Film Coating of Hydrophilic Matrix Tablets

Technical Bulletin

Hydrophilic matrices are the most commonly used oral extended release (ER) systems:

- wide range of drug dose and solubility
- relative simplicity, robust formulation
- cost-effective manufacture
- broad regulatory acceptance

METHOCEL™ premium cellulose ethers (hypromellose [HPMC]) are hydrophilic polymer of choice; an effective alternative is POLYOX™ water-soluble resins (polyethylene oxide [PEO]).

Why Film Coat: FDA Draft Guidance for Industry

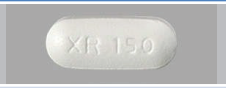
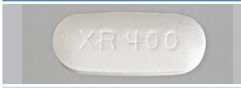
Safety Considerations for Product Design to Minimize Medication Errors, Dec 2012.

During development of an extended (ER) or delayed release (DR) product it is helpful to make the strengths of the ER or DR product distinct from the immediate release (IR)products.
Failures in prescribing, such as omission of modifiers or incorrect use of suffixes, can lead to dispensing and administration of the IR product instead of the intended ER or DR product. This can occur because all product characteristics overlap, or the strength is achievable from the marketed IR product strength.

Film Coating of Matrix Tablets: Dose Identification and Branding

FDA Draft Guidance: *"if multiple strengths are being developed, they should look different from each other, especially to reduce the chances of use errors that can result in harm if an overdose occurs due to administration of an incorrect strength"*

- Multiple doses of ER formulations are common (e.g. Seroquel XR from AstraZeneca)

50mg	150mg	200mg	300mg	400mg
				
Peach	White	Yellow	Light Yellow	White

Film Coating of Matrix Tablets: Ease of Swallowing

FDA Draft Guidance: *"consider the size, coating & palatability of oral products. A drug product can become a choking hazard due to the size of the tablet or capsule"*

- ER tablets are generally larger than IR equivalents
- Film coating improves swallowability & accelerates oesophageal transit time*
- Film coating reduces risk of tablets sticking in throat, causing localised mucosal irritation*

** The effect of surface coating of tablets on oesophageal transit (1985) Brit. J. of Pharm. Pract.*

Film Coating of Matrix Tablets: Anti-counterfeiting Deterrents

- Extended release tablets are high value products
- Film coating enables on-dosage deterrents to counterfeiting such as unique color, shape, logo, special effect coating and on-tablet taggants for authentication

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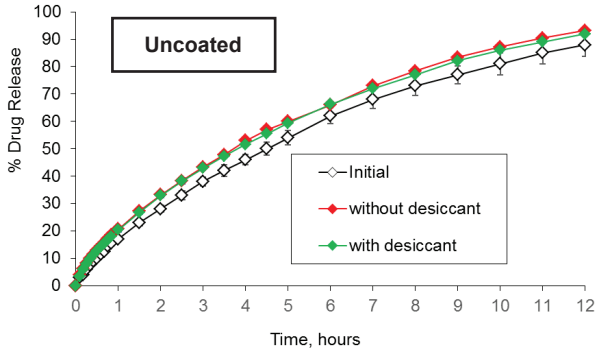
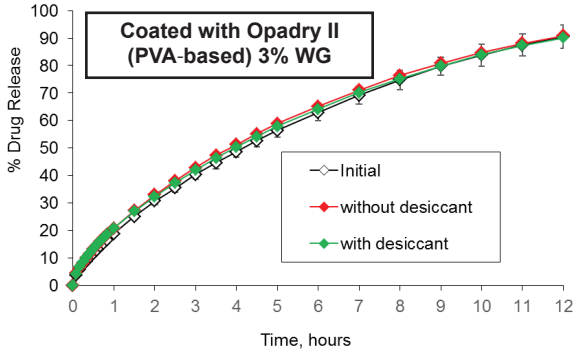
Film Coating of Matrix Tablets: Enhance Formulation Stability

- Film coating provides barrier to oxygen, light and/or moisture
- Film coating improves stability: 6 month @ 40°C/75% RH for propranolol matrix with POLYOX as rate controlling polymer

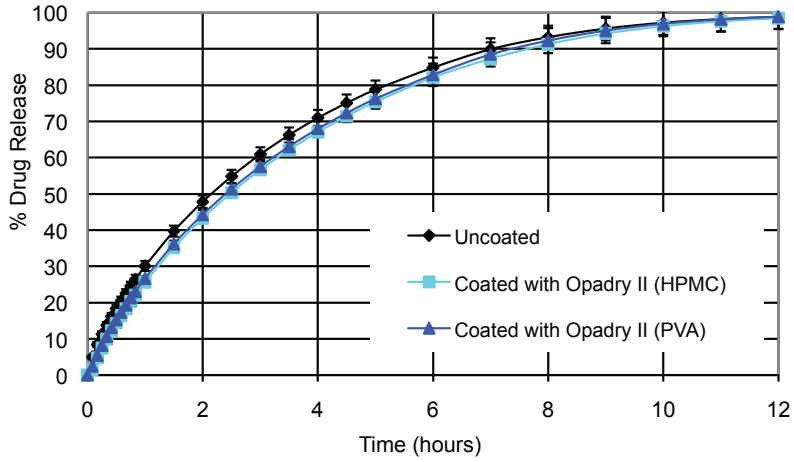




Matrix core: 30% propranolol HCl (160mg), 20% POLYOX WSR Coagulant, 49.5% Starch 1500®, 0.5% Mg stearate

Ref: Palmer, Levina, Nokhodchi, Farrell & Rajabi-Siahboomi (2011) CRS Conference, Maryland, USA)
http://www.colorcon.com/literature/marketing/mr/Extended%20Release/POLYOX/English/CRS_2011_Levina_FC_PEO_ER_Matrix_0.pdf

Film Coating of Matrix Tablets: Drug Release Unaffected at 4% WG using Opadry II



Core formulation: 50% metformin HCl (500mg), 30% METHOCEL K100M, 19% MCC, 0.5% fumed silica, 0.5% Mg stearate

Ref: Vuong, Levina & Rajabi-Siahboomi (2006) CRS Conference, Vienna, Austria
http://www.colorcon.com/literature/marketing/mr/Extended%20Release/METHOCEL/English/ads_methocel_effect_film_coat.pdf

Film Coating of Matrix Tablets: Accelerating Product Formulation Development & Design

- HyperStart® Oral Solid Dose Starting Formulation Service
- Brand Enhancement™ Service for Tablet Design

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For more information, contact your Colorcon representative or call:

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