MEDISCA® NETWORK INC.
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Suggested Formula	Tryptophan 200 mg Oral Rapid-Dissolve Tablets (Solid Suspension, 96 × 750 mg [0.93 mL] Tablets)	FIN	F 006 493v2

SUGGESTED FORMULATION

Ingredient Listing	Qty.	Unit	NDC #	Supplier	Lot Number	Expiry Date
Tryptophan, USP	19.200	g				
Raspberry Flavor (Powder)	0.50	g				
Stevia Powder (Stevioside)	0.20	g				
Bitterness Reducing Agent (NF01) Natural (Powder)	0.50	g				
Medi-RDT Base	TBD					

SPECIAL PREPARATORY CONSIDERATIONS

Ingredient-Specific Information

Light sensitive *(protect from light whenever possible):* *Tryptophan*

Hygroscopic *(protect from moisture whenever possible):* *Medi-RDT Base, Stevia Powder*

Suggested Preparatory Guidelines

■ Non-Sterile Preparation ☐ Sterile Preparation

Processing Error / Testing Considerations: To account for processing errors and 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.

IMPORTANT: This procedure involves heating the tablet mold at temperatures reaching 110°C. Ensure that your molds are able to withstand this temperature.

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SUGGESTED PREPARATION (for 96 Tablets)

Weigh and / or measure the following ingredients when appropriate:

Ingredient Listing	Qty.	Unit	Multiplication factor (*): ____	Processing Error	Qty. to measure
Tryptophan, USP §	19.200	g			
Raspberry Flavor (Powder)	0.50	g			
Stevia Powder (Stevioside) §	0.20	g			
Bitterness Reducing Agent (NF01) Natural (Powder)	0.50	g			
Medi-RDT Base §	TBD				

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

Preparatory Instruction	
1.	**Mold calibration:** Determine the required quantity of Medi-RDT Base for 96 tablets based on the actual size of the tablet mold being used. Refer to the Appendix for details.
2.	**Powder preparation:** A. Pass the Medi-RDT Base through a 40 or 50 mesh sieve and weigh the required quantity (amount calculated in Appendix Step 6Aiii). B. By geometric addition, combine and triturate the following ingredients together to form a homogeneous powder blend: -Tryptophan -Raspberry Flavor (Powder) -Stevia Powder (Stevioside) -Bitterness Reducing Agent (NF01) Natural (Powder) C. By geometric addition, combine and mix (DO NOT TRITURATE) the following ingredients together to form a homogeneous powder blend: -Sieved Medi-RDT Base (Step 2A) -Homogeneous powder blend (Step 2B) Note: Do not use excessive force as Medi-RDT Base should not be triturated. D. Prior to filling the tablet mold cavities, pass the homogeneous powder blend (Step 2C) through a 40 or 50 mesh sieve to improve flow properties and obtain content uniformity.

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3. **Mold filling and heating:**

A. Fill the 96 tablet mold cavities by tapping and pressing the homogeneous powder blend (Step 2D) into the cavities using the upper part of the mold. Repeat at least three times to ensure the cavities are completely filled. If necessary, add additional powder blend.

B. Gently heat the powder blend to 105°C – 110°C for 10 – 15 minutes. Do not overheat.

Specifications: Heat by placing the filled mold (base cavity plate only) in an appropriate oven, preheated to 105°C – 110°C.

End Result: Homogeneous solid dispersion.

4. **Cooling:**

A. Carefully remove the tablet mold from the heated oven, using a hot hand protector.

B. Immediately remove the tablets by flipping over the mold onto a piece of wax or ointment paper and gently tapping the mold with a mini mallet.

Note: Hold the tablet mold in place while tapping to avoid shaking and breaking the tablets.

C. Allow the tablets to cool for an additional 30 minutes at controlled temperature and relative humidity.

5. **Validation technique:**

A. Weigh 20 tablets separately.

B. The final weight of each tablet from Step 5A (not including the weight of the tablet mold) should be between 90 and 110% of the theoretically calculated weight (Appendix, Step 5B), in accordance to USP guidelines.

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		6 months, as per USP*.	Packaging Requirements		Manually put into light-resistant Medi-RDT blisters and cold seal with foil labels.
Auxiliary Labels	1	Use as directed. Do not exceed prescribed dose.	5		Discard container after use.
	2	Keep out of reach of children.	6		Keep at room temperature (20°C – 23°C).
	3	Keep in a dry place.	7		Consult your health care practitioner if any prescription or over-the-counter medications are currently being used or are prescribed for future use.
	4	Protect from light.	8		May impair mental and/or physical ability. Use care when operating a car or machinery.
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.			

*** The BUD is not later than the time remaining until the earliest expiration date of any API or 6 months, whichever is earlier.**

REFERENCES

1. Tablets. In: Allen, LV, Jr. *The Art, Science and Technology of Pharmaceutical Compounding Fourth Edition.* American Pharmaceutical Association; 2012: 175.
2. Tryptophan. In: Sweetman SC, ed. *Martindale: The Complete Drug Reference, 36th Edition.* London, England: The Pharmaceutical Press; 2009: 427.
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4. Tryptophan (Monograph). *United States Pharmacopeia XXXVIII / National Formulary 33*. Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 5710.
5. USP <795>. *United States Pharmacopeia XXXVIII / National Formulary 33.* Rockville, MD. US Pharmacopeial Convention, Inc. 2015: 559.

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Appendix	Tablet mold calibration		

SUGGESTED CALCULATION

Preparatory Instruction	
1.	**API weighing:** A. Pass the Medi-RDT Base through a 40 or 50 mesh sieve. B. Weigh and / or measure the following ingredients: **Notes:** Measure the exact amount specified. Do not consider processing error for calibration step. Data within this calibration table are based on a 0.93 mL mold size.
2.	**Powder preparation:** A. By geometric addition, combine and mix (DO NOT TRITURATE) the following ingredients together to form a homogeneous powder blend: -Tryptophan -Medi-RDT Base Note: Do not use excessive force as Medi-RDT Base should not be triturated.
3.	**Mold filling and heating:** A. Fill 5 tablet mold cavities by tapping and pressing the homogeneous powder blend (Step 2A) into the cavities using the upper part of the mold. Repeat at least three times to ensure the cavities are completely filled. If necessary, add additional powder blend. B. Gently heat the powder blend to 105°C – 110°C for 10 – 15 minutes. Do not overheat. Specifications: Heat by placing the filled mold (base cavity plate only) in an appropriate oven, preheated to 105°C – 110°C. End Result: Homogeneous solid dispersion.

Ingredient	Quantity
Tryptophan, USP	2.00 g
Medi-RDT Base	7.08 g

4. **Cooling:**

A. Carefully remove the tablet mold from the heated oven, using a hot hand protector.

B. Immediately remove the tablets by flipping over the mold onto a piece of wax or ointment paper and gently tapping the mold with a mini mallet.

Note: Hold the tablet mold in place while tapping to avoid shaking and breaking the tablets.

C. Allow the tablets to cool for an additional 30 minutes at controlled temperature and relative humidity.

5. **Calculate the average tablet weight:**

A. Weigh the five tablets and record the total weight here (not including the weight of the empty tablet mold): _____ g

B. Calculate the average tablet weight:

Combined weight of the tablets (from Step 5A)	_____ g
DIVIDED BY	
Number of Tablets	5
EQUALS	
Average (theoretical) tablet weight*	_____ **g**

***Note:** The weight of the Rapid-Dissolving Tablets is mainly affected by factors such as compression force, flow properties of the powder mixture (flow properties will vary depending on the Active Pharmaceutical Ingredient(s) and excipients in the formulation) and particle size distribution. The mixture must be sieved prior to filling.

The expected average weight of RDT's are as follows (data based on various experiments/troubleshooting completed in the past):

750mg ± 30mg (720mg - 780mg)
200mg ± 10mg (190mg - 210mg)
150mg ± 7.5mg (142.5mg - 157.5mg)
75mg ± 5mg (70mg - 80mg)

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6. **Ingredient calculation:**

A. Calculate the quantity of excipient blend required for 96 tablets:

Average tablet weight (from Step 5B)	_____ g
MINUS	
Quantity (in g) of Tryptophan and other ingredients per tablet	0.2125 g
EQUALS	
i. Quantity of Medi-RDT Base required per tablet	_____ g
MULTIPLIED BY	
Number of tablets required	96
EQUALS	
ii. Total quantity of Medi-RDT Base required for 96 tablets	_____ **g**
MULTIPLIED BY	
Processing error adjustments (5 to 9%)	1.05 to 1.09
EQUALS	
iii. Total quantity of Medi-RDT Base required *plus* processing error adjustments	_____ g