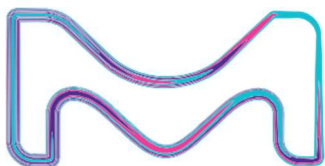


Chinese Regulation for excipients & API

List of Registration dossiers

Reg. No.	Co-review Status*	Catalogue No.	Usage as	Administration Route	ChP Compliance	Product Description
F20170000260	A	100201	Excipient	Parenteral	√	Phenol EMPROVE® ESSENTIAL Ph Eur,ChP,JP,USP
F20180001333	A	100419	Excipient	Oral	√	Parateck® M 200 (Mannitol) EMPROVE® ESSENTIAL Ph Eur, ChP,BP,JP,USP,E 421
F20180001333	A	100494	Excipient	Oral	√	Parateck® M 100 (Mannitol) EMPROVE® ESSENTIAL Ph Eur,ChP,BP,JP,USP,E 421
F20200000037		100590	Excipient	Injection/Oral/Ophthalmic	√	Glycine cryst. EMPROVE® EXPERT Ph Eur,BP,ChP,JP,USP
F20200000380		100681	Excipient	Oral/Parenteral	√	Succinic Acid cryst. EMPROVE® ESSENTIAL ChP, NF, JPE, ACS
F20170000066	A	100805	Excipient	Oral	√	Titanium(IV) oxide EMPROVE® ESSENTIAL Ph Eur, ChP,BP,USP,JP,E 171
F20170000107	A	100892	Excipient	Parenteral	√	Sucrose EMPROVE® ESSENTIAL Ph Eur,BP,ChP,JP,NF
F20200000375		100967	Excipient	Injection/Inhalation/Ophthalmic/topical and sublingual/Transdermal/Oral	√	Ethanol 96% EMPROVE® EXPERT Ph Eur,ChP, JP,USP
F20200000378		100986	Excipient	Oral/Injection/Ophthalmic preparation/ Topical and sublingual/Transdermal	√	Ethanol absolute EMPROVE® EXPERT Ph Eur,BP,ChP,JP,USP
F20200000340		101544	Excipient	Injection, oral, Other		L-Arginine monohydrochloride EMPROVE® EXPERT Ph Eur, BP, JP, USP
F20210000066		101587	Excipient	Oral, parenteral		L-Arginine EMPROVE® EXPERT Ph Eur,JP,USP
F20200000061		101806	Excipient	Inection/Oral		Benzyl benzoate EMPROVE® ESSENTIAL Ph Eur,BP,USP
F20190000622		102776	Excipient	Injection	√	Trehalose dihydrate EMPROVE® EXPERT Ph Eur,ChP,NF,JP
F20200000036		103669	Excipient	Injection/Oral/Ophthalmic	√	Glycine granulated EMPROVE® EXPERT Ph Eur,BP,ChP,JP,USP
F20190000564		103789	Excipient	Injection	√	Sucrose EMPROVE® EXPERT Ph Eur, ChP, JP, NF
F20200000384		104352	Excipient	Injection, oral	√	L-Histidine EMPROVE® EXPERT Ph Eur, ChP, USP, JP
F20200000399		104354	Excipient	Injection/Ophthalmic preparation/ Oral administration		L-Histidine monohydrochloride monohydrate EMPROVE® EXPERT Ph Eur, BP,JP
F20180000400	A	106143	Excipient	Parenteral	√	Meglumine low in endotoxins EMPROVE® API Ph Eur,ChP,JP,USP
F20180000401	A	106143	Excipient	Oral	√	Meglumine low in endotoxins EMPROVE® API Ph Eur,ChP,JP,USP
F20190000122	A	107583	Excipient	Oral	√	Parateck® SI 150 (Sorbitol) EMPROVE® ESSENTIAL Ph Eur,ChP,BP,JP,NF,JSFA,E 420
F20170000101	A	108386	Excipient	Parenteral	√	Tris(hydroxymethyl)aminomethane (Trometamol) EMPROVE® ESSENTIAL Ph Eur,BP,ChP,JPC,USP
F20190000386	A	108421	Excipient	Oral/Parenteral	√	Titriplex® III (ethylenedinitrilotetraacetic acid disodium salt dihydrate) EMPROVE® ESSENTIAL Ph Eur,BP,ChP,JP,USP



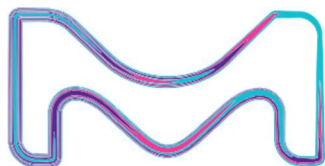
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Reg. No.	Co-review Status*	Catalogue No.	Usage as	Administration Route	ChP Compliance	Product Description
F20190000157		108800	Excipient	Parenteral/Transdermal/Oral		Zinc acetate dihydrate EMPROVE® ESSENTIAL Ph Eur,USP
F20200000381		108846	Excipient	Oral/Parenteral/ Transdermal	√	Zinc oxide EMPROVE® ESSENTIAL Ph Eur, ChP, BP, JP, USP
F20190000538		108915	Excipient	Injection		Zinc chloride Ph Eur,BP,USP
F20180001170	A	112635	Excipient	Oral	√	Parateck® Delta M (Mannitol) EMPROVE® ESSENTIAL Ph Eur,BP,USP,ChP, JP,E 421
F20200000042		128218	Excipient	Injection/Oral	√	Ammonium sulfate EMPROVE® EXPERT ACS, ChP, NF
F20200000498		128205	Excipient	Injection, ophthalmic, oral	√	Sodium acetate trihydrate EMPROVE® EXPERT Ph Eur,BP,ChP,JP,USP
F20190000387	A	137004	Excipient	Oral/Parenteral	√	Titriplex® III (ethylene dinitrilo tetraacetic acid disodium salt dihydrate) EMPROVE® EXPERT Ph Eur,BP,ChP,JP,USP,ACS
F20200000063		137017	Excipient	Oral/Injection/Ophthalmic preparation/ Topical and sublingual/Transdermal	√	Sodium chloride EMPROVE® EXPERT Ph Eur,BP,ChP,JP,USP
F20180000870	A	137096	Excipient	Parenteral	√	D(-)-Mannitol EMPROVE® EXPERT Ph Eur,BP,USP,ChP,JP
F20180001619	A	137120	Excipient	Injection	√	Benzyl Alcohol EMPROVE® EXPERT Ph Eur,ChP,JP,NF
F20210000254		141350	Excipient	Oral/ ophthalmic/ Transdermal	√	Polyvinyl alcohol 4-88 EMPROVE® ESSENTIAL Ph Eur,USP,JPE
F20190000493		141353	Excipient	Ophthalmic/Transdermal/Oral	√	Polyvinyl alcohol 40-88 EMPROVE® ESSENTIAL Ph Eur,ChP,USP,JPE
F20190000494		141355	Excipient	Ophthalmic/Transdermal/Oral	√	Polyvinyl alcohol 18-88 EMPROVE® ESSENTIAL Ph Eur,ChP,USP,JPE
F20190000562		141439	Excipient	Oral	√	Parateck® SRP 80 (Polyvinyl alcohol) EMPROVE® ESSENTIAL Ph Eur,ChP,USP,JPE
F20210000044		141464	Excipient	Oral	√	Parateck® MXP (Polyvinyl alcohol) EMPROVE® ESSENTIAL Ph Eur,JPE,USP
F20200000177		171597	Excipient	Injection/Topical and sublingual/Oral	√	Parateck® SI 400 LEX (Sorbitol) suitable for use as excipient EMPROVE® exp Ph Eur BP,ChP,NF,JP
F20200000193		817059	Excipient	Topical and sublingual/Transdermal/Oral	√	Triethyl citrate EMPROVE® ESSENTIAL Ph Eur,ChP,JPE,NF
F20180001635	A	817081	Excipient	Parenteral	√	Sodium caprylate suitable for use as excipient EMPROVE® exp Ph Eur,ChP,NF
Y20190009001	A	603430	API	oral		Urea-13C, UBT Grade

* Co-review Status A: "Active", which means Co-review Approved

If you want to raise a registration request for a API/Excipient that you don't find in that list, please contact your local representative. Please understand that the registration requests are prioritized with respect to our final marketing decision.



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