**MAY 2011**

**[KY 353]** **Sub. Code: 2914**

**M.PHARM. DEGREE EXAMINATION**

**(Regulations 2010)**
**(Candidates admitted from 2010-2011 onwards)**

**FIRST YEAR**

**BRANCH V – PHARMACEUTICAL ANALYSIS**

**PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS**

***Q.P. Code : 262914***

**Time : Three hours** **Maximum : 100 marks**

**Answer All questions**

**I. Essay Questions :** **(6 x 10 = 60)**

1. Explain any two drugs official in IP assay principle and procedure by UV and HPLC method.
2. Describe about ICH guidelines for impurities.
3. Explain any two preservatives identification and quantification test.
4. Discuss about ISI specification of quality of perfumes and colourants raw materials used in cosmetics.
5. Explain toxicity testing of cosmetics.
6. Discuss about ISI specification of high grade soap.

**II. Write Short Notes :** **(8 x 5 = 40)**

1. Antioxidants used in pharmaceuticals.
2. Radio chemical methods in analysis.
3. Accelerative stability studies.
4. QC of injections.
5. ISI specification of nail polish.
6. ISI specification of skin powders
7. Surfactants raw material used in cosmetics.
8. ISI specification of baby shampoo.

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**October 2011**

**[KZ 353]** **Sub. Code: 2914**

**M.PHARM. DEGREE EXAMINATION**

**FIRST YEAR**

**BRANCH V – PHARMACEUTICAL ANALYSIS**

**PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS**

*Q.P. Code : 262914*

**Time : 3 hours (180 Min)** **Maximum : 100 marks**

**Answer ALL questions in the same order.**

| **I. Elaborate on :** | **Pages (Max.)** | **Time (Max.)** | **Marks (Max.)** |
|---|---|---|---|
| 1. Explain the principle and procedure involved in the official assay of (i). Allopurinol (ii). Metronidzol (iii) Piperazine 4. Verapamil. | 17 | 40 | 20 |
| 2. Write a note on different raw materials used in cosmetics? | 17 | 40 | 20 |
| **II. Write notes on :** | | | |
| 1. How will you perform the test for toxicity in cosmetics? | 4 | 10 | 6 |
| 2. Enumerate the Indian Standard specifications of nail polish? | 4 | 10 | 6 |
| 3. List out the various Quality control test of tablets? | 4 | 10 | 6 |
| 4. Describe about the water raw material purification methods involved in quality control? | 4 | 10 | 6 |
| 5. Enumerate in detail about the sampling process of biological sample? | 4 | 10 | 6 |
| 6. Identification and Quantitative determination of any two preservatives? | 4 | 10 | 6 |
| 7. Write an account on cosmetic legislation? | 4 | 10 | 6 |
| 8. Describe the quality control tests for ointments? | 4 | 10 | 6 |
| 9. Explain the diazotization titration with example? | 4 | 10 | 6 |
| 10. Explain the principle and procedure involved in the IP official assay of (i) Ibuprofen (ii) Tolbutamide. | 4 | 10 | 6 |

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**[LA 353]** **MAY 2012** **Sub. Code: 2914**

**M.PHARM. DEGREE EXAMINATION**

**FIRST YEAR**

**BRANCH V – PHARMACEUTICAL ANALYSIS**

**PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS**

***Q.P. Code: 262914***

**Time: 3 hours** **Maximum: 100 marks**

**(180 Min)**

**Answer ALL questions in the same order.**

| **I. Elaborate on:** | **Pages (Max.)** | **Time (Max.)** | **Marks (Max.)** |
|---|---|---|---|
| 1. Write in detail discussion on in process quality control test for the following pharmaceutical dosage forms (i) Parenterals (ii) Tablets. | 17 | 40 | 20 |
| 2. Explain the different methods of analysis to assess the quality of the following cosmetic products. (i) Lipsticks (ii) Hair care Products (iii) Baby Powder (iv) Dental products. | 17 | 40 | 20 |
| **II. Write notes on :** | | | |
| 1. Explain principle and procedure involved in the official (IP 1996) assays of (i) Calcium gluconate tablets (ii) Chloramphenicol eye drops. | 4 | 10 | 6 |
| 2. List out different solvents used in cosmetics and discuss quality control test for any one of solvent used in cosmetics. | 4 | 10 | 6 |
| 3. How do you determine microbial contamination in cosmetics? | 4 | 10 | 6 |
| 4. Explain the method of identification and determination of any two antioxidants. | 4 | 10 | 6 |
| 5. Write ICH guidelines for related substance and impurity detection in drugs. | 4 | 10 | 6 |
| 6. Explain toxicity testing of cosmetics. | 4 | 10 | 6 |
| 7. BIS specification for Shampoo. | 4 | 10 | 6 |
| 8. Discuss in process quality control test for ointments. | 4 | 10 | 6 |
| 9. Discuss ICH guidelines for stability studies of drugs. | 4 | 10 | 6 |
| 10. Explain various extraction process involved in biological sample analysis and their limitation and applications. | 4 | 10 | 6 |

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**[LB 353]** **NOVEMBER 2012** **Sub. Code: 2914**

**M.PHARM. DEGREE EXAMS**

**FIRST YEAR**

**BRANCH V – PHARMACEUTICAL ANALYSIS**

**PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS**

***Q.P. Code : 262914***

**Time : 3 hours** **Maximum : 100 marks**

**(180 Min)**

**Answer ALL questions in the same order.**

| **I. Elaborate on :** | **Pages (Max.)** | **Time (Max.)** | **Marks (Max.)** |
|---|---|---|---|
| 1. In detail explain the identification and qualitative determination of antioxidants used in pharmaceutical preparations. | 17 | 40 | 20 |
| 2. What are the procedures used for the extraction of drugs from biological samples and explain the factors affecting extraction procedures. | 17 | 40 | 20 |

**II. Write Notes on :**

| | | | |
|---|---|---|---|
| 1. How is the toxicity testing done for cosmetics? | 4 | 10 | 6 |
| 2. Write the method for determination of related substances present in metronidazole IP and paracetamol IP. | 4 | 10 | 6 |
| 3. What are the in process quality control tests carried out for different types of capsules? | 4 | 10 | 6 |
| 4. What are radio pharmaceuticals? How does the quality of them determined? | 4 | 10 | 6 |
| 5. What re the raw materials used in cosmetics? Explain quality control two of them. | 4 | 10 | 6 |
| 6. How is the QC test for controlled release dosage forms performed? | 4 | 10 | 6 |
| 7. List out the preservatives used in pharmaceutical preparations, giving their limit and estimation procedures. | 4 | 10 | 6 |
| 8. Explain with few examples how the Complexometric titration utilized for the estimation of official compounds. | 4 | 10 | 6 |
| 9. What is shelf life of formulations? How shelf life is predicted with accelerated stability testing? | 4 | 10 | 6 |
| 10. Write on testing of color cosmetics. | 4 | 10 | 6 |

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**[LC 353]** **APRIL 2013** **Sub. Code: 2914**

**M.PHARM. DEGREE EXAMS**

**FIRST YEAR**

**BRANCH V – PHARMACEUTICAL ANALYSIS**

**PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS**

***Q.P. Code : 262914***

**Time : 3 hours** **Maximum : 100 marks**

**I. Elaborate on :** **(2x20=40)**

1. Explain the principle and procedure involved in the official (IP 1996) assays of the following drugs.
   a. Dapsone tablets
   b. Phenytoin sodium tablets
   c. Paracetamol tablets.
   d. Captopril tablets.

2. Write in detail about in process quality control test for the followings :
   a. Tablets.
   b. Suppositories.

**II. Write Notes on :** **(10x6=60)**

1. Write a note on different raw materials used in cosmetics.
2. Write briefly stability testing for pharmaceutical dosage forms.
3. Write identification and quantification for Butylated Hydroxy Anisole.
4. How do you determine the quality of tooth powder?
5. Discuss toxicity testing in cosmetics.
6. Enumerate principle involved in Liquid-Liquid extraction process and discuss factors affecting extraction.
7. Explain quality control test for lipsticks.
8. List out different preservatives used in pharmaceutical formulation and give an estimation of sodium benzoate.
9. Write ICH guidelines for related substance and impurity detection in drugs.
10. Explain sodium sulfate determination in Shampoo.

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**[LD 353]** **OCTOBER 2013** **Sub. Code: 2914**

**M.PHARM. DEGREE EXAMINATIONS**

**FIRST YEAR**

**BRANCH V – PHARMACEUTICAL ANALYSIS**

**PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS**

***Q.P. Code : 262914***

**Time: Three Hours** **Maximum: 100 marks**

**Answer ALL questions in the same order.**

**I. Elaborate on :** **(2 x 20 = 40)**

1. Explain the identification and quantitative determination for few of the following additives used in formulations.
   i) Emulsifiers and stabilizers
   ii) Preservatives
2. Give in detail on the analysis of various raw materials used in cosmetic preparations.

**II. Write notes on :** **(10 x 6 = 60)**

1. Describe the in process quality control tests employed for controlled released products.
2. Write on any TWO radio pharmaceutical components used for the treatment of diseases.
3. With example write on the principle and practice of gravimetric methods for assaying official compounds.
4. Give a note on the residual solvent determination according to ICH guidelines.
5. Explain various quality control tests employed for shampoos.
6. Briefly add note on accelerated stability testing and its limitation.
7. Write on evaluation of parenteral and sterile products.
8. How and why skin irritation tests are carried out for cosmetic products?
9. How does extraction of drugs carried out by Liquid Extraction?
10. Explain principle & procedure of drugs assayed by UV spectroscopic methods with suitable examples.

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**[LE 353]** **APRIL 2014** **Sub. Code: 2914**

**M.PHARM. DEGREE EXAMS**
**FIRST YEAR**
**BRANCH V – PHARMACEUTICAL ANALYSIS**
**PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS**

***Q.P. Code : 262914***

**Time : 3 hours** **Maximum : 100 marks**

**I. Elaborate on :** **(2x20=40)**

1. What are impurities? Write in detail on ICH guidelines for the determination of impurities and related substances present in drugs.
2. According to IP'96 explain the principle and procedure involved in the assay of following
   i) Metronidazole tablets ii) Metformin HCI tablets iii) Diclofenac sodium tablets iv) Riboflavin.

**II. Write notes on :** **(10x6=60)**

1. How the stability testing does carry out to predict shelf life formulations?
2. What are the factors affecting extraction of drugs from biological samples by LLE methods?
3. How does the cosmetics are tested for their suitability to be used on skin applications?
4. What is the importance of radio pharmaceuticals? Give the quality control tests for sodium iodide ($^{131}$I) injection.
5. According to BIS how the quality of water and glycerol used in cosmetic preparations was determined?
6. Write on the principle and practice of solid phase extraction of drugs from biological fluids.
7. Explain the sampling and finished product analysis of hair care preparations.
8. Write on use and determination of benzyl chloride and methyl paraben used in pharmaceutical products.
9. Explain various factors used in quality control test of tablets.
10. How does the quality of baby care products ascertained?

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**[LF 353]** **OCTOBER 2014** **Sub. Code: 2914**

**M.PHARM. DEGREE EXAMINATION**
**FIRST YEAR**
**BRANCH V – PHARMACEUTICAL ANALYSIS**
**PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS**

***Q.P. Code : 262914***

**Time : Three hours** **Maximum : 100 marks**

**I. Elaborate on:** **(2 x 20 = 40)**

1. a) Write the principle, reaction and procedure involved in the assay of the following drugs: a) calcium lactate tablets b) tolbutamide tablets.

   b) Explain the principle, reaction, procedure and method of assay involved in the determination of Piperazine citrate.

2. Elaborate the related substances and impurities present in drugs. Add a note on their effect on drug stability and therapeutic action.

**II. Write notes on:** **(10 x 6 = 60)**

1. Explain the in process quality control of cream preparation.
2. State the methods of extraction of drugs from biological sample.
3. Write a note on quality control of radio pharmaceutical.
4. Specify the significant of accelerated stability and analysis.
5. Explain in detail Quality control tests for the coated and uncoated tablets with the specifications as stated in pharmacopoeias.
6. Enumerate the Methods of test for nail polish.
7. Write in brief on quality control test for dental products.
8. Write a note on preservative raw material used in cosmetics.
9. How will you determine the related substance present in Albendazole and diclofenac as per IP?
10. Discuss the ICH guidelines for stability studies of drugs.

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**[LG 353]** **APRIL 2015** **Sub. Code: 2914**

**M.PHARM. DEGREE EXAMINATION**

**FIRST YEAR**

**BRANCH V – PHARMACEUTICAL ANALYSIS**

**PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS**

***Q.P. Code : 262914***

**Time: Three Hours** **Maximum: 100 marks**

**Answer ALL questions**

**I. Elaborate on :** **(2 x 20 = 40)**

1. Explain the various extraction process involved in biological sample analysis and their limitation and applications.

2. Explain the different method of analysis to assess the quality of the following cosmetic products.

   a) Lipsticks b) Baby powder c) Dental products d) Hair care products

**II. Write notes on :** **(10 x 6 = 60)**

1. Write the principle and procedure involved in the Assay of Calcium Gluconate tablets.

2. Discuss the ICH Guidelines for stability studies of drugs.

3. Write note on Radiochemical methods in analysis.

4. Give an account on safety and legislation of cosmetic products.

5. How the antioxidants present in pharmaceutical formulations are identified and determined?

6. How the dyes soluble in both Water and Alcohol are determined?

7. Quality control tests for Injections.

8. ISI Specification of Baby Shampoo.

9. Preservatives identification and quantification tests.

10. Discuss about ISI Specification of high grade Soap.

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**[LH 353]** **OCTOBER 2015** **Sub. Code: 2914**

**M.PHARM. DEGREE EXAMINATION**
**FIRST YEAR**
**BRANCH V – PHARMACEUTICAL ANALYSIS**
**PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS**

***Q.P. Code: 262914***

**Time: Three hours** **Maximum : 100 marks**

**I. Elaborate on:** **(2 x 20 = 40)**

1. Discuss the methodology involved for sampling and testing by the Indian standards for cosmetics in the finished form.

2. How the following are determined in the finished form as per the specifications recommended by the Bureau of Indian Standards?
   a) Face powder b) Shampoo

**II. Write notes on:** **(10 x 6 = 60)**

1. Write identification and quantitative determination of colouring materials in formulations.
2. Write an account on Shelf life prediction.
3. Write quality control tests for Dental products.
4. Write note on personal hygiene products.
5. What are Complexometric titrations? Explain the principle and procedure for any one drug determined by this assay method.
6. How is the efficacy of Body care products determined?
7. Write the principle and procedure involved in the assay of Ibuprofen.
8. Write the ICH Guidelines for the determination of impurities in drugs.
9. Bureau of Indian standards specifications for Nail polish.
10. Quality control tests for Ointments.

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**[LI 353]** APRIL 2016 **Sub. Code: 2914**

**M.PHARM. DEGREE EXAMINATION**
**FIRST YEAR**
**BRANCH V – PHARMACEUTICAL ANALYSIS**
**PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS**

***Q.P. Code: 262914***

**Time: Three hours** **Maximum : 100 Marks**

**I. Elaborate on:** **(2 x 20 = 40)**

1. Write the principle and procedures involved in the assay (IP 2007) of:
   a) Atenolol Tablets b) Calcium Gluconate Tablets
   c) Metronidazole Tablets d) Sulphamethoxazole

2. a) Explain toxicity testing of Skin care cosmetics.
   b) Describe about ISI specification of soaps.

**II. Write notes on:** **(10 x 6 = 60)**

1. Explain about the impurities affect the drugs stability and therapeutic action.
2. ISI specification of aftershave lotion.
3. Identification and determination of preservatives in formulations.
4. ISI specification of dental products.
5. In process quality control of capsules.
6. Write notes on sampling of cosmetics.
7. Discuss about SPE.
8. ISI specification of baby shampoos.
9. ICH guidelines for stability studies of drugs.
10. ISI specification of lipsticks.

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**[LJ 353]** OCTOBER 2016 **Sub. Code: 2914**

**M.PHARM. DEGREE EXAMINATION**
**FIRST YEAR**
**BRANCH V – PHARMACEUTICAL ANALYSIS**
**PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS**

***Q.P. Code: 262914***

**Time: Three hours** **Maximum : 100 Marks**

**I. Elaborate on:** **(2 x 20 = 40)**

1. Write the principle and procedures involved in the assay (IP 2007) of

   a) Sulphadoxine b) Diphenhydramine Hydrochloride
   c) Frusemide d) Tinidazole

2. a) Explain sampling techniques of cosmetic.

   b) Describe about ISI specification of any two baby care products.

**II. Write notes on:** **(10 x 6 = 60)**

1. ICH guidelines for impurities.
2. ISI specification of personal hygiene products.
3. Identification and determination of colouring agents in formulations.
4. ISI specification of hair dye.
5. In process quality control of parenterals.
6. Write notes on toxicity testing of eye shadows.
7. Discuss about LLE.
8. ISI specification of transparent soap.
9. Write notes on stability testing of drugs.
10. Write notes on QC of radio pharmaceuticals.

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**[LK 353]** MAY 2017 **Sub. Code: 2914**

**M.PHARM. DEGREE EXAMINATION**
**FIRST YEAR**
**BRANCH V – PHARMACEUTICAL ANALYSIS**
**PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS**

***Q.P. Code: 262914***

**Time: Three hours** **Maximum : 100 Marks**

**I. Elaborate on:** **(2 x 20 = 40)**

1. Explain in detail about the various extraction process for biological samples and discuss its merits and demerits.

2. Discuss in detail in process quality control test for parenteral and creams.

**II. Write notes on:** **(10 x 6 = 60)**

1. Write the principle, reactions and procedure involved in the official assay of aluminium hydroxide gel.
2. How shelf life is predicted with accelerated stability testing?
3. How do you evaluate the quality of an ointments?
4. Discuss quality control test for soap.
5. List out raw materials used in cosmetics and discuss quality control test for any one of solvent used in cosmetics.
6. What is gravimetric analysis and explain with any one example?
7. Explain softening point and breaking point test of lipsticks.
8. What are preservatives? Classify them and explain identification and quantification of sodium benzoate.
9. Explain residual solvent impurities and their quality control test in pharmaceutical formulations.
10. Give different quality control tests for Radio pharmaceuticals.

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**[LL 353]** OCTOBER 2017 **Sub. Code: 2914**

**M.PHARM. DEGREE EXAMINATION**
**FIRST YEAR**
**BRANCH V – PHARMACEUTICAL ANALYSIS**
**PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS**

***Q.P. Code: 262914***

**Time: Three hours** **Maximum : 100 Marks**

**I. Elaborate on:** **(2 x 20 = 40)**

1. How do stability testing of formulations carried out? Add note on shelf life predictions of drugs.

2. Discuss about identification and quantitative determination of preservatives and anti-oxidants used in pharmaceutical formulations.

**II. Write notes on:** **(10 x 6 = 60)**

1. Write on concepts and practice of solid phase extraction.
2. Explain procedure for testing shaving cream and shaving lotion.
3. Give principle and procedure for the assay of benzoic acid IP and riboflavin IP.
4. Write on determination of related substances in pharmaceuticals.
5. Explain assay of drugs by Non Aqueous titration method.
6. Write briefly as radio pharmaceuticals and radiochemical methods.
7. Give various QC methods for Suppositories and creams.
8. Write on following raw materials used in cosmetics:
   a) anti-oxidants b) Preservatives
9. Write QC for a) baby lotion b) Skin creams.
10. Explain the safety assessment test method for skin cosmetics.

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

**[LM 353]** MAY 2018 **Sub. Code: 2914**

**M.PHARM. DEGREE EXAMINATION**
**FIRST YEAR**
**BRANCH V – PHARMACEUTICAL ANALYSIS**
**PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS**

***Q.P. Code: 262914***

**Time: Three hours** **Maximum : 100 Marks**

**I. Elaborate on:** **(2 x 20 = 40)**

1. Write the principle and procedure involved in the official assay of the following:
   a) Calcium gluconate tablets b) Nitrazepam
   c) Dapsone tablets d) Paracetamol tablets

2. Explain in detail about the quality control test for the following:
   a) After shave lotion b) Tooth powder

**II. Write notes on:** **(10 x 6 = 60)**

1. Write briefly about radio chemical analysis.
2. Explain about pyrogen test.
3. Explain disintegration test for uncoated and enteric coated tablets.
4. Discuss theory, merits and demerits of Liquid-Liquid Extractions (LLE).
5. Write on anti-microbial testing for cosmetic preparation.
6. Explain shelf life prediction of new drug formulations.
7. Write ICH guidelines for related substance and impurity detection in drugs.
8. How do you assess arsenic and lead in cosmetics?
9. List out emulsifiers and stabilizers used in pharmaceutical formulations and explain the quantification of sodium lauryl sulfate.
10. How do you evaluate baby powder?

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THE TAMIL NADU DR. M.G.R. MEDICAL UNIVERSITY

**[LO 353]** MAY 2019 **Sub. Code: 2914**

**M.PHARM. DEGREE EXAMINATION**
**FIRST YEAR**
**BRANCH V – PHARMACEUTICAL ANALYSIS**
**PAPER II – PHARMACEUTICAL AND COSMETIC ANALYSIS**

***Q.P. Code: 262914***

**Time: Three hours** **Maximum : 100 Marks**

**I. Elaborate on:** **(2 x 20 = 40)**

1. Write in detail discussion on in process quality control test for the following pharmaceutical dosage forms.
   a) Suppositories b) Enteric coated tablets

2. Explain the different methods of analysis to assess the quality of the following cosmetics.
   a) Shampoo b) Lipsticks

**II. Write notes on:** **(10 x 6 = 60)**

1. Explain in detail about principle and procedure involved in the official (IP 1996) assay of chloroquine phosphate tablets.
2. Discuss residual solvents and its effect on drug stability.
3. Write identification and quantification of Butylated hydroxy anisole and benzoic acid in pharmaceutical formulations.
4. Explain theory and limitations of solid phase extraction.
5. Discuss about ICH guidelines for stability studies of new drug formulations.
6. List out the raw materials used in cosmetic industry and explain quality control test for water.
7. BIS specifications for hair dye.
8. Explain theory and principle involved in estimation of metronidazole tablets (IP1996).
9. Explain toxicity tests carried out in cosmetic preparation.
10. Explain various in process quality control tests in parentral products.

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