



# Excipient's List

SR CHEMIE

S R Chemie

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# Topical Excipients

| Excipient/s Description   | Manufacturer          | Country | Monograph             |
|---|-----------------------|---------|-----------------------|
| White Mineral Oil USP/JP; Light Liquid Paraffin/ Liquid Paraffin<br>Haikol M is manufactured under GMP<br>Grades: M 52, M72 & M 172: Light Liquid Paraffin<br>Grade: M352-Liquid Paraffin   | Kaneda                | Japan   | USP/JP                |
| Castor Oil  | Kaneda                | Japan   | USP/JP                |
| USP NF Refined vegetable oils: Corn, Castor, Soybean, Olive, Safflower; Cottonseed;<br>Peanut, Olive, Sesame; Sweet Almond<br>Welch Holme and Clark is USA's biggest producer of USP oils and approved in all major pharma companies. | Welch, Holme & Clarke | USA     | USP-NF                |
| TWEEN 20, 60,80<br>A leading producer of Tweens- distributed across US Territory  | Oxiteno               | Brazil  | USP-NF                |
| KEMESTRENE- GLYCERINE NATURAL 99.7%<br>Largest natural Glycerine Plant in the world and USA. This glycerine is not plant derived and synthesized. The process is FDA Validated and approved as adult glycerine laxative suppository.  | PMC Biogenix          | USA     | USP-NF                |
| BENZALDEHYDE, BENZOATES, BENZYL ALCOHOL parenteral<br>Only Kalama has 0 aldehyde content.   | Emerald Kalama        | USA     | USP-NF;<br>Ph.Eur, JP |
| FRAGRANCE CHEMICALS-Benzaldehyde, Cinnamic alcohol; C-8;C-9 aldehydes   | Emerald Kalama        | USA     | USP-NF                |



# Topical Excipients

| Excipient/s Description   | Manufacturer | Country  | Monograph      |
|---|--------------|----------|----------------|
| Palmsurf MCT 60:40, MCT 70:30 USP NF, Ph.Eur  | IOI Oleo     | Malaysia | USP/Ph.Eur.    |
| Triethanolamine USP-NF  | Ineos        | USA      | USP NF         |
| Cetareth-6, 12,10, 20, 25; PEG 40 Castor Oil, Caustic Soda Flakes Pharmaceuticals; Oleth-10; 20; Sodium hypochlorite  | PCC          | Poland   | Ph.Eur; USP-NF |
|   | Ueno         | Japan    | JP/USP         |
| USP Waxes: Beeswax; Candelilla Wax ; Carnauba Wax; Microcrystalline Wax; Ozokerite Wax; Paraffin Wax; Ceresine Wax; Soy Wax; Cocoa Butter; Shea Butter refined; Hydrogenated Soyabean oil; Hydrogenated Castor Oil. | Ross Wax     | USA      | USP- NF        |
| BORIC ACID EP; USP; BORIC ACID EP; USP POWDER; BORIC ACID FG; BORIC ACID FG POWDER; SODIUM TETRABORATE DECAHYDRATE EP; USP; SODIUM TETRABORATE DECAHYDRATE EP; USP POWDER   | SCL Italia   | USA      | USP-NF; Ph.Eur |
| Kaolin Lion; Kaolin SIM 90; Bentonite; Zinc Oxide   | CB Minerals  | USA      | USP, Ph.Eur.   |



# Topical Excipients

| Excipient/s Description  | Manufacturer | Country | Monograph         |
|--|--------------|---------|-------------------|
| Isopropyl myristate, Isopropyl palmitate   | Oleon        | Belgium | USP/JP            |
| Lanolin, Anhy. Lanolin, Lanolin Alcohol; PEG 30 Lanolin; PEG 75 Lanolin, Lanolin Wax, Lanolin Oil; Lanolin Alcohol SSR EP, Lanolin Alcohol SSR USP.<br>Stella is a GMP manufacturer from France.   | Stella       | France  | USP/JP            |
| Propyleneglycol derivative- stearate; laurate, caprylate etc. USP; Ph.Eur.; Ph.Eur.; Propylene glycol dicaprylate/dicaprate Ph.Eur; USP; Oleic acid USP/Ph.Eur; Sorbitan esters- all; Polyethylene glycol derivatives: Laurate, cocoate, stearate etc. | Oleon;       | Belgium | USP-NF            |
| Parabens- Methyl, propyl, butyl, ethyl<br>Ueno is world leader in paraben production and these are non-sticky powders with high surface Area   | Ueno         | Japan   | JP/USP            |
| USP Waxes: Beeswax; Candelilla Wax ; Carnauba Wax; Microcrystalline Wax; Ozokerite Wax; Paraffin Wax; Ceresine Wax; Soy Wax; Cocoa Butter; Shea Butter refined; Hydrogenated Soyabean oil; Hydrogenated Castor Oil.                                    | Ross Wax     | USA     | USP- NF           |
| BORIC ACID EP; USP; BORIC ACID EP; USP POWDER; BORIC ACID FG; BORIC ACID FG POWDER; SODIUM TETRABORATE DECAHYDRATE EP; USP; SODIUM TETRABORATE DECAHYDRATE EP; USP POWDER  | SCL Italia   | USA     | USP-NF;<br>Ph.Eur |
| Kaolin Lion; Kaolin SIM 90; Bentonite; Zinc Oxide  | CB Minerals  | USA     | USP, Ph.Eur.      |



# Solid Excipients

| Excipient/s Description   | Manufacturer              | Country  | Monograph   |
|---|---------------------------|----------|-------------|
| Stearic Acid; Magnesium Stearate fine powder, Zinc Stearate, Calcium Stearate<br>PMC is the leader in stearate production in the USA.         | PMC Biogenix              | USA      | USP         |
| Citric Acid anhydrous powder, coarser, granular grades<br>Leading US producer   | Archer Daniels<br>Midland | USA      | USP/Ph.Eur. |
| Maltodextrin (Clintose); Soy lecithin NF; Propylene Glycol 9Corn origin)<br>Similar to Glucidex   | Archer Daniles<br>Midland | USA      | USP-NF      |
| Xanthan Gum 40#; 80#, 200# Transparent, Sorbitol 70% crystalline, and powders   | Archer Daniles<br>Midland | USA      | USP-NF      |
| Glyceryl Monostearate USP/ Ph.Eur Type 1 , 2 &3<br>95%, 40-55%  | Oleon                     | Malaysia | USP-NF      |
| Light Dicalcium Phosphate Anhydrous USP; JP Ph=7; bd: 580; median:50<br>Light Dicalcium Phosphate Dihydrate USP/JP Ph= 7; bd: 650, median: 70 | Kyowa Chemicals           | Japan    | USP-NF; JP  |
| Mg: Oxide, heavy and light; Hydroxide; Trisilicate;<br>Al: hydroxide gel, dihydroxy aluminium aminoacetate; synthetic hydrotalcite, Silicate  | Kyowa Chemicals           | Japan    | USP-NF; JP  |



# Solid Excipients

| Excipient/s Description   | Manufacturer              | Country  | Monograph   |
|---|---------------------------|----------|-------------|
| Stearic Acid; Magnesium Stearate fine powder, Zinc Stearate, Calcium Stearate<br>PMC is the leader in stearate production in the USA.         | PMC Biogenix              | USA      | USP         |
| Citric Acid anhydrous powder, coarser, granular grades<br>Leading US producer   | Archer Daniels<br>Midland | USA      | USP/Ph.Eur. |
| Maltodextrin (Clintose); Soy lecithin NF; Propylene Glycol 9Corn origin)<br>Similar to Glucidex   | Archer Daniles<br>Midland | USA      | USP-NF      |
| Xanthan Gum 40#; 80#, 200# Transparent, Sorbitol 70% crystalline, and powders   | Archer Daniles<br>Midland | USA      | USP-NF      |
| Glyceryl Monostearate USP/ Ph.Eur Type 1 , 2 &3<br>95%, 40-55%  | Oleon                     | Malaysia | USP-NF      |
| Light Dicalcium Phosphate Anhydrous USP; JP Ph=7; bd: 580; median:50<br>Light Dicalcium Phosphate Dihydrate USP/JP Ph= 7; bd: 650, median: 70 | Kyowa Chemicals           | Japan    | USP-NF; JP  |
| Mg: Oxide, heavy and light; Hydroxide; Trisilicate;<br>Al: hydroxide gel, dihydroxy aluminium aminoacetate; synthetic hydrotalcite, Silicate  | Kyowa Chemicals           | Japan    | USP-NF; JP  |



# Solid Excipients

| Excipient/s Description   | Manufacturer           | Country | Monograph  |
|---|------------------------|---------|------------|
| Dipac Directly compressible Sugar- Sucrose NF - Domino  | Domino                 | USA     | USP-NF     |
| Carnauba Wax- Powder  | Foncepi                | Brazil  | USP NF     |
| L- Arabinose, Xylitol, Xylose   | Shandong Longlive      | China   | USP-NF     |
| Simethicone Powders and dispersion: USD MF Type 2 approved as an active.<br>Simethicone 100 F: USP ; Simethicone C 100 EP; Simethicone C 100 LV; Simethicone PD 30S | KCC Basildon           | USA     | USP-NF     |
| Triacetin   | Tennants Fine Chemical | USA     | USP-NF     |
| Light Dicalcium Phosphate Anhydrous USP; JP Ph=7; bd: 580; median:50<br>Light Dicalcium Phosphate Dihydrate USP/JP Ph= 7; bd: 650, median: 70                       | Kyowa Chemicals        | Japan   | USP-NF; JP |
| Mg: Oxide, heavy and light; Hydroxide; Trisilicate;<br>Al: hydroxide gel, dihydroxy aluminium aminoacetate; synthetic hydrotalcite, Silicate                        | Kyowa Chemicals        | Japan   | USP-NF; JP |



# Solid Excipients

| Excipient/s Description   | Manufacturer    | Country | Monograph   |
|---|-----------------|---------|-------------|
| PEG 6000 Powder USP/ EP   | Poliolles,      | Mexico  | USP, Ph.Eur |
| Iron Oxide various grades, Titanium Dioxide various Grades; Zinc Oxide  | CB Minerals     | USA     | USP/Ph.Eur. |
| Calcium Sulfate Dihydrate Snowwhite- granular, powder and anhydrous   | CB Minerals     | USA     | USP-NF      |
| Calcium Carbonate PCC Light and Dense   | CB Minerals     | USA     | USP-NF      |
| Potassium Carbonate/ Potassium Bicarbonate  | Armand Products | USA     | USP-NF      |
| Citric Acid Monohydrate: Only producer in the world<br>Citric Acid Anhydrous; Trisodium Citrate dihydrate; Monosodium Citrate Anhydrous<br>Citric Acid Solution- 46%, 50% | Citrique Belge  | Belgium | USP-NF; JP  |
| L-Arabinose; D-Xylose; Xylose; Xylitol  | Longlive China  | China   | USP-NF; JP  |
| Sucralose USP, EP; Aspartame USP/EP; Folic Acid USP/EP  | Niutang         | China   | USP-NF; JP  |





# Solid Excipients

| Excipient/s Description  | Manufacturer           | Country | Monograph       |
|--|------------------------|---------|-----------------|
| <b>Gum Acacia/ Gum Arabic USP NF/Ph.Eur/JP</b><br><b>Agri-Rapid:</b><br>Standard : max 15% <75µm<br>Medium : max 50% <140µm<br>Coarse: min 40% >200µm<br><b>Agri- Spray:</b> min 90% <200µm  | Agrigum                | UK      | USP, Ph.Eur, JP |
| Tartaric Acid Powder<br>900um to 40um.   | Tydsa Spain            | USA     | USP/Ph.Eur.     |
| Sodium Alginate; Calcium Alginate, Alginic acid; Potassium Alginate; Ammonium alginate   | Kimica Alginates       | Japan   | USP-NF, JP      |
| High intensity sweeteners: Acesulfame K; Sucralose, Aspartame; Stevia<br>Erythritol, D-Xylose; Bulking agent: Polydextrose   | Hyet Sweet             | USA     | USP-NF          |
| Acidulants-Citric Acid, Potassium and Sodium Citrate Maltodextrin (Clintose®)<br>Alcohol-Beverage Grade Monk Fruit (VerySweet™); Allulose (JustSweet™) Polyols-Liquid, Dry and Non-Crystallizing; Corn Starch-Food Grade Resistant Maltodextrins (Fibersol®); Corn Syrup-Liquid and Solids Stevia (SweetRight™); Crystalline Dextrose (Clintose®); Sucralose (VivaSweet™); Crystalline Fructose (CornSweet®); Sucrose*-Dry, Liquid and Invert; Erythritol Sweetener Blends; High Fructose Corn Syrups (CornSweet®) Xanthan Gum (NovaXan™ and OptiXan™) | Archer Daniels Midland | Japan   | USP-NF; JP      |
| Mg: Oxide, heavy and light; Hydroxide; Trisilicate;<br>Al: hydroxide gel, dihydroxy aluminium aminoacetate; synthetic hydrotalcite, Silicate   | Kyowa Chemicals        | Japan   | USP-NF; JP      |



# Liquid Orals Excipients

| Excipient/s Description   | Manufacturer           | Country | Monograph |
|---|------------------------|---------|-----------|
| <b>Xanthan Gum 200#, 80#, 40#</b><br>Transparent equal to FNCS and Xantural<br>ADM is the leader in Xanthan Gums in USA   | Archer Daniels Midland | USA     | USP       |
| <b>Sorbitol 70% non-crystalline, Sorbitol powder, coarser, coarse</b><br>Only competitor to Neosorb; highest quality, ready stock   | Kaneda                 | Japan   | USP/JP    |
| <b>USP NF Refined vegetable oils: Corn, Castor, Soybean, Olive, Safflower; Cottonseed; Peanut, Olive, Sesame; Sweet Almond</b><br>Welch Holme and Clark is USA's biggest producer of USP oils and approved in all major pharma companies.   | Welch, Holme & Clarke  | USA     | USP-NF    |
| <b>TWEEN 20, 60,80</b><br>A leading producer of Tweens- distributed across US Territory   | Oxiteno                | Brazil  | USP-NF    |
| <b>KEMESTRENE- GLYCERINE NATURAL 99.7%</b><br>Largest natural Glycerine Plant in the world and USA. This glycerine is not plant derived and synthesized. The process is FDA Validated and approved as adult glycerine laxative suppository. | PMC Biogenix           | USA     | USP-NF    |
| <b>BENZALDEHYDE, BENZOATES, BENZYL ALCOHOL parenteral</b><br>Only Kalama has 0 aldehyde content.  | Emerald Kalama         | USA     | USP-NF    |
| <b>FRAGRANCE CHEMICALS-Benzaldehyde, Cinnamic alcohol; C-8;C-9 aldehydes</b>  | Emerald Kalama         | USA     | USP-NF    |



# Liquid Orals Excipients

| Excipient/s Description   | Manufacturer          | Country | Monograph |
|---|-----------------------|---------|-----------|
| Aspartame, Sucralose; Polydextrose, Stevia, Acesulfame K  | Hyet Sweets           | USA     | USP       |
| <b>Sorbitol 70% non-crystalline, Sorbitol powder, coarser, coarse</b><br>Only competitor to Neosorb; highest quality, ready stock   | Kaneda                | Japan   | USP/JP    |
| <b>USP NF Refined vegetable oils: Corn, Castor, Soybean, Olive, Safflower; Cottonseed; Peanut, Olive, Sesame; Sweet Almond</b><br>Welch Holme and Clark is USA's biggest producer of USP oils and approved in all major pharma companies.   | Welch, Holme & Clarke | USA     | USP-NF    |
| <b>TWEEN 20, 60,80</b><br>A leading producer of Tweens- distributed across US Territory   | Oxiteno               | Brazil  | USP-NF    |
| <b>KEMESTRENE- GLYCERINE NATURAL 99.7%</b><br>Largest natural Glycerine Plant in the world and USA. This glycerine is not plant derived and synthesized. The process is FDA Validated and approved as adult glycerine laxative suppository. | PMC Biogenix          | USA     | USP-NF    |
| <b>BENZALDEHYDE, BENZOATES, BENZYL ALCOHOL parenteral</b><br>Only Kalama has 0 aldehyde content.  | Emerald Kalama        | USA     | USP-NF    |
| FRAGRANCE CHEMICALS-Benzaldehyde, Cinnamic alcohol; C-8;C-9 aldehydes   | Emerald Kalama        | USA     | USP-NF    |



# Injectable Excipients

| Excipient/s Description  | Manufacturer   | Country               | Monograph          |
|--|--|-----------------------|--------------------|
| <p><b>Chlorides:</b> Ammonium Chloride; Calcium Chloride Dihydrate; Magnesium Chloride Hexahydrate; Magnesium Chloride Tetrahemihydrate; Potassium Chloride Sodium Chloride</p> <p><b>Sulphates:</b> Ammonium Sulphate; Calcium Sulphate Dihydrate; Magnesium Sulphate Dried; Magnesium Sulphate Heptahydrate; Sodium Sulphate Anhydrous Zinc Sulphate Heptahydrate; Zinc Sulphate Monohydrate</p> <p><b>Acetates:</b> Potassium Acetate; Sodium Acetate Anhydrous; Sodium Acetate Trihydrate; Sodium Carbonate Monohydrate; Sodium Di-Acetate</p> <p><b>Oxides / Hydroxides:</b> Calcium Hydroxide; Magnesium Oxide heavy, light Sodium Hydroxide; Potassium Hydroxide</p> <p><b>Carbonates:</b> Potassium Hydrogen Carbonate: Sodium Hydrogen Carbonate</p> <p>Nitrates: Potassium Nitrate</p> | <p><b>Macco Organique SRO</b></p> <p>CERTIFICATIONS:<br/>GMP Q-7<br/>FSSC 22000<br/>ISO 9001<br/>FDA INSPECTED</p> <p>REGISTRATIONS:<br/>MHLW&amp;PMDA JAPAN<br/>US DMF<br/>CoS/CEP<br/>ASMF<br/>Jap DMF</p> | <p>Czech Republic</p> | <p>USP/Ph.Eur</p>  |
| <p><b>Ca:</b> Gluconate; glucoheptonate; gluconolactate; glycerophosphate</p> <p><b>Fe:</b> Gluconate; glucoheptonate; glycerophosphate</p> <p><b>Mg:</b> Citrate nonahydrate; gluconate; glycerophosphate, lactate, aspartate;</p> <p><b>Nicotinate:</b> Methyl, hexyl, ethyl</p> <p><b>K:</b> Aspartate; glycerophosphate<br/>Undecylenic acid</p> <p><b>Zn:</b> Acetate; carbonate, citrate; gluconate; salicylate</p>  | <p>Isaltis</p>   | <p>France</p>         | <p>USP/Ph.Eur.</p> |



# Injectable Excipients

| Excipient/s Description   | Manufacturer                | Country | Monograph          |
|---|-----------------------------|---------|--------------------|
| Glycocholic Acid  | Prodotti Chimici Alimentari | Italy   | USP/Ph.Eur         |
| Thioglycolic Acid, Monothioglycerol   | Evans Chemetics             | USA     | USP/JP             |
| USP NF Refined vegetable oils: Corn, Castor, Soybean, Olive, Safflower; Cottonseed; Peanut, Olive, Sesame; Sweet Almond<br>Welch Holme and Clark is USA's biggest producer of USP oils and approved in all major pharma companies.          | Welch, Holme & Clarke       | USA     | USP-NF             |
| Dexolve (SBECD) – Only option to captisol based drugs<br>Alfa, beta, gamma CDs, HPBCD GMP and injectable grades   | Cyclolab                    | Hungary | USP-NF, Ph.Eur, JP |
| <b>KEMESTRENE- GLYCERINE NATURAL 99.7%</b><br>Largest natural Glycerine Plant in the world and USA. This glycerine is not plant derived and synthesized. The process is FDA Validated and approved as adult glycerine laxative suppository. | PMC Biogenix                | USA     | USP-NF             |
| <b>BENZALDEHYDE, BENZOATES, BENZYL ALCOHOL parenteral</b><br>Only Kalama has 0 aldehyde content.  | Emerald Kalama              | USA     | USP-NF             |
| Vitamin E TPGS or D- $\alpha$ -Tocopherol polyethylene glycol-1000 succinate or Tocophersolan or Tocofersolan or Vitamin E PEG succinate  | Emerald Kalama              | USA     | USP-NF             |



# Injectable Excipients

| Excipient/s Description   | Manufacturer | Country | Monograph         |
|---|--------------|---------|-------------------|
| Egg Yolk Lecithin PC 98 N; PL 100 M<br>PC 98 N: Flurbiprofen; Diazepam; Propofol<br>PL 100 M: Alprostadil (PGE-1); Amphotericin B; Doxorubicin  | Kewpie       | Japan   | USP/Ph.Eur<br>/JP |
| PLGA: Poly(DL-lactic-co-glycolic acid)<br>PLA: Poly lactic acid<br>PLGA-SA : Copolymer of DL-lactic acid and glycolic acid polymerized without catalyst<br>PDLLA-DA :Poly DL-lactic acid polymerized without catalyst<br>D Lactic Acid; L-Lactic Acid, lactates | Mushashino,  | Japan   | USP/JP            |
| EDTA Acid – USP; EDTA Calcium Disodium USP; EDTA Disodium USP, FCC, ACS; EDTA Iron Sodium Trihydrate; DTPA Acid USP XXIII Grade   | SCL Italia   | Italy   | USP-NF/<br>Ph.Eur |
| Myristyl gamma-picolinium chloride  | Dalton       | USA     |                   |
| Triethylene Glycol Polyorthoester- TEG POE (Base polymer of biochnomoer technology)- Developmental- kindly inquire to collaborate   | Cyclolab     | Hungary | N/A               |



# Injectable Excipients

| Excipient/s Description   | Manufacturer | Country | Monograph         |
|---|--------------|---------|-------------------|
| Acetonitrile  | Ineos        | USA     | USP/Ph.Eur<br>/JP |
| Sodium Bisulfite, Sodium Bisulfite  | Akkim Denox  | Germany | USP/Ph.Eur.       |
| EDTA Acid – USP; EDTA Calcium Disodium USP; EDTA Disodium USP, FCC, ACS; EDTA Iron Sodium Trihydrate; DTPA Acid USP XXIII Grade   | SCL Italia   | Italy   | USP-NF/<br>Ph.Eur |
| Myristyl gamma-picolinium chloride  | Dalton       | USA     |                   |
| Triethylene Glycol Polyorthoester- TEG POE (Base polymer of biochnomoer technology)- Developmental- kindly inquire to collaborate | Cyclolab     | Hungary | N/A               |



# Injectable Excipients

| Excipient/s Description   | Manufacturer         | Country        | Monograph                 |
|---|----------------------|----------------|---------------------------|
| <p>Propylene Glycol Ph. Eur./USP/JP; Propylene Glycol Ph. Eur./USP/JP parenteral grade<br/>           Disodium Edetate Ph. Eur./USP VERSENE™ NA Chelating Agent<br/>           Macrogols Ph. Eur./USP (NF) CARBOWAX™ SENTRY™ Polyethylene Glycols<br/>           Glycerol Ph. Eur./USP/JP 99.7% (synth.) OPTIM™ Glycerine 99.7% USP/EP; Glycerol<br/>           Ph. Eur./USP/JP 99.7% (synth.) LA parenteral grade OPTIM™ Plus Glycerine 99.7%<br/>           USP/EP ; Glycerol 85% Ph. Eur. (produced with Purified Water Ph. Eur./USP by<br/>           Hedinger) ; Glycerol 85% Ph. Eur./JP LA/API/parenteral grade<br/>           Acetone Ph. Eur./USP (NF) INEOS Acetone SQ<br/>           Isopropyl Alcohol GMP Ph. Eur./USP/JP (pharmaceutical starting material/biocidal active<br/>           substance)<br/>           Isopropyl Alcohol 70% API grade; Isopropyl Alcohol 70% (V/V) API grade/USP Isopropyl<br/>           Rubbing Alcohol USP<br/>           Petroleum Spirit (boiling range 40°C to 60°C) DAB<br/>           Hydrogen Peroxide Solution (30%) Ph. Eur. API grade<br/>           Acetic Acid, Glacial (99.9%) Ph. Eur./USP/JP ; Acetic Acid, Glacial (99,9%) Ph.<br/>           Eur./USP/JP parenteral grade<br/>           Acetic Acid 80% API grade (produced with Purified Water Ph. Eur./USP by Hedinger)<br/>           Metacresol Ph. Eur./USP parenteral grade<br/>           Butylhydroxytoluene Ph. Eur./USP/JPE GMP grade<br/>           Purified Water Ph. Eur.<br/>           Sodium Hypochlorite solution DAC/API grade</p> | <p>Hedinger GMBH</p> | <p>Germany</p> | <p>USP/Ph.Eur<br/>/JP</p> |





# Softgels Excipients

| Excipient/s Description   | Manufacturer             | Country | Monograph  |
|---|--------------------------|---------|------------|
| <p>Gelatin USP/ Ph.Eur: Bovine bone<br/>           140 bloom; 160 bloom; 180 bloom, 220 bloom<br/>           ISO9001, GMP, FSSC2000 ect certificates and have<br/>           four factories to specialize in production and the annual output can reach 20,000 ton<br/>           s. The company is a gelatin supplier for many powerful softgel manufacturers in<br/>           India, and the only company in China that ACG is willing to audit.</p> | Henan Boom;              | China   | USP/Ph.Eur |
| <p>Castor Oil</p>   | Kaneda                   | Japan   | USP/JP     |
| <p>USP NF Refined vegetable oils: Corn, Castor, Soybean, Olive, Safflower; Cottonseed;<br/>           Peanut, Olive, Sesame; Sweet Almond<br/>           Welch Holme and Clark is USA's biggest producer of USP oils and approved in all<br/>           major pharma companies.</p>   | Welch, Holme<br>& Clarke | USA     | USP-NF     |
| <p>TWEEN 20, 60,80<br/>           A leading producer of Tweens- distributed across US Territory</p>   | Oxiteno                  | Brazil  | USP-NF     |
| <p>KEMESTRENE- GLYCERINE NATURAL 99.7%<br/>           Largest natural Glycerine Plant in the world and USA. This glycerine is not plant<br/>           derived and synthesized. The process is FDA Validated and approved as adult glycerine<br/>           laxative suppository.</p>   | PMC Biogenix             | USA     | USP-NF     |



# APIs.

| Excipient/s Description   | Manufacturer                       | Country      | Monograph         |
|---|------------------------------------|--------------|-------------------|
| URSODEOXYCHOLIC ACID or URSODIOL; TAUROURSODEOXYCHOLIC ACID; CHENODEOXYCHOLIC ACID PHARMACEUTICAL GRADE; CHENODEOXYCHOLIC ACID SODIUM SALT; CHOLIC ACID PHARMACEUTICAL GRADE; DEHYDROCHOLIC ACID; DEOXYCHOLIC ACID; DIHYDROXYPROPYLTHEOPHYLLINE; GLICODEOXYCHOLIC ACID SODIUM SALT; GLYCOCHOLIC ACID; GLYCOCHOLIC ACID SODIUM SALT; GLYCOURSODEOXYCHOLIC ACID; LITHOCHOLIC ACID; NATURAL TAURINE; SODIUM CHOLATE; SODIUM DEOXYCHOLATE; TAUROCHOLIC ACID SODIUM SALT; TAURODEOXYCHOLIC ACID SODIUM SALT; TAUROURSODEOXYCHOLIC ACID SODIUM SALT; THEOPHYLLINE 7 ACETIC ACID                           | <b>Prodotti Chimici Alimentari</b> | <b>Italy</b> | <b>USP/Ph.Eur</b> |
| <b>Sucralfate Hydrate: Active DMF – Zero FDA Observation DMF Support on all APIs.</b><br><b>Ecabet sodium hydrate (Ecabet Sodium Hydrate)</b><br>■ Psychoneurotic agent<br><b>Levomepromazine maleate (Levomepromazine Maleate)</b><br><b>Propericiazine</b><br><b>Milnacipran hydrochloride</b><br><b>Zotepine</b><br>■ Antiphlogistic analgetic<br><b>Indomethacin (Indometacin)</b><br>■ Autonomic agent<br><b>Titanium bromide (Tiquizium Bromide)</b><br>■ Bronchial asthma · Allergic rhinitis treatment agent (Bronchial asthma agent, Allergic rhinitis agent)<br><b>Pranlukast hydrate</b> | <b>Ace Japan</b>                   | <b>Japan</b> | <b>USP/JP</b>     |



# APIs.

| Excipient/s Description   | Manufacturer   | Country      | Monograph         |
|---|--|--------------|-------------------|
| <ol style="list-style-type: none"> <li>1. <b>Natural Paclitaxel</b></li> <li>2. 10-DAB Semi-synthetic Paclitaxel</li> <li>3.. Cabazitaxel</li> <li>4. 10-Deacetylbaccatin III- <b>Main intermediate for Docetaxel</b></li> <li>5. 13-Acetyl-90dihydrobaccatin III</li> <li>6. 7-O- (Trithylsilyl) Paclitaxel</li> <li>7. Paclitaxel EP Impurity C</li> <li>8. 10- Docacetyl Paclitaxel</li> <li>9. 7-Epi-10-Deaetyl-Taxol</li> <li>10- Baccatine III</li> <li>11. Caphalomannine</li> <li>12. 7-(2,2,2-trichloroethyloxycarbonyl) taxol</li> <li>13. 10-Dimethoxy-10-DAB III</li> <li>14. 2-DECETYL-PACLITAXEL</li> </ol> | <p>Yunnan<br/>Hande- Only<br/>FDA approved<br/>site for<br/>Paclitaxels in<br/>China</p> | <p>China</p> | <p>USP/Ph.Eur</p> |
| <ol style="list-style-type: none"> <li>1. TRYPSIN: CHYMOTRYPSIN USP<br/>Tigher Limits:<br/>NLT 2400 USP TRYPSIN AND<br/>400 USP CHYMOTRYPSIN</li> <li>2. PANCREATIN USP: 4X, 6X, 8X, 10X</li> <li>3. PANCREATIN EP: &gt;70 lipase content</li> </ol>  | <p>Boading<br/>Faithful China</p>  | <p>China</p> | <p>USP/Ph.Eur</p> |



# APIs.

| Excipient/s Description  | Manufacturer              | Country | Monograph  |
|--|---------------------------|---------|------------|
| 1. TRYPSIN: CHYMOTRYPSIN USP<br>Tigher Limits:<br><br>NLT 2400 USP TRYPSIN AND<br>400 USP CHYMOTRYPSIN<br><br>2. PANCREATIN USP: 4X, 6X, 8X, 10X<br><br>3. PANCREATIN EP: >70 lipase content | Boading<br>Faithful China | China   | USP/Ph.Eur |
| <b>Product</b>   | Ace Japan                 | Japan   | USP/JP     |

Thank  
you