Fagron
personalizing medicine

Pinetonina™
Introduction document
6 December 2018

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1. Introduction

Pinetonina™ Compounding manual is a tool for pharmacists. It contains information about the compounding steps and the key elements of the process. All the information was collected from the quality documents of the manufacturer and literature review. Compounding manual can be used for training of compounding pharmacists and technical staff.

2. Compounding process of Pinetonina™

2.1 General tips for nasal sprays

- pH is a critical parameter for nasal preparations
- Physiological pH range of nasal cavity is within 6-8. Nasal preparations should have a pH within this range in order to be compatible with the physiological pH and not to have a negative effect on the activity of cilia[1]. Pinetonina™ has a pH of 6-7.5 which is compatible with physiological pH of nasal cavity.
- pH is also a critical factor for the preservative action of Benzalkonium chloride. Benzalkonium chloride is a preservative that is active in a pH range between 4-10[1]. Pinetonina™ pH range between 6-7,5 allows Benzalkonium chloride to show its preservative activity.
- Oxidation is a key factor that leads to chemical degradation. According to literature, essential oils avoid oxidation when stored properly. pH changes are one of the critical marks for any oxidative event that has occurred[2].

According to literature, the average suggested volume that can be administered per nostril is 25-150µl, with a maximum of 200µl[1]. If greater volume is administered, it goes through the nasopharynx to the gastrointestinal tube, so it does not have an effect in the nasal cavity.

2.2 Compounding process of Pinetonina™

Pinetonina™ concentrated is a phyto-complex which was especially developed to be used as a raw material for compounding a 50% v/v nasal spray. The following ingredient should be used:

Ingredients	**Quantity**
Pinetonina™ (concentrated)	50% v/v
Physiological saline solution 0.9% w/v	50% v/v

The compounding process of Pinetonina™ 50% v/v nasal spray is an easy and simple 3 step process.

1. Calculate the volume of each ingredient in the final volume and measure the quantities by using a measuring cylinder.
2. Add the calculated Pinetonina™ (concentrated) and physiological saline solution 0,9% w/v volume in the conical measure and mix.
3. Transfer to final container.[3]

2.3 Final quality checks

1. pH within 6-7.5.[1] pH should be checked and adjusted if needed.
2. Total volume.[1]

2.4 Container

1. Plastic HDPE (high density polyethylene) squeeze bottles with an atomizer.[1]
2. Glass or plastic PP/HDPE bottles with a pump atomizer.[1]
3. Please contact with your local sales representative for packaging information:
    - Glass bottle of 10ml, 20ml and 50ml
    - Precise nasal spray dispenser (screw on – 0.1ml dose volume/ pump) . Very important in order to administer the appropriate dose of the active ingredients in each intranasal application.

2.5 Labeling

1. Label product “for nasal use”.
2. Patients should be advised that nasal products are for one patient only and should not be passed around due to risk of inter patient contamination.[1]

2.6 Storage and shipping conditions

Pinetonina™ concentrated
Pinetonina™ should be shipped and stored at room temperature. Pinetonina™ should not be kept under refrigeration and should not be frozen. Pinetonina™ should be maintained in its original packaging.

Pinetonina™ 50% v/v nasal spray
Pinetonina™ 50% v/v nasal spray should be stored at room temperature in a dry place, protected of the light, and in its original packaging.

2.7 Stability of Pinetonina™ concentrated

Pinetonina™ concentrated is stable for 2 years.

2.8 Stability of Pinetonina™ 50% v/v nasal spray

The suggested stability of the product after batch production is 3 months while the beyond use date after opening is 1 month.[1]

3. References

1. Bouwman-Boer et al*. Practical Pharmaceutics*, Fifth ed., Springer, 2009.
2. Claudia Turek et al., *Stability of Essential Oils: A Review, Comprehensive Reviews in Food Science and Food Safety*, 2013, Vol.12.
3. Marriot, John F, et al. *Pharmaceutical Compounding and Dispensing*. Second ed., Pharmaceutical Press, 2010.

4. Disclaimer

The contents of the Pinetonina™ Compounding manual has been written with the greatest possible care. However, Fagron cannot guarantee the accuracy or completeness of the information. The content of Fagron’s Pinetonina™ Compounding manual therefore is not legally binding. Fagron accepts no liability which might arise from the content of the Pinetonina™ Compounding manual.