

## Summaries of Official Spectrophotometric Methods

## 4) Pharmaceuticals and cosmetics analysis

## Introduction

As introduced in Application Note 49, there are a wide range of spectrophotometric analyses designated as Official Analytical methods. The methods for pharmaceutical testing are important in maintaining quality and in toxicological testing (see also the section Ultraviolet-Visible Spectrophotometry Applications, Molecular biology, clinical and toxicological analysis in Encyclopaedia of Analytical Science, Academic Press, 1995).

The methods are used in the following areas:

- Analysis of additives and colouring materials
- · Analysis of pathological specimens
- Quality control of pharmaceutical products
- Safety testing of medications
- Toxicological testing

These methods show an outline of the preparation procedure, indicating any specific reagents required. Measurement wavelengths are listed providing quick reference to the spectrophotometer requirements. Spectrophotometers and Acquire software from the Biochrom Libra range are recommended for each method as appropriate. More details on instrument settings are shown in the user manuals and other application notes.

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Summary of Analytical Methods - Pharmaceuticals and Cosmetics (Libra Application Note 52)			RECOMMENDED INSTRUMENT					
			LIBRA SS	LIBRA S12	LIBRA S22	LIBRA S22 + ACQUIRE	LIBRA S32	LIBRA S32PC
COMMODITY ANALYSIS	OUTLINE OF METHOD	WAVELENGTHS nm						
Aflatoxins in mycotoxin characterisation/confirmation  Amyl p-dimethylaminobenzoate in suntan preparations	TLC separation/isolation of aflatoxins/methanol extract. CHCl3 extr, ads col, ethanol elution.	Scan & measure maxima 200-400 220-360, compare spectra, read 314				X X	X X	x x
Anot(zoalene metabolite) in animal tissues	CHCl <sub>3</sub> extr, ads col, ethanol elution.	540	X	X	X		X	X
Arsenic in physiological samples	Silver diethyldithiocarbamate reagent.	540	x	X	X		x	X
Chloramben in formulations	Alkaline extract.	297 & 360		X	X		X	X
Dye in colour additive	Pure dye in solvent free from suspended material.	400-750				X	X	X
Food, Drug and Cosmetic Act (USA) listed colours	Dye dissolved in isopropanol.	350-700				X	X	X
Hexachlorophene in deoderants	Adsorption column + acid/ethanol extr.	220-360. max 297				X	X	X
Intermediate compounds in FD&C Red 40	Cellulose column/20% ammonium sulphate elution.	240,252,280,360				X	X	X
Intermediate compounds in FD&C Yellow No 6	Cellulose column/20% ammonium sulphate elution.	232,250,240,360				X	X	X
Methapyrilene in expectorants	Acidic solution.	315		X	X		X	X
Phenolsulfonates in deoderants	Aqueous HCI reflux/CHCl3 extract. NaOH solution.	253				X	X	X
Phenylalkanolamine salts in elixirs and sirups	Basic silica column/CH2Cl2 extract. Periodate reaction.	230-350 (benzaldehyde)				X	x	x
Phosphatase in casein	Casein incubated carbonate buffer. + dichloroquinonechloroamide.	650	X	X	X		X	X
Pyrilamine in cough syrup	Dissolve in acidic solution.	314		X	X		X	X
Zoalene residues in animal tissues	Acetone extract/alumina column/1:3diaminopropane.	560	X	X	X		X	X