

International Association

Drug 20< >02 Manufacturers

High Quality Low Cost Drug Development & Manufacturing Excellence World Wide

Innovative & Generic

HANDBOOK OF DRUG DEVELOPMENT Series

Part I - Drug Development - CMS

Part II - Drug Development
CMC/ANALYTICAL/VALIDATION

US

CHEMISTRY MANUFACTURING CONTROL

Know How Technology

&

EU

DOSSIERS

Know How Technology

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**HANDBOOK of DRUG DEVELOPMENT
+120 Title Specific Series****Part I - CMC DATA****Part II - ANALYTICAL STABILITY VALIDATION DATA****Generic Development ISSN Series number 0793 7407****Generic Development ISSN Series number 0793 7792 - Electronic Issue (Disk/CD ROM)**

IAGIM's HBGD HANDBOOKS KNOW-HOW SERIES are available in the most common dosage forms namely solid, semisolid and liquid dosage forms. The presentation of the actual data is based on commercial manufactured production batches and the format of all sections is similar to the data in the standard ANDA or EU Dossier. Commercial batches based on IAGIM technology are suitable for, and are in standard commercial production worldwide.

Drug Development Series	Form	Strength	Level	Part
Alendronate Sodium	Tablets	5 - 10 mg	US CMC	1 & 2
Alendronate Sodium	Tablets	40 mg	US CMC	1 & 2
Aluminium / Magnesium	Suspension		US CMC	1 & 2
Amitriptyline HCl	Tablets	10 mg	US CMC	1 & 2
Azithromycin	Suspension	200 mg	US CMC	1 & 2
Azithromycin	Capsules	250 /600 mg	US CMC	1 & 2
Azithromycin	Tablets	600 mg	US CMC	1 & 2
Atenolol EU	Tablets	50 /100 mg	US CMC	1 & 2
Atenolol US	Tablets	50 /100 mg	US CMC	1 & 2
Amoxicillin	Capsules	250/500mg	US CMC	1 & 2
Bisoprolol Fumerate/HCTZ=ZIAC	Tablets US + EU	5,10, 25/6.25mg	US CMC	1 & 2
Bromhexine Hydrochloride	Tablets +Syrup	8mg	US CMC	1 & 2
Bromocriptine Mesylate	Tablets	2.5mg	US CMC	1 & 2
Bupropion	Tablets	75.0/100 mg	US CMC	1 & 2
Bupirone HCl	Tablets	5 mg /10 mg	US CMC	1 & 2
Carbamazepine=Geigy (EU + US)	Tablets	200mg	US CMC	1 & 2
Carbamazepine=Geigy ChewTabs	ChewTabs	100 mg	US CMC	1 & 2
Carbamazepine (Extended Release) ≡ Geigy TEGRATOL 400 mg XR™	ER Coated Tab	400 mg	US CMC	1 & 2
Carbidopa/Levodopa	Tablets	10/100 mg	US CMC	1 & 2
Carbidopa/Levodopa	Tablets	25/100 mg	US CMC	1 & 2
Carbidopa/Levodopa	Tablets	25/250mg	US CMC	1 & 2
Carbidopa/Levodopa ER	Tablets	50/200mg	US CMC	1 & 2
Cefaclor Oral Suspension USP	Suspension	125 /187 mg/5mL	US CMC	1 & 2
Cefaclor Oral Suspension USP	Suspension	250/375 mg/5mL	US CMC	1 & 2
Cefaclor Oral Suspension EU	Suspension	250 mg/5mL	US CMC	1 & 2
Cefaclor	Capsules	250/500mg	US CMC	1 & 2
Cefalexin (≡ Keflex)	Capsules	250/500mg	US CMC	1 & 2
Cefuroxime Sodium USP	Vials	750-1500mg	US CMC	1 & 2
Clonazepam Tablets USP	Tablets USP	0.5/1.0/ 2.0mg	US CMC	1 & 2

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+120 Series

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Clomiphene Citrate	Tablets USP	50mg	US CMC	1 & 2
Clomipramine HCl	Capsules	25 / 50 / 75 mg	US CMC	1 & 2
Cloramphenicol / Prednisolone	Cream	3.0 / 0.5%	US CMC	1 & 2
Cimetidine Chew Tablets	Tablets	100 mg	US CMC	1 & 2
Diclofenac Potassium	Tablets	25 / 50 mg	US CMC	1 & 2
Diclofenac K + Misoprostol 200mcg	Tablets	25 / 50 mg	US CMC	1 & 2
Diclofenac Sodium + Misoprostol 200mcg	Tablets	50 / 75 mg	US CMC	1 & 2
Diclofenac Sodium	Tablets	50 / 75 mg	US CMC	1 & 2
Diclofenac Sodium	Tablets SR	100 mg	US CMC	1 & 2
Diclofenac Sodium	Clear Gel	10 mg/g	US CMC	1 & 2
Dorzolamide HCL Ophthalmic	Solution	2%	US CMC	1 & 2
Etodolac ≡ Wyeth Lodine	Capsules IR	200/300mg	US CMC	1 & 2
Etodolac ≡ Wyeth Lodine™	Tablets IR	400/500 mg	US CMC	1 & 2
Etodolac ≡ WyethAyerst Lodine XL ™	Tablets ER	400/500/600mg	US CMC	1 & 2
Enalapril Maleate	Tablets	40 mg	US CMC	1 & 2
Etidronate Disodium	Tablets		US CMC	1 & 2
Famotidine ≡ Merck's Pepsid	Tablets	10 / 20 / 40 mg	US CMC	1 & 2
Famotidine ≡ Merck's Pepsid AC	Chew Tabs	10mg	US CMC	1 & 2
Felodipine	Tablets	5/10mg	US CMC	1 & 2
Felodipine Extended Release	Tablets ER	2.5 / 5 / 10 mg	US CMC	1 & 2
Fluocinolone acetate	Cream	0.25%	US CMC	1 & 2
Fluozamine Malate ≡Solway's Luvox™	Tablets	20,50 100mg	US CMC	1 & 2
Flunisolide Hemihydrate solution	Nasal solution	1mg/5mL	US CMC	1 & 2
Flunitazepam	Tablets	2 mg	US CMC	1 & 2
Fluoxetine	Capsules	10 / 20 mg	US CMC	1 & 2
Fluoxetine	Tablets DC	10 / 20 mg	US CMC	1 & 2
Fusemide	Capsules	40 mg	US CMC	1 & 2
Gabapentin (≡Neurontin-Park Davis)	Capsules	100/200 mg	US CMC	1 & 2
Gabapentin (≡Neurontin-Park Davis)	Capsules	300/400 mg	US CMC	1 & 2
Gemfibrosil	Tablets	450 mg	US CMC	1 & 2
Gemfibrosil	Tablets	600 mg	US CMC	1 & 2
Glibenclamide	Tablets	5 mg	US CMC	1 & 2
Glipizide Extended Release	Tablets ER	2.5 mg	US CMC	1 & 2
Ibuprofen	Tablets	200-800mg	US CMC	1 & 2
Imodium	Caplet	2mg	US CMC	1 & 2
Isosorbide Mononitrate	Tablets	20 mg	US CMC	1 & 2
Ketorolac Tromethamine	Tablets	10 mg	US CMC	1 & 2
Levodopa/ Benserazide HCl	Tablets	200/50 mg	US CMC	1 & 2
Labetalol HCL (100; 200; 300mg)	Tablets	100/200/300mg	US CMC	1 & 2
Loperimide	Tablets	2mg	US CMC	1 & 2
Lovistatin ≡ Ayerst	Tablets	10 20 40mg	US CMC	1 & 2
Mesalamine (Enteric Coated)	Tablets	400mg	US CMC	1 & 2
Metformin HCl≡GLUCOPHAGE® BMS	Tablets	500/850mg	US CMC	1 & 2
Miconazole/Hydrocortisone	Cream	2% + 1%	US CMC	1 & 2
Miconazole Nitrate	Cream	2%	US CMC	1 & 2
Miconazole Nitrate	Gel	2%	US CMC	1 & 2
Nabumatone	Tablets	500/750mg	US CMC	1 & 2

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Naproxen (Enteric Coated)	Tablets DR	250 /375 / 500mg	US CMC	1 & 2
Naproxen Sodium DR	Tablets	220 mg	US CMC	1 & 2
Naproxen Sodium DR	Tablets DR	275 / 550mg	US CMC	1 & 2
Norfloxacin USP	Tablets	400 mg	US CMC	1 & 2
Ofloxacin ≡TARAVID	Tablets EU	100, 200, 400 mg	US CMC	1 & 2
Ofloxacin ≡TARAVID	Tablets USA	100, 200, 400 mg	US CMC	1 & 2
Oxolamine	Syrup	10 mg/mL	US CMC	1 & 2
Paclitaxel Concentrate for Injection	30/100mg vial	6.0 mg/mL	US CMC	1 & 2
Paracetamol - sugar/dye-free	Syrup	125 mg	US CMC	1 & 2
Paracetamol Chewable Fruit Flavors	Tablets	160 mg	US CMC	1 & 2
Pentoxifylline ≡Hoechst 400 XL	Tablets ER	400 mg	US CMC	1 & 2
Penfluridol	Capsules	10 mg	US CMC	1 & 2
Potassium Chloride 600+1200mg (SR)	Tablets	10+20 mEq	US CMC	1 & 2
Piroxicam	Capsules	20 mg	US CMC	1 & 2
Quinidine Bisulphate Tetrahydrate	Tablets	250 mg	US CMC	1 & 2
Ranitidine HCl	Tablets	150/300 mg	US CMC	1 & 2
Simvastatin	Tablets	5 / 10mg	US CMC	1 & 2
Simvastatin	Tablets	20 / 40 mg	US CMC	1 & 2
Scopolamine Butylbromide	Tablets	10 mg	US CMC	1 & 2
Selegiline	Tablets	5 /10 mg	US CMC	1 & 2
Sotalol (=Betapace™/ Berlex)	Tablets EU+ US	80, 120 160 240 mg	US CMC	1 & 2
Silver Sulphadiazine	Cream	1%	US CMC	1 & 2
Tamoxifen EU	Tablets	10 / 20 mg	US CMC	1 & 2
Tamoxifen EU	Tablets	30 / 40mg	US CMC	1 & 2
Tamoxifen US Aqueous Coated	Tablets	10/20/40mg	US CMC	1 & 2
Tamoxifen US Non Coated	Tablets	10/20/40mg	US CMC	1 & 2
Terbutaline Sulfate	Syrup	0.3 mg/mL	US CMC	1 & 2
Terazosin	Tablets	1mg / 2mg	US CMC	1 & 2
Terazosin	Tablets	5mg / 10mg	US CMC	1 & 2
Terfenadine	Tablets	60 mg	US CMC	1 & 2
Tetrahydrozoline HCl USP	Eye Drops	2,5mg/5mL	US CMC	1 & 2
Ticlopidine	Tablets	250 mg	US CMC	1 & 2
Timolol maleate Drops USP	Eye Drops	0.25 / 0.5%	US CMC	1 & 2
Tolmetin Sod.	Capsules	400 mg	US CMC	1 & 2
Tolmetin Sod.	Tablets	600 mg	US CMC	1 & 2
Trazodone	Tablets	50/100 mg	US CMC	1 & 2
Trazodone	Tablets	150 mg	US CMC	1 & 2
Tretinoin	Cream USP	0.025%	US CMC	1 & 2
Sulfamethoxazole Trimethoprim	Tablets USP	80/400mg	US CMC	1 & 2
Sulfamethoxazole Trimethoprim	Tablets USP	160/800mg	US CMC	1 & 2
Sulfamethoxazole Trimethoprim	Suspension	80/400mg	US CMC	1 & 2
Sodium Valproate	Syrup	200mg/5mL	US CMC	1 & 2
Verapamil Hydrochloride	Tablets	40/80/120mg	US CMC	1 & 2

AN ONGOING SERIES - NEW ADDITIONS ADDED TO SERIES

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Second International Edition - 02 (First to Fourth Print). Fourth printing published and distributed in UK, US, EU, Israel, Asia, and Japan in January 1998 by Locum International Publishing House (Houston, Israel, South Africa) in Hard Cover; Soft and Spiral Cover; Electronic Diskette; and e-mail attachment versions. All print and electronic versions identical in content and format