

## COMPOUNDING WITH PHLOJEL<sup>®</sup> Ultra (PU)

### 1. Diclofenac sodium (DCF)

Strength: 2 – 20%w/w

Equipment: Slab & Spatula or mortar & pestle

Procedure:

S & S:

- Place the required amounts of PU and DCF on the slab in separate locations.
- Add a portion of PU to the DCF and triturate thoroughly to form a smooth nucleus. Add the remaining PU by geometric dilution, triturating until homogeneous.

M & P:

- Place the DCF in the mortar and triturate.
- Add a portion of PU and triturate thoroughly
- Add the remaining PU by geometric dilution, trituration until homogeneous.

Comments:

Do not add alcohol to maintain thickness. If a thicker product is desired acidify with 0.5 – 1 percent citric acid or place in the refrigerator. Mixing 10% DCF produces a thick cream without acidifying.

## 2. Ketoprofen (KTP)

Strength: 10 – 30%w/w  
Equipment: Mortar & Pestle

### Procedure:

- Add sufficient alcohol to the KTP in the mortar to form a paste. Levigate.
- Add all of the PU and triturate until homogeneous.

### Comments:

With some concentrations of KTP the final product may be thinner than desired. Although the product is still effective it can be stored in the refrigerator to firm up.

3. Ibuprofen (IBP)

Strength: 10 – 20 %w/w  
Equipment: Slab & Spatula

Procedure:

- Add approximately an equal amount of PU to the IBP on the slab. Levigate thoroughly.
- Add the remaining PU by geometric dilution, triturating and blending until homogeneous.

Comments;

The final product is a smooth, nongritty, firm white cream.

4. Naproxyn (NPX)

Strength: 5 – 10%w/w  
Equipment: Slab & Spatula

Procedure:

- Add alcohol to NPX on the slab sufficient to form a paste. Levigate.
- Add an equal amount (approximately) of PU to the paste.
- Triturate and blend to form a smooth nucleus.
- Add the remaining PU by geometric dilution, triturating and blending thoroughly until homogeneous.

Comments:

The final product is a smooth, non-gritty, white cream.

5. Indomethacin (IDM)

Strength: 20 %w/w  
Equipment: Slab & Spatula

Procedure:

- Add enough alcohol\* to the IDM on the slab to form a paste. Levigate.
- Add an equal amount (approximately) of PU to the paste. Triturate and blend.
- Add the remaining PU by geometric dilution, triturating and blending thoroughly to make homogeneous.

Comments:

The final product is a nongritty, soft, white cream.

6. Piroxicam (PXM)

Strength: 2.5%w/w  
Equipment: Slab & Spatula

Procedure:

- Add enough alcohol\* to the PXM on the slab to form a paste. Levigate..
- Add an equal amount (approximately) of PU to the paste. Triturate and blend.
- Add the remaining PU by geometric dilution, triturating and blending thoroughly to make homogeneous.

Comments:

The final product is a nongritty, yellow cream.

7. Ibuprofen, 10% and Naproxen, 10%

Equipment: Slab & Spatula

Procedure:

- Incorporate the IBP in the PU (see IBP monograph)
- Separately, add enough alcohol\* to the NPX to form a paste. Levigate.
- Gradually, incorporate the NPX paste in the IBP/PU mixture by geometric dilution, triturating and blending thoroughly to make homogeneous.

Comments:

The final product is a smooth, nongritty, thick, white cream.

8. Ibuprofen, 10% and Piroxicam, 2.5%

Equipment: Slab & Spatula

Procedure:

- Incorporate the IBP in the PU (see IBP monograph)
- Separately, add enough alcohol\* to the PXM to form a paste. Levigate.
- Gradually, incorporate the PXM paste in the IBP/PXM mixture by geometric dilution, triturating and blending thoroughly to make homogeneous.

Comments:

The final product is a smooth, nongritty, pale yellow cream.

9. Metronidazole (MDZ)

Strength: 5 %w/w  
Equipment: Slab & Spatula

Procedure:

- Add enough alcohol\* to the MDZ on the slab to form a paste. Levigate.
- Add an equal amount (approx.) of PU to the paste. Triturate and blend.
- Add the remaining PU by geometric dilution, triturating and blending thoroughly to make homogeneous.

Comments:

The final product is a smooth, nongritty, white cream.

10. Lidocaine HCl (LDN)

Strength: 4%w/w  
Equipment: Slab & Spatula

Procedure:

- Add glycerol (~5%) to the LDN on the slab to form a paste. Levigate.
- Spread the paste over the slab and layer the PU. Triturate and blend until homogeneous.

Comments:

The final product is a uniform, nongritty, off-white cream.

11. Progesterone (PG)

Strength: 3 – 6%w/w  
Equipment: Slab & Spatula

Procedure:

- Add an equal amount (approx.) of PU to the PG on the slab. Levigate and blend to form a smooth nucleus.
- Add the remaining PU by geometric dilution, triturating and blending thoroughly to make homogeneous.

Comments:

The final product is a smooth, nongritty, white cream.

12. Tri-est

Estriol	8 parts
Estradiol	1 part
Estrone	1 part

Strength: 0.625 – 5 mg per dose; avg. 1.25 mg per dose

The compounded cream is loaded into 1 ml or 5 ml syringes and patients are directed to dispense a stated volume.

Procedure: 50 g of final product @ 1.25 mg/0.5 cc

- Dissolve 125 mg estradiol, 125 mg estrone and 1000 mg estriol in alcohol qs 10 ml.
- Withdraw 1 ml by pipette or graduated cylinder and incorporate with PU using the slab & spatula method to produce 50 g.

Procedure: 10 g final product @ 1.25 mg/0.1 cc

- Same as above except incorporate the tri-est solution with PU to make 10 g.

The syringe should be stored in a cool, dry place (not the refrigerator) between uses.

13. Clindamycin (CM)

Strength: 2%w/w  
Equipment: Slab & Spatula

Procedure:

- Add enough alcohol\* to the CM on the slab to form a paste. Levigate.
- Add an equal amount (approx.) of PU to the paste. Triturate and blend.
- Add the remaining PU by geometric dilution, triturating and blending thoroughly to make homogeneous.

Comments:

The final product is a smooth, nongritty, white cream.

14. 5% Lidocaine base, 7.5% Ketoprofen, 5% amitriptyline HCl, 50 g

Equipment: Slab & Spatula

Procedure:

- Levigate the lidocaine with alcohol to make a slurry.
- Add the amitriptyline HCl and levigate.
- Add the ketoprofen and levigate, adding more alcohol if necessary to make a slurry.
- Add the PU (41.25 g) to the slurry, triturate and blend until homogeneous.

Comments:

During mixing of the PU with the levigated drugs, the PU had a chunky appearance but no physical separation of the phases was observed. After mixing for a few minutes, the mixture appeared more homogeneous but had a lotion consistency. Adding 5 g talc gave a smoother, whiter appearance but it retained its lotion consistency. Placing it in the refrigerator caused it to solidify and could be applied in the “cool” state.

15. 5% Ketoprofen, 2% Cyclobenzaprine HCl, 50 g

Equipment: Slab & Spatula

Procedure:

- Place the ketoprofen, cyclobenzaprine HCl and PU on the slab in three separate quadrants.
- Incorporate 1 ml of 2M NaOH solution in the PU.
- Spread the PU on the slab then sprinkle a portion of cyclobenzaprine HCl on the surface. Blend. Repeat this process until all has been added.
- Add alcohol to the ketoprofen to make a soft paste and levigate thoroughly.
- Incorporate a portion of the levigated ketoprofen and blend it with the cyclobenzaprine HCl/PU mixture. Quickly repeat this process until all the levigated ketoprofen has been added and the alcohol has not all evaporated.

Comments:

The final product is a pale yellow, creamy mixture. Compounding without the addition of NaOH yields a thinner but creamy product.

16. Gabapentin (GPN)

Strength: 5%

Equipment: Slab & Spatula

Procedure:

- Levigate the GPN with a portion of PU.
- Incorporate the remaining PU by geometric dilution.

Comments:

A creamy, grit-free gel is formed with little change in consistency.

## 17. Testosterone free base (crystalline) (TFB)

Strength: 0.4%  
Equipment: Slab & Spatula

### Procedure:

- Levigate the TFB with a minimum amount of alcohol or olive oil.
- Incorporate the TFB with approximately one-third of the PU and triturate until uniform.
- Combine the remaining PU by geometric dilution.

### Comments:

A creamy, grit-free gel is formed with little change in consistency.

18. Testosterone free base (crystalline) (TFB)

Strength: 20%

Equipment: Slab & Spatula

Procedure for 50 g:

- Triturate and levigate 10 g testosterone with 13 ml (11 g) Olive Oil until non-gritty.
- Incorporate 40 g PU in divided portions until complete. The olive oil is considered a pharmaceutical necessity and is not included in the total weight.

Comments:

The final product is soft but firm and non-gritty.

19. 10% Ketoprofen, 10% Gabapentin, and 2% Lidocaine HCl.

Equipment: Mortar & pestle

Procedure:

- Thoroughly triturate the ketoprofen and gabapentin in the mortar together with a minimal amount of alcohol.
- Triturate with an equal amount of PU.
- Gradually add the lidocaine HCl and triturate until homogeneous. Transfer to a jar and refrigerate.

Comments:

The powders require time and effort to reduce particle size to avoid grittiness. The addition of the drugs makes the preparation runny which could be used as a lotion. Otherwise, place in the refrigerator to firm up. When applied to the skin it becomes a liquid.

## COMPOUNDING WITH PHLOJEL®

PHLOJEL® is prepared by combining PHLOJEL® Hydrophilic with PHLOJEL® Organic liquids in a 3-to-1 volume ratio with drug(s) in a suitably-sized mortar then triturating vigorously to produce the final gel product.

The following monographs describe some typical and some atypical compounding methods.

### 1. Diclofenac sodium (DCF)

Strength: 2 – 5%w/w

Procedure 1:

- Disperse the DCF in PHLOJEL® Organic in the mortar (no alcohol)
- Gradually add the PHLOJEL® Hydrophilic (ca. 15 °C) while triturating vigorously until a smooth gel forms.

Procedure 2:

- Pre-mix PHLOJEL® Organic and PHLOJEL® Hydrophilic in the mortar to form a gel.
- Mechanically incorporate the DCF in the gel using either the mortar & pestle or the slab & spatula method.

Strength: 8 – 12%w/w

Procedure:

- Follow either procedure 1 or 2 above.
- If the product is thin, incorporate 0.8%w/w citric acid to thicken up (50 – 100g). Alternatively, incorporate 2 ml of 2M HCl per 100g.

2. Ketoprofen (KTP)

Strength: 10%w/w

Procedure:

- Levigate KTP in the mortar with 4 ml alcohol\* for 50 g.
- Add PHLOJEL<sup>®</sup> Organic and disperse the KTP thoroughly.
- Add PHLOJEL<sup>®</sup> Hydrophilic (ca. 15 °C) and triturate until a smooth gel is formed.

Comments:

A smooth, grit-free gel is formed.

3. Naproxyn (NPX)

Strength: 5 – 10%w/w  
Equipment: Mortar & Pestle

Procedure:

- Add alcohol to NPX in the mortar to form a paste. Levigate.
- Add PHLOJEL Organic to the paste and triturate until uniformly dispersed.
- Add PHLOJEL Hydrophilic previously cooled and triturate until a uniform gel has formed..

Comments:

The final product is a smooth, non-gritty, off-white gel.

4. Ibuprofen (IBP)

Strength: 10 – 20 %w/w  
Equipment: Mortar & Pestle

Procedure:

- Add IBP to the mortar and triturate.
- Add PHLOJEL Organic and thoroughly disperse the IBP.
- Add PHLOJEL Hydrophilic previously cooled and triturate until a gel is formed.

Comments;

The final product is a thick, nongritty, yellowish gel.

5.. 5% Lidocaine base, 7.5% Ketoprofen, 5% amitriptyline HCl, 50 g

Equipment: Mortar & Pestle, Slab & Spatula

Procedure for 50 g:

- Pre-mix PHLOJEL<sup>®</sup> in a mortar.
- Levigate lidocaine with alcohol to make a slurry.
- Add the amitriptyline HCl and levigate.
- Add the ketoprofen and levigate, adding more alcohol if necessary.
- Incorporate the levigated drugs with the premixed PHLOJEL<sup>®</sup> (41.25 g) using the slab & spatula.

Comments:

The drug(s) slurry incorporates well with the premixed PHLOJEL<sup>®</sup> yielding a less viscous, creamy consistency with an off-white appearance. It spreads evenly on the skin.

6 Gabapentin (GPN)

Strength: 5%  
Equipment: Mortar & Pestle

Procedure:

- Disperse the GPN in the mortar with a minimal amount of alcohol.
- Add PHLOJEL<sup>®</sup> Organic and thoroughly disperse.
- Gradually add PHLOJEL<sup>®</sup> Hydrophilic previously cooled to about 12 °C while triturating vigorously.
- Continue triturating for 2-3 min after the gel has formed.

Comments:

A smooth, grit-free gel is formed.

7. 5% Ketoprofen, 5% Ketamine, 2% Carbamazepine,  
2% Amitriptyline

Equipment: Mortar & Pestle

Procedure:

- Levigate ketoprofen and carbamazepine in the mortar with alcohol forming a soft paste.
- Add the ketamine and amitriptyline and continue to blend and levigate.  
Add the PHLOJEL<sup>®</sup> Organic and triturate thoroughly.
- Gradually add the PHLOJEL<sup>®</sup> Hydrophilic while vigorously triturating the organic phase (the Hydrophilic is previously cooled for pouring).
- Triturate until homogeneous.

Comments:

The end product may be thin because of the drug and alcohol load allowing it to be dispensed in droplet form. Ideally, diethylene glycol monoethyl ether (Transcutol) should be used as the levigating agent.

If this procedure does not result in an emulsion then the drugs should be incorporated in pre-mixed PHLOJEL<sup>®</sup> on the ointment slab.

Sig. 4 – 10 drops tid.

8. 2% Cyclobenzaprine HCl, 10% Ketoprofen, 10% Lidocaine HCl

Procedure:

- Levigate ketoprofen and lidocaine HCl in the mortar or on the ointment slab with alcohol forming a soft paste.
- Add the cyclobenzaprine HCl and continue to blend and levigate, adding more alcohol if necessary.
- Gradually incorporate the levigated drugs with pre-mixed PHLOJEL<sup>®</sup> (geometric dilution) until homogeneous.

Comments:

The final product is a nongritty, pale yellow gel.

9. 10% Ketoprofen, 10% Gabapentin, and 10% Lidocaine

Equipment: Mortar & pestle

Procedure:

- Thoroughly triturate the ketoprofen, gabapentin and lidocaine HCL in the mortar together with a minimal amount of alcohol.
- Triturate with an equal amount of pre-mixed PHLOJEL<sup>®</sup> until homogeneous.
- Add the remaining pre-mixed PHLOJEL<sup>®</sup> and triturate until homogenous. Transfer to a jar and refrigerate.

Comments:

The powders require time and effort to reduce particle size to avoid grittiness. The addition of the drugs makes the preparation runny which could be used as a lotion. Otherwise, place in the refrigerator to firm up and apply to the skin in the cold state.

10. 5% Ketamine, 10% Ketoprofen, 10% Lidocaine HCl

Equipment: Mortar & Pestle

Procedure:

- Triturate and blend the powders in the mortar
- Add alcohol sufficient to form a soft paste or thick slurry
- Triturate until homogeneous
- Add approximately half the required amount of PHLOJEL PM
- Triturate until homogeneous (may be runny)
- Add the remaining amount of PHLOJEL PM and triturate until homogeneous
- Dispense in a jar

Comments:

The final product is a non-gritty, pale yellow gel.