

## FORMULATION RECORD

Name: Nystatin Oral Paste  
Strength: 16.7% w/w  
Dosage Form: buccal  
Route of Administration: buccal

Date of Last Review or Revision: 10/24/03  
Person Completing Last Review or Revision: Robert Shrewsbury

### Formula:

| Ingredient    | Quantity  | Physical Description  | Solubility                            | Therapeutic Activity  |
|---------------|-----------|---|---------------------------------------|-----------------------|
| Nystatin      | 16.7% w/w | yellow to light tan powder, cereal-like odor; not less than 5000 USP Nystatin Units/mg      | slightly soluble in water and alcohol | antifungal antibiotic |
| Orabase Plain | qs        | contains gelatin, pectin, sodium carboxymethylcellulose in polyethylene and mineral oil gel | NA                                    | vehicle               |

### Additional Information:

Nystatin USP used in extemporaneous compounding must be at least 5,000 Nystatin USP units.

### Equipment Required:

- Class A prescription balance
- pile tile

### Method of Preparation:

- Accurately weigh the required amount of each ingredient.
- Levigate the nystatin with a small portion of the base.
- Incorporate the remaining portion of the base using geometric dilution.

### Description of Finished Product:

Golden color gel with high viscosity; approximates the consistence of a paste

### Quality Control Procedures:

Product weight  
No apparent particles aggregates on spreading

### Packaging Container:

Tight, light-resistant containers

### Storage Requirements:

Store in a refrigerator

### Beyond-Use Date Assignment:

Stability demonstrated to be at least 3 months (Egodage KL et al, Pharm. Res. (Suppl);14:S659, 1997)

### Label Information:

For Buccal Use Only  
Protect From Light  
Store in Refrigeration

**Source of Recipe:**

Allen's Compounded Formulations, American Pharmaceutical Association, Washington DC, 2003, pp. 58-59

**Literature Information:**