MEDISCA® NETWORK INC.
TECHNICAL SUPPORT SERVICES
FORMULATION CHEMISTRY DEPARTMENT
TOLL-FREE: 866-333-7811
TELEPHONE: 514-905-5096
FAX: 514-905-5097
technicalservices@medisca.net

Suggested Formula	Penicillin V Potassium 300 mg/5 mL Oral Liquid (Solution, 100 mL)	FIN	F 000 339v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Penicillin V Potassium, USP	6.000	g				
Xanthan Gum, NF	0.20	g				
Methylparaben, NF	0.10	g				
Stevia Powder	0.20	g				
Glycerin, USP	5.0	mL				
Wild Cherry Concentrate Flavor	1.0	mL				
Purified Water, USP	80.0	mL				
Purified Water, USP	q.s. to 100.0	mL				
Hydrochloric Acid 1N Solution	as needed					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Plastic reactive / adsorbent *(do not allow to come into contact):* *Methylparaben*

Hygroscopic *(protect from moisture whenever possible):* *Glycerin, Stevia Powder*

Suggested Preparatory Guidelines

■ Non-Sterile Preparation ☐ Sterile Preparation

Processing Error / Testing Considerations: To account for processing errors and pH testing considerations during preparation, it is suggested to measure an additional **5 to 9%** of the required quantities of ingredients.

Special Instruction: Protective apparel, such as a lab coat, disposable gloves, eyewear and face-masks should always be worn.

This procedure requires the use of very small quantities of ingredients. All calculations and preparation techniques must be verified before dispensing the final product.

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SUGGESTED PREPARATION (for 100 mL)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Penicillin V Potassium, USP	6.000	g			
Xanthan Gum, NF	0.20	g			
Methylparaben, NF §	0.10	g			
Stevia Powder §	0.20	g			
Glycerin, USP §	5.0	mL			
Wild Cherry Concentrate Flavor	1.0	mL			
Purified Water, USP	80.0	mL			
Purified Water, USP	q.s. to 100.0	mL			
Hydrochloric Acid 1N Solution	as needed				

* Takes into account increased batch size conversions and density conversions, if required.
§ Weigh / measure just prior to use.

	Preparatory Instruction
1.	**Powder-liquid preparation:** A. Combine and triturate the following ingredients together to form a fine, homogeneous powder blend: -Penicillin V Potassium -Xanthan Gum -Methylparaben -Stevia Powder B. Levigate the fine, homogeneous powder blend (Step 1A) with Glycerin. End result: Homogeneous paste-like dispersion
2.	**Medium preparation:** A. Incrementally add the Wild Cherry Concentrate Flavor to the Purified Water (80.0 mL *plus* processing error adjustments). Specifications: Continuously mix. End result: Homogeneous liquid-like solution.

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3. **Medium integration:**

A. Incrementally add the homogeneous paste-like dispersion (Step 1B) to the homogeneous liquid-like solution (Step 2A).

Specifications: Continuously mix until all solid particles have completely dissolved.

End result: Homogeneous liquid-like solution.

4. **pH testing:**

1. Draw an appropriate amount of the mixture (Step 3A).
2. Test the pH of the sample. It should lie between 6.0 and 7.0.

C. If the pH > 7.0, carefully add in a dropwise manner the Hydrochloric Acid 1 N Solution to the mixture:

1. Draw and transfer 1 or 2 drops of the Hydrochloric Acid 1 N Solution to the mixture.
2. Stir for at least 5 minutes to evenly disperse the Hydrochloric Acid 1 N Solution.
3. Re-test the pH.
4. Continue to add the Hydrochloric Acid 1 N Solution until the pH of 6.0 to 7.0 is obtained.

IMPORTANT: Do not allow the pH to fall below 6.0.

5. **Filling to volume:**

A. Add additional Purified Water to the above mixture to fill to the required batch size (100.0 mL *plus* processing error adjustments).

Specification: Continuously mix

End result: Homogeneous liquid-like solution

6. **Product transfer:**

Transfer the final product into the specified dispensing container (see “Packaging Requirements”).

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SUGGESTED PRESENTATION

Estimated Beyond-Use Date		14 days, refrigerated, as per USP.	Packaging Requirements		- Tightly closed dispensing bottle - To be administered with a metered dose-measuring device.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.		4	Keep refrigerated. Do not freeze.
	2	Keep out of reach of children.		5	Cap tightly after use.
	3	Keep in a dry place.		6	Consult your health care practitioner if any other prescription or over-the-counter medications are currently being used or are prescribed for future use.
Pharmacist Instructions	Add any auxiliary labels specific to the API to the dispensing container as deemed necessary.				
Patient Instructions	Contact your pharmacist in the event of adverse reactions.				

REFERENCES

1. Apo-Pen-VK. In: Canadian Pharmacists Association. *Compendium of Pharmacists and Specialties, 2003.* 119.
2. Nadopen-V. In: Canadian Pharmacists Association. *Compendium of Pharmacists and Specialties, 2003.* 993.
3. Novo-PenVK. In: Canadian Pharmacists Association. *Compendium of Pharmacists and Specialties, 2003.* 1074.
4. Penicillin V (Monograph). In: O'Neil MJ. *The Merck Index 13th Edition*. Whitehouse Station, NJ: Merck & Co, Inc.; 2001: 1273.
5. Penicillin V Potassium. In: Trissel LA. *Trissel's Stability of Compounded Formulations, 2nd Edition.* American Pharmaceutical Association; 2000: 288.