

**Packaging and storage**—Preserve in tight containers.  
**Residue on ignition** (281): not more than 2.0%, from 100 mg.

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### Coal Tar Ointment

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» Prepare Coal Tar Ointment as follows.

Coal Tar .....	10 g
Polysorbate 80 .....	5 g
Zinc Oxide Paste .....	985 g
to make .....	1000 g

Blend the Coal Tar with the Polysorbate 80, and incorporate the mixture with the Zinc Oxide Paste.

**Packaging and storage**—Preserve in tight containers.

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### Coal Tar Topical Solution

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» Prepare Coal Tar Topical Solution as follows.

Coal Tar .....	200 g
Polysorbate 80 .....	50 g
Alcohol, a sufficient quantity, to make .....	1000 mL

Mix the Coal Tar with 500 g of washed sand (see under *Reagents* in the section *Reagents, Indicators, and Solutions*), and add the Polysorbate 80 and 700 mL of Alcohol. Macerate the mixture for 7 days in a closed vessel with frequent agitation. Filter, and rinse the vessel and the filter with sufficient Alcohol to make the product measure 1000 mL.

**Packaging and storage**—Preserve in tight containers.  
**Alcohol content** (611): between 81.0% and 86.0% of C<sub>2</sub>H<sub>5</sub>OH.

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### Cyanocobalamin Co 57 Capsules

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Vitamin B<sub>12</sub>-<sup>57</sup>Co.  
 Vitamin B<sub>12</sub>-<sup>57</sup>Co [41559-38-0; 13115-03-2].

» Cyanocobalamin Co 57 Capsules contain Cyanocobalamin in which a portion of the molecules contain radioactive cobalt (<sup>57</sup>Co) in the molecular structure. Each Capsule contains not less than 90.0 percent and not more than 110.0 per cent of the labeled amount of <sup>57</sup>Co as cyanocobalamin expressed in megabecquerels (microcuries) at the time indicated in the labeling. The cyanocobalamin content is not less than 90.0 per cent and not more than 110.0 per cent of the labeled amount.

**Specific activity:** not less than 0.02 MBq (0.5 μCi) per μg of cyanocobalamin.

**Packaging and storage**—Preserve in well-closed, light-resistant containers, and store in a cold place.

**Labeling**—Label the Capsules to include the following: the date of calibration; the amount of cyanocobalamin expressed in μg per Capsule; the amount of <sup>57</sup>Co as cyanocobalamin expressed in megabecquerels (microcuries) per Capsule at the time of calibration; the expiration date; and the statement “Caution—Radioactive Material.” The labeling indicates that in making dosage calculations, correction is to be made for radioactive decay, and also indicates that the radioactive half-life of <sup>57</sup>Co is 270.9 days.

**USP Reference standards** (11)—  
 USP Cyanocobalamin RS

**Radioisotope identification**—A solution of 1 or more Capsules in water responds to the test for *Radioisotope identification* under *Cyanocobalamin Co 57 Oral Solution*.

**Disintegration** (701): 30 minutes, testing 1 Capsule in 1 N hydrochloric acid maintained at 37 ± 2° as the immersion fluid.

**Uniformity of dosage units:** meet the requirements.

*Procedure for content uniformity*—Determine the instrument response of each of 10 Capsules by measurement in a suitable counting assembly and under identical geometric conditions. Calculate the average radioactivity per Capsule. The radioactivity of none of the Capsules differs by more than 10% from the average. The relative standard deviation is less than 3.5%.

**Radiochemical purity**—Dissolve the contents of 1 Capsule in 1 mL of water, allow to stand for about 10 minutes, and centrifuge. Use the supernatant as the *Test solution*. It meets the requirements of the test for *Radiochemical purity* under *Cyanocobalamin Co 57 Oral Solution*.

**Radioisotopic purity**—Dissolve the contents of 1 Capsule in 1 mL of water, allow to stand for about 10 minutes, and centrifuge. Use the supernatant. It meets the requirements of the test for *Radioisotopic purity* under *Cyanocobalamin Co 57 Oral Solution*.

**Content of cyanocobalamin**—Determine the content, in μg per Capsule, of cyanocobalamin as directed under *Vitamin B<sub>12</sub> Activity Assay* (171).

**Assay for radioactivity**—Using a suitable counting assembly (see *Selection of a Counting Assembly* under *Radioactivity* (821)), determine the radioactivity, in MBq (μCi) per Capsule, of Cyanocobalamin Co 57 Capsules by use of a calibrated system as directed under *Radioactivity* (821).

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### Cyanocobalamin Co 57 Oral Solution

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Vitamin B<sub>12</sub>-<sup>57</sup>Co.  
 Vitamin B<sub>12</sub>-<sup>57</sup>Co [41559-38-0; 13115-03-2].

» Cyanocobalamin Co 57 Oral Solution is a solution suitable for oral administration, containing Cyanocobalamin in which a portion of the molecules contain radioactive cobalt (<sup>57</sup>Co) in the molecular structure. Cyanocobalamin Co 57 Oral Solution contains not less than 90.0 per cent and not more than 110.0 per cent of the labeled amount of <sup>57</sup>Co as cyanocobalamin expressed in megabecquerels (microcuries) per mL at the time indicated in the labeling. The cyanocobalamin content is not less than 90.0 per cent and not more than 110.0 per cent of the labeled amount. Cyanocobalamin Co 57 Oral Solution contains a suitable antimicrobial agent.

**Specific activity:** not less than 0.02 MBq (0.5  $\mu$ Ci) per  $\mu$ g of cyanocobalamin.

**Packaging and storage**—Preserve in tight containers, protected from light, and store in a cold place.

**Labeling**—Label it to include the following: the date of calibration; the amount of  $^{57}\text{Co}$  as cyanocobalamin expressed as total megabecquerels (microcuries) and as megabecquerels (microcuries) per mL at the time of calibration; the amount of cyanocobalamin expressed in  $\mu$ g per mL; the name and quantity of the added preservative; the expiration date; and the statement "Caution—Radioactive Material." The labeling indicates that in making dosage calculations, correction is to be made for radioactive decay, and also indicates that the radioactive half-life of  $^{57}\text{Co}$  is 270.9 days, and directs that the Oral Solution be protected from light.

**USP Reference standards** (11)—

USP Cyanocobalamin RS

**Radionuclide identification** (see *Radioactivity* (821))—Its gamma-ray spectrum is identical to that of a specimen of  $^{57}\text{Co}$  of known purity that exhibits a major photopeak having an energy of 0.122 MeV.

**Uniformity of dosage units** (905)—

FOR ORAL SOLUTION PACKAGED IN SINGLE-UNIT CONTAINERS: meets the requirements.

**Deliverable volume** (698)—

FOR ORAL SOLUTION PACKAGED IN MULTIPLE-UNIT CONTAINERS: meets the requirements.

**pH** (791): between 4.0 and 5.5.

**Radiochemical purity**—

*Mobile phase*—Prepare a solution of 10.0 g of dibasic sodium phosphate in 1000 mL of water, and adjust with phosphoric acid to a pH of 3.5. Prepare a mixture of this solution and methanol (73.5:26.5), mix, and degas. Use within 2 days.

*Test solution*—Use the Oral Solution.

*Standard solution*—Transfer about 10 mg of cyanocobalamin, accurately weighed, to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix. Transfer 2.0 mL of this solution to a 100-mL volumetric flask, dilute with *Mobile phase* to volume, and mix.

*Chromatographic system* (see *Chromatography* (621))—The liquid chromatograph is equipped with a 361-nm detector, a gamma detector adjusted for  $^{57}\text{Co}$  and a 4.6-mm  $\times$  25-cm stainless steel column that contains 5- $\mu$ m packing L7. The flow rate is about 1 mL per minute.

*Procedure*—Inject about 100  $\mu$ L of the *Standard solution* into the chromatograph, record the chromatogram for 30 minutes, and note the retention time of the cyanocobalamin peak. Inject 100  $\mu$ L of the *Test solution* into the chromatograph, and record the chromatogram for three times the retention time of cyanocobalamin. Measure the peak areas using the gamma detector, and calculate the percentage of cyanocobalamin present as cyanocobalamin  $^{57}\text{Co}$  in the portion of Oral Solution taken by the formula:

$$100(r_u / r_T)$$

in which  $r_u$  is the peak response for cyanocobalamin  $^{57}\text{Co}$  obtained from the *Test solution*; and  $r_T$  is the total of all the peak area responses in the radiochromatogram obtained from the *Test solution*. Not less than 90% of the total radioactivity is found as cyanocobalamin  $^{57}\text{Co}$ .

**Radionuclidic purity**—Using a suitable calibrated instrument (see *Radioactivity* (821)) and standardized solutions of  $^{58}\text{Co}$ ,  $^{57}\text{Co}$ , and  $^{60}\text{Co}$ , record the gamma spectrum of the Oral Solution. The spectrum does not differ significantly from that of the standardized  $^{57}\text{Co}$  solution. Determine the relative amounts of  $^{58}\text{Co}$ ,  $^{57}\text{Co}$ , and  $^{60}\text{Co}$  present. Cobalt 58 has a half-life of 70.9 days, and its presence is shown by 0.511-MeV and 0.811-MeV gamma photons. Cobalt 60 has a half-life of 5.27 years, and its presence is shown by 1.173-MeV and 1.333-MeV gamma photons. Not more than 1% of the total radioactivity is due to

$^{60}\text{Co}$ ; and not more than 2% of the total radioactivity is due to  $^{58}\text{Co}$ ,  $^{60}\text{Co}$ , and other radionuclidic impurities.

**Content of cyanocobalamin**—Determine the content, in  $\mu$ g per mL, of cyanocobalamin as directed under *Vitamin B<sub>12</sub> Activity Assay* (171).

**Assay for radioactivity**—Using a suitable counting assembly (see *Selection of a Counting Assembly* under *Radioactivity* (821)), determine the radioactivity, in MBq ( $\mu$ Ci) per mL, of Oral Solution by use of a calibrated system as directed under *Radioactivity* (821).

## Cyanocobalamin Co 58 Capsules

Vitamin B<sub>12</sub>- $^{58}\text{Co}$

» Cyanocobalamin Co 58 Capsules contain Cyanocobalamin in which a portion of the molecules contain radioactive cobalt ( $^{58}\text{Co}$ ) in the molecular structure. Each Capsule contains not less than 90.0 percent and not more than 110.0 per cent of the labeled amount of  $^{58}\text{Co}$  as cyanocobalamin expressed in megabecquerels (or microcuries) at the time indicated in the labeling. The cyanocobalamin content is not less than 90.0 per cent and not more than 110.0 per cent of the labeled amount.

**Specific activity:** not less than 0.02 MBq (or 0.5  $\mu$ Ci) per  $\mu$ g of cyanocobalamin.

**Packaging and storage**—Preserve in well-closed, light-resistant containers, and store in a cold place.

**Labeling**—Label it to include the following: the date of calibration; the amount of cyanocobalamin expressed in  $\mu$ g per Capsule; the amount of  $^{58}\text{Co}$  as cyanocobalamin expressed in MBq (or  $\mu$ Ci) per Capsule at the time of calibration; the expiration date; and the statement "Caution—Radioactive Material." The labeling indicates that in making dosage calculations, correction is to be made for radioactive decay, and also indicates that the radioactive half-life of  $^{58}\text{Co}$  is 70.9 days.

**USP Reference standards** (11)—

USP Cyanocobalamin RS

**Disintegration** (701): 30 minutes, testing one Capsule in 1 N hydrochloric acid maintained at  $37 \pm 2^\circ$  as the immersion fluid.

**Radionuclide identification** (821)—

**A:** Its gamma-ray spectrum is identical to that of a specimen of  $^{58}\text{Co}$  that exhibits major photopeaks at 0.511 MeV (annihilation radiation) and 0.811 MeV.

**B:** The retention time of the major peak in the radiochromatogram of the *Test solution* corresponds to that in the chromatogram of the *Standard solution*, as obtained in the test for *Radiochemical purity*.

**Uniformity of dosage units** (905): meet the requirements.

*Procedure for content uniformity*—Determine the instrument response of each of 10 Capsules by measurement in a suitable counting assembly and under identical geometric conditions. Calculate the average radioactivity per Capsule. The radioactivities of none of the Capsules differ by more than 10% from the average. The relative standard deviation is less than 3.5%.

**Radiochemical purity**—

*Mobile phase*—Prepare a solution of 10.0 g of dibasic sodium phosphate in 1000 mL of water, and adjust with phosphoric acid to a pH of 3.5. Prepare a mixture of the solution so obtained and methanol (73.5:26.5), mix, and degas. Use within 2 days. Make adjustments if necessary (see *System Suitability* under *Chromatography* (621)).