position in NxGen?

Mainly customer service and purchasing officer, but I pretty much get involved in everything in the company!

How long have you been with the Company?

Two years.

Whats your greatest achievement in this time?

I think getting to know all the customers and learning about all the products we sell. I have really established some great relationships with some of the customers, they are great to work with.

Whats your favourite quote?

"Teamwork... means never having to take all the blame yourself."

What would I find in your refrigerator right now?

Well not much in the one at work... Andrew eats it all! And not much at home, because I have been away overseas for four weeks. I'm really hungry!

Anything else you would like to say to your customers?

Really looking forward to the conference... can't wait to see you all there and show everyone what a cool bunch of people NxGen are!

Need caffeine citrate? Here is a helpful tip on how to make your own!

Martin A. Erickson III, RPh director of professional affairs at Gallipot Inc.

■ **Q:** Could you please provide me with a formulation for compounding caffeine citrate?

A: Caffeine USP is a white crystalline powder or "silky white crystal." It has a molecular weight of 194.2 when anhydrous. It also occurs as the monohydrate, which is efflorescent in air and is soluble in water 1:50; in alcohol 1:75. The monohydrate is stored in airtight containers.

Caffeine citrate ("citrated caffeine") may be compounded easily by combining equal amounts of caffeine and citric acid. Citrated caffeine is a white, bitter-tasting powder with a molecular weight of 386.3. Precaution is advised when caffeine is written: verify that the prescriber did not intend caffeine citrate—an overdose (or underdose) could occur if verification is not obtained.

Caffeine is a methylxanthine and, like theophylline, inhibits phospho-

diesterase; it has an antagonistic effect at central adenosine receptors. It stimulates the central nervous system, especially the higher centers, producing wakefulness and increased mental activity.

Orally administered caffeine is absorbed readily and widely distributed. Absorption when given intramuscularly can be slower than when given orally. Rectal absorption is slow and erratic. Caffeine passes into the placenta and saliva and is present in low concentrations in breast milk. Metabolism of caffeine in adults is almost completely hepatic; its metabolites are excreted in urine. Neonates have dramatically less capacity to metabolize caffeine—until hepatic metabolism is developed significantly (at about 6 months of age), it is mostly excreted unchanged in urine. Elimination half-lives vary greatly—3 to 7 hours for adults and possibly greater than 100

hours in neonates.

Caffeine's stimulation of respiration and its long half-life make it a useful oral or injected short-term treatment for apnea in premature neonates. The initial dose for caffeine citrate is 20 mg/kg (equivalent to 10 mg/kg caffeine), followed by maintenance dosing of 5 mg/kg of caffeine citrate daily. Before starting caffeine therapy in neonates, blood levels should be checked if the patient was given theophylline, which is metabolized to caffeine in infants, or if the mother consumed caffeine before delivery.

Unfortunately, caffeine citrate has been discontinued by NxGen, but by using the above formulation you will be able to make your own and save money!

NxGen Pharmaceuticals is a fully integrated service in product development to ensure your R&D investment is a success.